KoKo Legend Spirometer
Operations Manual

Part Number 606055

Document Version/Revision 9.A

Keystone PF Diagnostics WRIGHT™ Respirometers ZAN Messgerate KOKO® Spirometry
Collins® Pulmonary Diagnostics PIKO® Monitors POCKET PEAK™ POCKET CHAMBER™

KoKo

THE LEGEND OF KOKOPELLI

The Southwest region of the United States is home to KoKopelli. His image can be found as a petroglyph throughout this region. Many legends surround this mysterious figure that played a prominent role in early Native American culture. He is often portrayed as the bearer of health and plenty.

For Ferraris Respiratory, KoKopelli represents new directions of excellence in pulmonary diagnostic testing.

Caution:

Federal law restricts this device to sale by or on the order of a physician.

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Printed and Bound in the United States of America.

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	This symbol indicates that this device provides a certain level of protection against electric shock because the patient applied part is floating.
	This symbol indicates that the user must read and understand all instructions and warnings prior to use.
CE 0086	This symbol indicates this software supports Class IIA equipment that complies with the Medical Devices Directive of the European Economics Community.
	This symbol indicates that the associated jack is for a Universal Serial Bus connection.

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This section provides a sequence of tasks to perform to get you started using your Legend as quickly as possible. If you need additional instructions, refer to the associated section of the manual.

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2 Introduction

Congratulations! You have purchased a quality instrument that will give you many years of excellent service. Ferraris Respiratory's personnel are ready to help you in any way necessary to assure your satisfaction with your purchase. The KoKo Legend Spirometer is a desktop portable device capable of performing both pre- and post-bronchodilator forced and slow expiratory maneuvers and calculating the standard spirometric indices.

Please take the time to:

- Inspect the contents of this package for completeness.
- Read the Essential Prescribing Information, especially the Precautions.
- Complete the enclosed warranty card.

2.1 Using the Manual

This manual will provide detailed instructions on the use of the KoKo Legend Spirometer and an overview of related topics. The user is encouraged to supplement this manual with additional reading in published literature. Appendix F - References of this manual provides a reference for some additional reading material. The user instructions in the following chapters assume the user is adequately familiar with the intended use and application of a spirometer.

2.1.1 Documentation Conventions

The following format conventions are used in this document to identify special information:

Warning statements identify conditions or practices that could result in personal injury.

Caution statements identify conditions or practices that could result in damage to equipment or loss of data.

Variable names are enclosed in angle brackets and presented in italicized text (e.g.: <*Graph Name*>).

Notes: The screen illustrations and the displayed data in this document are for example purposes only. They may differ from the screens on your PC.

The graphical illustrations in this document are for example purposes only and the hardware illustrated may differ from your hardware.

2.2 Essential Prescribing Information

2.2.1 Device Description and Specifications

Table 2 – Device Description and Specifications

Tests Performed:	FVC (Pre-Post Rx), SVC
Parameters Measured:	• Expiratory: FVC, FEV.5, FEV.5/FVC%, FEV1, FEV1/FVC%, FEV3, FEV3/FVC%, FEV6, FEV6/FVC%, FEV1/FEV6%, $^{+}$PEFR, FEF25%, FEF50%, FEF75%, FEF25-75%, FEF.2-1.2, FEF75-85%, Tpeak(mSec), Vext%, Vext(L), MET(S), Texp(S), Veot(L) • Inspiratory: FIVC, FIV.5, FIV.5/FIVC, FIV1/FIVC, FIV3, FIV3/FIVC, PIFR, FIF50%, FIF25-75%, FIF.2-1.2, FIF50/FEF50, MIT(S), Tinsp(S)

Table 2 – Device Description and Specifications	
Pneumotach:	Accuracy: < ±3% or 100 ml, whichever is greater Flow Range: -12 to +16 L/s Type: Flexible Variable Orifice Pneumotach
Filter Requirement:	KoKoMoe (model #810000 or 819000)
Power Equipment:	Supplied external 100-240 VAC Switching Power Supply / Recharger, 12 VDC Output, 2.5 Amp; Rechargeable internal NiMH battery.
Reproducibility:	< ±0.5%
Volume Range:	±16L
Resistance:	< 1.5 cmH20/L/sec when tested with KoKoMoe filter
Software Compatibility	Downloadable to KoKo PFT Spirometry Software version 4.6 (build 6) or higher; operating on Windows 2000, XP or higher
Predicted Sets:	Hankinson (NHANES III (USA)), Crapo 1981 (USA), Polgar (Pediatrics (USA)), ERS 93 (ECCS), Perriera (Brazil), Gore (Australia), Dejsomritrutai (Thai), SEPAR (Spain), Forche (Austria), Gulsvik (Norway), Viljanen (Finland), Knudson 76 (USA), and Hedenstrom (Sweden)
Interpretation Algorithm:	McKay (ATS / ARRD 1991)
Reports:	Formats for both Internal and External Printers: 1. FVC Standard Best 2. FVC Pre-Post Best 3. FVC Complete Best 3 4. FVC Complete Best Pre/Post 5. FVC V/T Full Size 6. Pre-Post + V/T Full Size 7. Standard Best 3 8. Pre-Post Best 3 9. SVC Complete Best 3 10. SVC Pre-Post Best
Incentive Graphics:	Photo-realistic Color Candles

Table 2 – Device Description and Specifications	
Connectivity:	Downloadable to KoKo PFT Software via built-in USB port; Uploadable patient demographics from KoKoPFT via built-in USB port.
Physical Specifications	Construction: High-impact Polycarbonate Dimensions: 23.5 x 25.4 x 7.0 cm; 9.25 x 10.0 x 2.75 inches Weight: 1.6 kg; 3.6 lbs.
Operating Environment:	10 - 40°C; 0 – 80% relative humidity non-condensing at temperatures to 31°C
Safety:	Use only supplied Class II Power adapter; Ordinary equipment (not protected against harmful ingress of moisture); Not suitable for use with flammable anesthetics; Suitable for continuous use.
EMC Rating:	Radiation and conducted emissions and immunity per EN 60601-1-2
Performance Standards:	ATS 1994 – properly measures all 26 flow-time waveforms; ERS; BTS; NIOSH; ACOEM
Quality standards:	• Quality System Regulations: FDA QSR [21 CFR 820], ISO 13485:1996 CMDCAS • European Directives: MDD 93/42/EEC • Product Standards: EN 60601-1, 60601-1-1, 60601-1-2

2.2.2 Intended Use and Indications

This device is intended to be used as a pulmonary function diagnostic testing device. The flow sensor assembly is held by the patient, but it does not in any way interact with or influence the patient when used as specified. This device is indicated for use in the diagnosis and monitoring of asthma and other respiratory diseases.

2.2.3 Conformance to Standards

Ferraris Respiratory and this device conform to the following standards:

Quality System Regulations	FDA QSR [21 CFR 820], ISO13485:1996 CMDCAS
European Directives	MDD 93/42/EEC
Product Standards	EN 60601-1, 60601-1-1, 60601-1-2

2.2.4 Warnings and Precautions

Federal Law restricts this device to sale by or on the order of a physician.

CAUTION: Always use the AC adapter that accompanied the system. Using a different AC adapter can cause permanent damage to your system.

CAUTION: Always use the USB cable that accompanied the system in order to comply with radiation and conducted emissions and immunity per EN 60601-1-2.

WARNING: The operator must not create a "bridge" between the KoKo Legend I/O ports and the patient by simultaneously touching both.

CAUTION: Do not attempt to wash or immerse the KoKo Legend or accessories in water or cleaning fluid, as there are electronic components inside that will be permanently damaged.

CAUTION: This device complies with the minimum electromagnetic compatibility requirements of the Medical Device Directive (MDD). However, electromagnetic interference may still be encountered. If the device is behaving erratically due to electromagnetic interference, contact our service department (refer to page iii for contact information).

2.2.5 Maintaining Device Effectiveness

The recommended operating conditions for the KoKo Legend Spirometer are 10° to 40°C, 0 to 80% humidity non-condensing at temperatures to 31°C, decreasing linearly to 50% relative humidity at 40°C. The recommended transport and storage conditions are -20°C to 50 °C; 0 to 95% non-condensing humidity; -1000 to 10,000 feet or 787.9-522.7 mm Hg.

The KoKo Legend Spirometer housing may be wiped clean with a soft cloth dampened with soapy water. Refer to the section 7, Maintenance, for complete cleaning instructions.

Your KoKo Legend Spirometer has been assembled with care and tested thoroughly to provide you with a quality instrument for many years of use. We ask that you provide the extra effort and care required to familiarize yourself with all of its features to assure proper and effective use.

3 Getting Started

This section describes the components of your KoKo Legend spirometer. We strongly recommend that you read it before using your KoKo Legend - even if you are already familiar with spirometers.

3.1 Unpacking

When you receive your KoKo Legend, unpack it carefully, and compare the parts you have received with the items listed below:

Figure 1 – KoKo Legend Parts

Figure Legend

1 – AC Adapter with AC Power Cord	6 – Flow Sensor Assembly
2 – KoKo Legend Desk Top Spirometer	7 – Nose Clip
3 – Printer Paper	8 – Disposable Filter
4 – KoKo Legend Operator's Guide	9 – Optional Software Configurator
5 – Handset Cable	10 – USB Cable

Once you have checked and confirmed that your KoKo Legend is complete, read through the following pages to learn all about your spirometer's capabilities.

3.2 Assembling

Be sure to observe the safety precautions listed in section 2.2.4, Warnings and Precautions, of this manual.

3.2.1 Connecting the Flow Sensor Assembly

The flow sensor assembly is connected to the desktop spirometer with the handset cable.

Figure 2 – Handset Cable

The small jack located on the right side of the KoKo Legend device is used to connect the flow sensor assembly. To connect the flow sensor assembly follow these steps:

1. Align the connector on the handset cable with the port opening labeled: ( )
2. Push the connector into the port until it is seated.
3. Plug the other end into the matching port on the bottom of the flow sensor assembly.

3.2.2 Connecting the AC Adapter

Caution: Do not operate the KoKo Legend using any other power supply than the one provided with the system.

The Legend is powered by an external AC adapter, which also functions as a charger for the internal NiMH rechargeable battery.

Figure 3 – External Power Supply

Notes: Only authorized service personnel should replace the battery.

Charge the battery for approximately four hours prior to initial use if using under battery power. It is acceptable to use the device immediately if it is plugged into AC power.

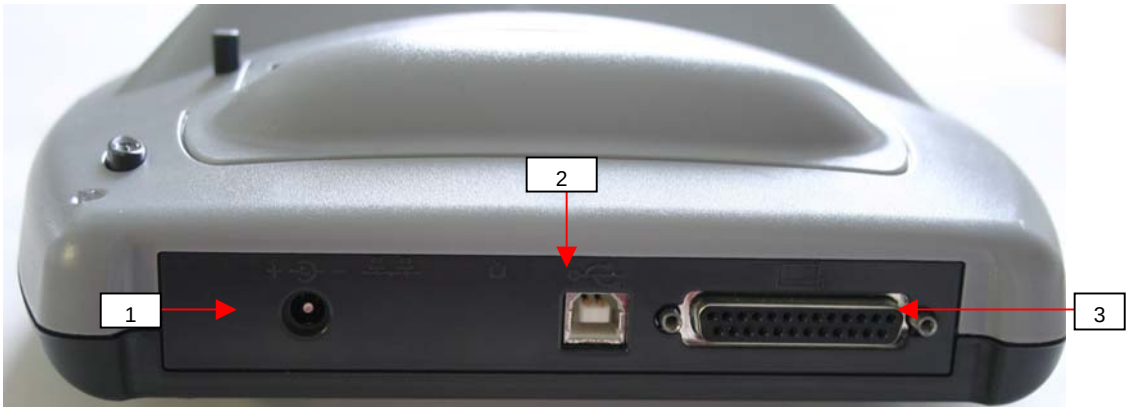


Figure 4 – Parallel Printer Compatible KoKo Legend Rear View

Figure Legend

1 Power port
2 USB port (optionally used to connect to a PC)
3 External printer port (parallel printer)

Figure 5 – USB Printer Compatible KoKo Legend Rear View

Figure Legend

1 Power port
2 USB port (optionally used to connect to a PC)
3 Reset button
4 External printer port (USB printer)

1. Plug the round end of the power adapter cable into the matching round DC power input jack on the back panel of the KoKo Legend.

   The jack is labeled: + ⊃ -
2. Plug the AC adapter into an AC electrical outlet.

3.2.3 Connecting to an External Printer (Optional)

There are two Legend models, one has a parallel printer port and the other has a USB printer port. Refer to Figure 4 and Figure 5.

The KoKo Legend has been designed to interface with HP printers supporting PCL 3 or later.

Note: Since many printers support this character set, the Legend device has not been validated with every model. It has been validated with the HP 5650.

1. Connect the cable to the printer.
2. Connect the other end of the printer cable to the back panel of the Legend device.
    a. If you have a parallel printer compatible Legend device, plug the parallel printer cable into the parallel printer port on the back panel of the KoKo Legend device.

    The port is labeled: 

    b. If you have a USB printer compatible Legend device, plug the USB printer cable into the USB printer port on the back panel of the KoKo Legend device.

    The port is labeled: 
3. Connect the printer to a power supply.
4. Turn on the printer.

3.2.3.1 Opening and Closing the Internal Printer Cover

To open the internal printer cover, perform the following:

1. Press the printer cover release button. The cover releases from the unit.

Figure 6 – Printer Cover Release Button

2. Remove the cover from the unit and set aside.
3. Perform the desired maintenance.
4. Replace the cover by positioning it on to the unit. Make sure the end of the paper supply passes through the slot in the cover. Slide the two tags on the cover into the slots on the unit.
5. Press the door down on the doomed area until it engages.

3.2.3.2 Loading the Printer Paper

To load the paper roll for the internal printer, perform the following:

1. Open the printer cover (refer to section 3.2.3.1).
2. Remove the old paper roll.

3. Insert a new roll of paper in the well with the feed of the paper originating from underneath the paper roll and feeding towards the front of the unit.
4. Pull the paper through the serrated slot opening in the printer cover, attempting to keep it centered.

Figure 7 – Paper Feed

5. Replace the printer cover. Refer to section 3.2.3.1.

3.2.4 Attaching the Disposable Filter

Ferraris Respiratory disposable KoKoMoe filters are the viral/bacterial filters recommended for use with the KoKo Legend. Filters are designed for single use and should be replaced for each patient and before calibration.

The use of viral/bacteria filters will assist in protecting the spirometer from contamination.

The disposable filter/mouth piece is a single use filter and needs to be replaced for each new patient. It is a friction fit and is pressed onto the flow sensor as shown below:

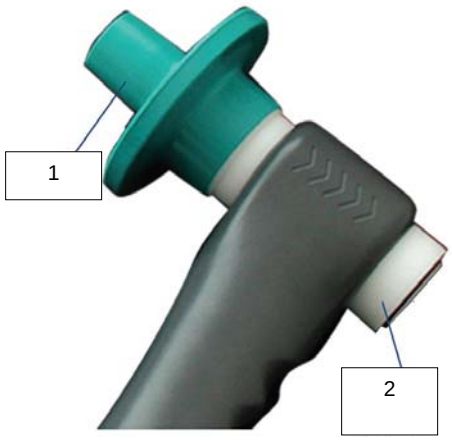


Figure 8 – Filter Attached to the Flow Sensor

Figure Legend

1 – Disposable Filter	2 – Flow Sensor

3.2.5 Battery Mode

The KoKo Legend has an internal battery supply. It can operate without power for approximately two hours under continuous use. The battery will drain faster if you do excessive printing while the unit is battery powered.

Note: When the unit is operated without external power, the icon is displayed in the lower right corner of the screen.

When operating the KoKo Legend using the battery power, the following sequence of events occur if you do not use the KoKo Legend:

- The screen will dim after two minutes.
- The unit will turn off after 10 minutes.

3.2.5.1 Low Battery Condition

When the battery has less than 10 minutes of supply left, the low battery mode is activated. The unit starts to beep and the battery capacity indicator ( ) starts flashing. When this condition exists, connect the unit to the external power supply.

3.2.6 Recharging the Battery

To recharge the battery, connect the KoKo Legend to the external power supply. Verify the power supply is plugged in.

4 Preparation for Use

This section describes how to power on the device and perform the set-up procedures.

4.1 Starting your KoKo Legend Spirometer (Power On)

Once you have connected your AC adapter (or have previously allowed the internal battery to be charged), you can power on your KoKo Legend.

1. Press the gray button (labeled: ⏻) located in the upper right hand corner to turn on system, please allow the KoKo Legend startup screen to load, it will take several seconds. The very first time the KoKo Legend is turned on, a screen is displayed showing the flags of nations that reflect the languages supported in the device.
2. Select the appropriate flag based upon the language choice. This will automatically activate that language and open the Setup screen to adjust any other settings. Ordinarily, the Setup screen can be accessed during the start-up period by pressing the Setup button in the lower right corner.

Note: If you select a flag on the normal start-up opening screen, the setup mode is invoked (the Setup (1/4) screen is displayed).

After the startup screen is displayed for a few seconds, the FVC screen appears, containing any current data from the last patient tested.

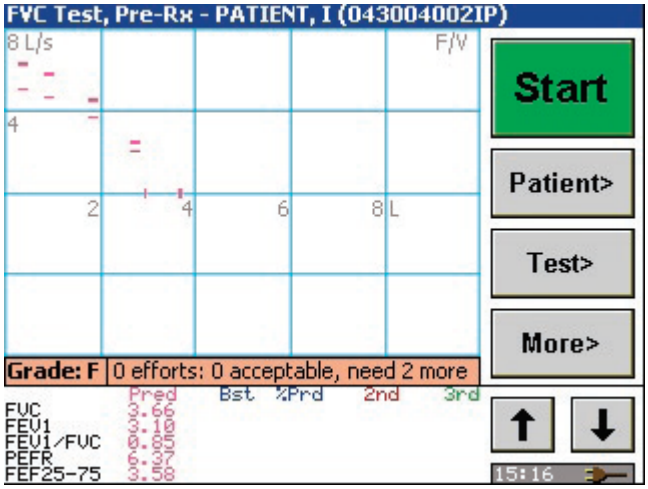


Figure 9 – Main FVC Testing Screen

4.2 Calibrating the Spirometer

Please refer to section 7.1.1, Calibration, for instructions in calibrating your KoKo Legend spirometer. It is important to calibrate each day you plan on performing spirometry tests with the device. On the initial start-up of the KoKo Legend, you will be prompted to perform a calibration.

4.3 Setup

The Setup options enable you to configure your device settings (time and date format, units of measure, language, etc.).

To setup your device, perform the following:

1. Press **[More]** on the testing screen; this action will display three additional buttons. Then press **[Setup]**. This will allow the configuration of four screens of items as follows:

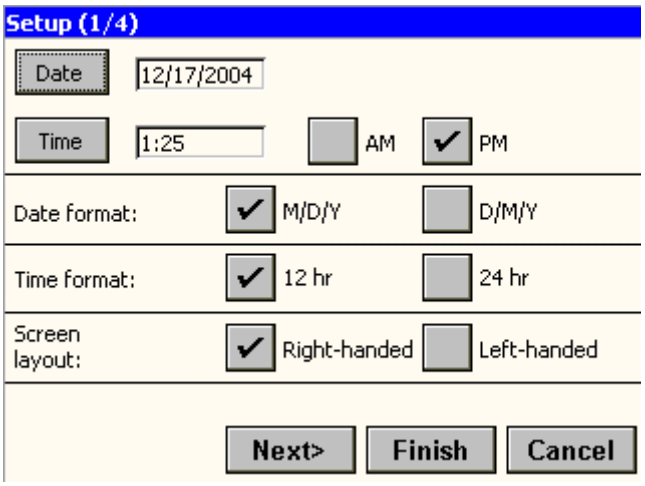


Figure 10 – Setup Screen 1/4

Date: Enter either as mm/dd/yyyy or as dd/mm/yyyy format (depending on choice of Date Format below). It is important to enter the year as four digits and to include the (/) slashes.

Time: Enter either as 12-hour time format and check the [AM] or [PM] button or as 24-hour time format.

Date format: Select either M/D/Y or D/M/Y (relates to your entry in the Date field above).

Time format: Select either 12 hr or 24 hr (relates to your entry in the Time field above).

Screen layout: On each of the screens with buttons on the side, it changes the position of the buttons to the left or right side as selected **[Right-handed]** or **[Left-handed]**.

2. When finished with the items on this screen, press **[Next>]**. The following screen is displayed:

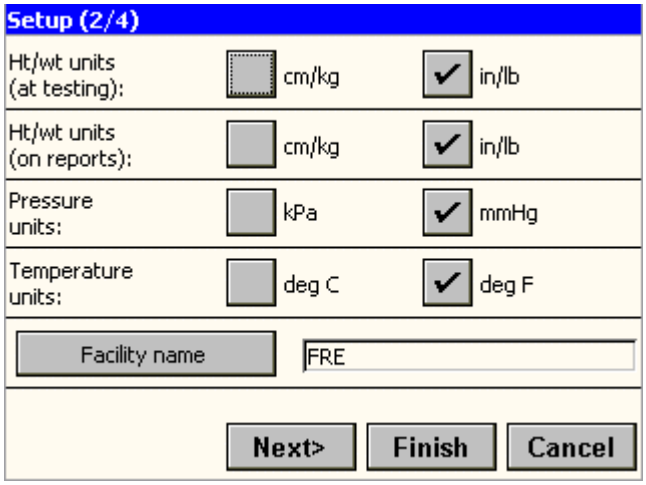


Figure 11 – Setup Screen 2/4

Ht/wt units (at testing): Select either cm/kg or in/lb to define the units for entering height and weight on the patient entry screen.

Ht/wt units (on reports): Select either cm/kg or in/lb to define the units for height and weight on reports.

Pressure units: Select either kPa or mmHg.

Temperature units: Select either deg C or deg F.

Facility name: Enter the name to appear at the top of the reports (optional).

3. When finished with the items on this screen, press **[Next>]**. The following screen is displayed:

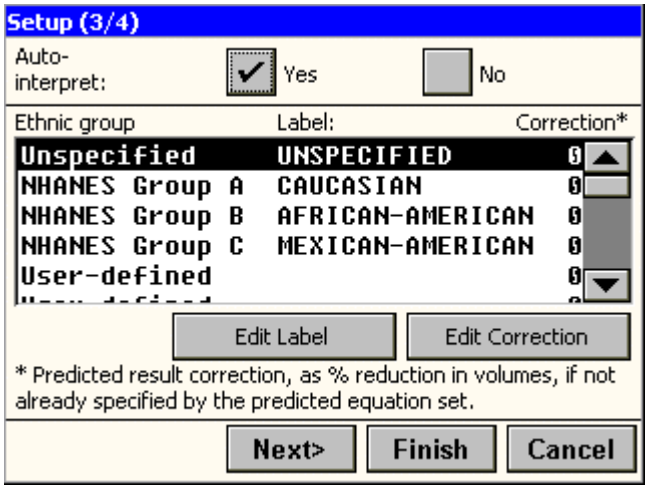


Figure 12 – Setup Screen 3/4

Auto-interpret: Select either Yes or No – if set to No, it will not show an interpretation on screen or on the reports.

Ethnic group: This function allows the entry of new ethnic groups for the patient data entry field called ETHNICITY. It also allows the entry of a specific ethnic correction value to be associated with any chosen ethnic group. Remember that ethnic correction is based upon a percentage reduction (compared to the predicted value for Caucasian) of the predicted values for volume measurements only (i.e. FVC, FEV1, FEV3, FEV6), not for flow measurements (i.e. PEFR, FEF25-75). To add a new ethnic group, scroll to User-Defined (using the UP an DOWN arrow buttons), then press **[Edit Label]** to give it a name for the patient entry screen, and then press **[Edit Correction]** to enter a value for the percentage reduction. Use the same procedure to edit the correction value for any ethnic group (except Caucasian) already defined.

4. When finished with the items on this screen, press **[Next>]**. The following screen is displayed:

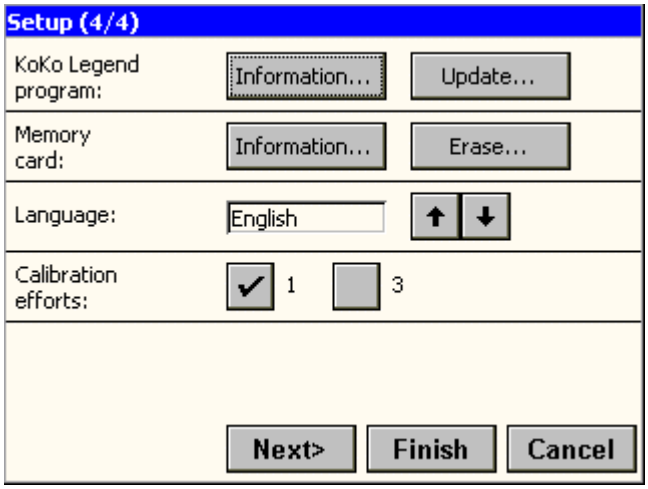


Figure 13 – Setup Screen 4/4

KoKo Legend program:

[Information…] this function displays the current internal software (firmware) version number of the KoKo Legend.

[Update] this function allows updating of the current internal software (firmware) version number of the KoKo Legend via a USB cable.

Memory Card:

[Information…] this function displays the current number of tests stored and available memory in the Compact Flash RAM memory card.

A memory card can store the following information:

- 767 patients
- 6136 test series (8 test series per patient)
- 24544 tests (4 tests per test series: pre- and post- FVC and SVC)
- 122720 efforts (based on an average of 5 efforts per test)

Ferraris Respiratory will only warranty data integrated on memory cards purchased from our company.

[Erase] this function erases all the tests stored in the Compact Flash RAM memory card.

Language:

This function allows the KoKo Legend to select the current active language. Available languages include: English, Spanish, French, Portuguese, German, Italian, Dutch, Danish, Norwegian, Swedish, and Finnish.

When finished with the items on this screen, press **[Next>]**. This will return you to the Setup Screen 1 of 4. If you are finished with the Setup items, press the **[Finish]** button.

Calibration efforts:

This function enables you to select the desired calibration technique:

- One Push (1)
- Three Push (3)

5. When finished with the items on this screen, press **[Next>]** to modify any of your selections on the previous Setup screens, or select **[Finish]** to complete your Setup selections.

4.4 Advanced Configuration of the KoKo Legend Spirometer

Refer to the section 7.3.3.1, to review the additional advanced items available for extended configuration.

5 Testing Options

There are various testing options that affect the way a test is performed, viewed, evaluated and commented. There are testing options for the FVC and the SVC test. Since the SVC options are a subset of the FVC options, this document uses the FVC screens to illustrate the options.

A maximum of eight test series, with up to eight acceptable efforts in each series, can be stored for one patient.

1. On the main FVC test screen, press the **[More]** button, then press the **[Options]** button.

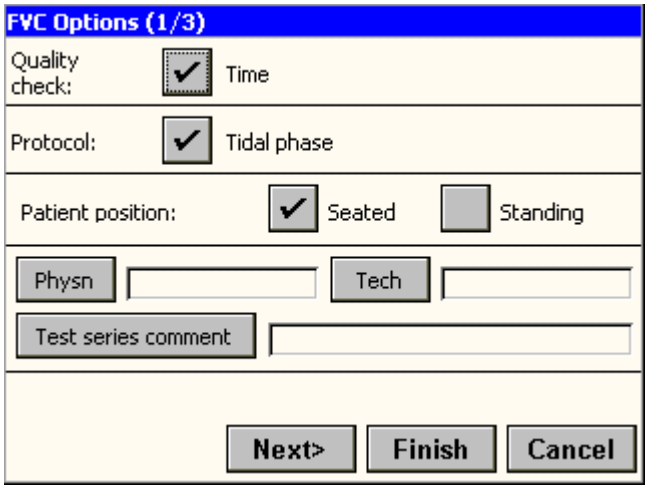


Figure 14 – FVC Options 1/3

Quality Check: If selected, allows tests under 6 seconds in length to be considered acceptable as long as no other error conditions exist.

Protocol: If selected, at least one tidal breath is required at the start of a test.

Patient position: Enables you to enter a comment (applies to this test series only) documenting whether the patient is being tested seated or standing. Both the ATS and ERS recommend testing in the standing position unless a patient is incapable of testing in the standing position or if there is a history of vertigo or light-headedness.

Physn: Enables you to enter a comment (applies to this test series only) documenting the Physician's name (or initials).

Tech: Enables you to enter a comment (applies to this test series only) documenting the Technician's name (or initials).

Test series comment: Allows entry of a free form entry comment about this specific test. This entry is limited to 35 characters.

Note: Only 30 characters are displayed on the Options 1/3 screen, but all 35 characters are included in the patient report. If you need to review your input, reselect the [Test series comment] button and review your input from the Test series comment screen.

2. When finished with the items on this screen, press **[Next>]**. The following screen is displayed:

Note: The Best effort and Retain efforts fields are not displayed until after some patient testing is performed.

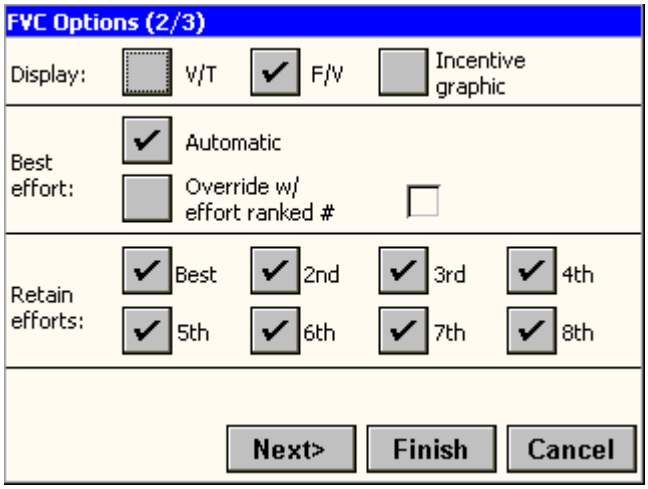


Figure 15 – FVC Options 2/3

Display:

[V/T] This function allows the FVC test to be performed with a real time on-screen Volume/Time Graph.

[F/V] This function allows the FVC test to be performed with a real time on-screen Flow/Volume Loop.

[Incentive Graph] This function allows the FVC test to be performed with a real time on-screen display of 8 realistic animated candles. The goal of this incentive graphic is to blow out all the candles, indicating 100% of the predicted value.

Figure 16 – Candle Incentive Display

Best effort:

Automatic Allows the KoKo Legend software to use standard ATS and ERS criteria for the automatic choice of best test in the test series.

Override w/effort ranked # [ ] Enables you to choose a specific test to be defined as best test, irrespective of the software's automatic choice. If you want to specify a test, select the checkbox and select a test number using the up and down arrows.

Retain efforts:

Allows the data from up to eight different efforts to be retained in memory and long-term storage on the compact Flash RAM card. The check boxes for each effort do not appear until that effort has been completed.

3. When finished with the items on this screen, press **[Next>]**. The following screen is displayed:

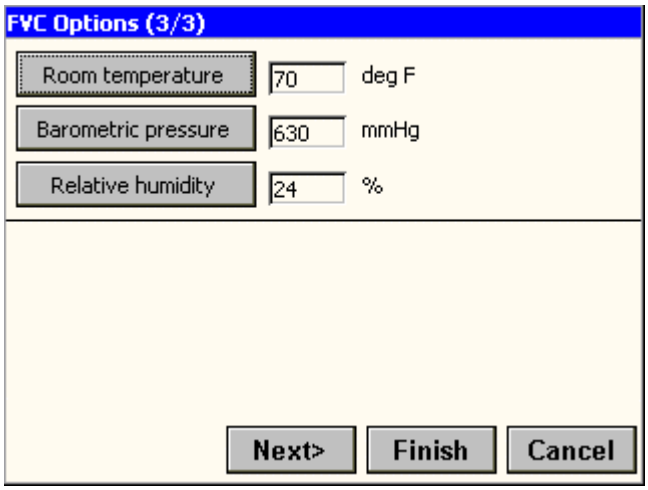


Figure 17 – FVC Options 3/3

Room temperature: Enter the current room temperature if different from the last calibration. Enter in either degrees F or degrees C, depending on the choice in Figure 11 – Setup Screen 2/4.

Barometric pressure: Enter the current barometric pressure if different from the last calibration. Enter in either mmHg or kPa, depending on the choice in Figure 11 – Setup Screen 2/4.

Relative humidity: Enter the current relative humidity percentage if different from the last calibration.

4. When finished with the items on this screen, press **[Next>]** to modify any of your selections on the previous Options screens, or select **[Finish]** to complete your Option selections.

5.1 Patient Preparation

Spirometry is subject to data variability from a number of sources. A major source of variability is the patient. To minimize patient inconsistency it is important to develop a standardized approach used with each patient. Teaching the patient how to perform a spirometry test properly is critical for achieving meaningful results. Spirometry is a patient effort dependent test, so proper coaching of the subject is very important. The coach should fully explain the test to the patient. First explain that the purpose of the test is to measure the function and health of his or her lungs. Remind the patient that the test is painless. Simulate the correct maneuver using a spare filter reserved for that purpose. The FVC instructions should be as follows:

1. "We're going to be doing a test to check your lung function. We will be repeating this test a few times to get what we need."
2. "First I am going to have you breathe normally using the mouthpiece." (Show the patient the mouthpiece.)

3. “At one point I will have you take a quick DEEP breath in and then BLAST it out hard and fast.”
4. “When I tell you to take a DEEP breath I want you to take as much air into your lungs as you can.”
5. “When I tell you to BLAST it out I want you to blow out as hard and fast as you can, and keep blowing until you cannot get any more air out.”
6. “Once you are sure that you are completely empty, take another great big breath in. Then you can take the mouthpiece out and breathe normally.”

Actually blow through a spare filter yourself, using body language to emphasize the importance of a maximal inhalation, maximal force and prolonged effort. Immediately after your demonstration, ask the patient if he or she noticed how you squeezed the last little bit of air out of your lungs. It is advisable to have the patient stand while performing spirometry, however, keep a chair immediately behind the patient in case they feel lightheaded. Loosen any restrictive clothing such as a tight belt, tie, vest, bra, girdle, or corset. It is recommended to remove loose dentures that can become dislodged during the test. Nose clips are not necessary for forced expiratory maneuvers since the nasopharynx reflexively closes during the maneuver.

5.1.1 Pre-Test Checklist

- Position: patient is standing unless otherwise indicated for health or disability reasons.
- Clothing: ideally patient should be dressed comfortably to allow good chest, and diaphragmatic excursion. Loosen the patient’s belt or tie (or other clothing and accessories) if necessary.
- Remove dentures or other possible obstructions to the mouthpiece.
- Thoroughly explain the procedure to the patient.
- Demonstrate the procedure to the patient, remembering to be very thorough.
- Have the patient demonstrate the procedure for you.
- Ask the patient if they have any questions.

5.2 Entering Patient Data

1. Press **[Patient]** and then press **[New Patient]**. Complete all patient data fields.

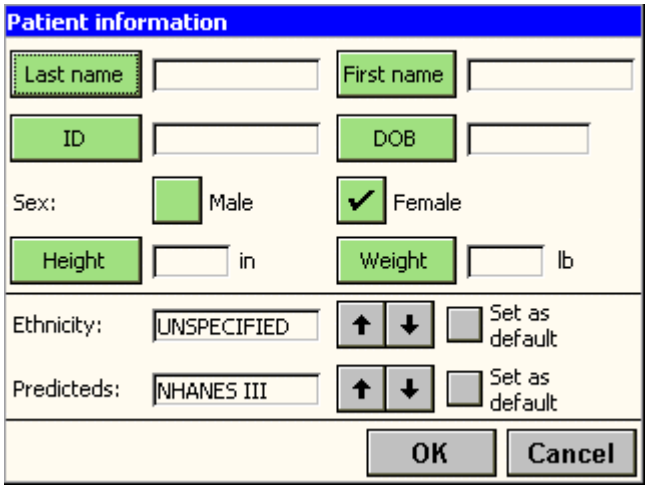


Figure 18 – Entering a New Patient

2. Pressing on any alphanumeric field in the “Patient information” screen displays the “Keypad” screen.

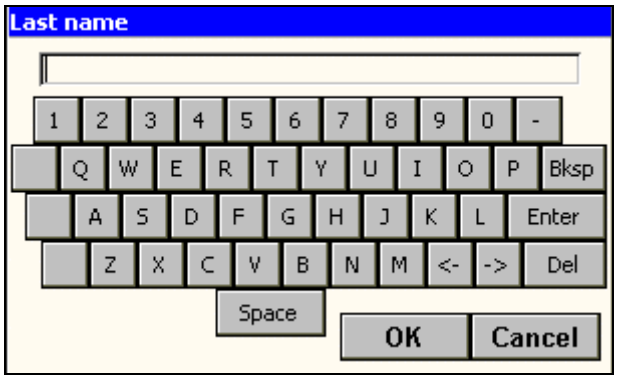


Figure 19 – Keypad

3. Complete the required fields: Last Name, First Name, ID, DOB (Date of Birth), Sex, Height, and Ethnicity.
4. If you choose to, you can set the selected Ethnic group and Predicted set as defaults by selecting the **Set as default** checkbox next to each selection. The selected choices will then be presented first for subsequent new patients.
5. When completed Press **[OK]**.

5.3 Recalling Patient Data

At a test screen, press **[Patient]** then press **[Recall Pt]**. The following screen is displayed.

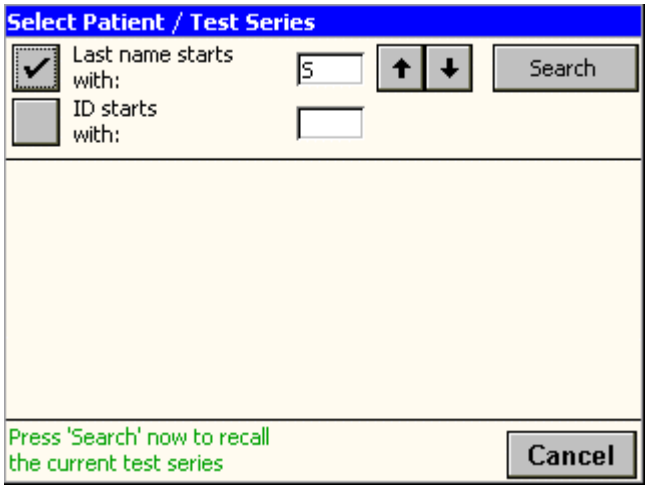


Figure 20 – Select Patient Screen

To search for a patient, you can specify the first letter of the last name or the first number of the patient ID.

1. To search for a patient, perform one of the following:
    a. To search for a patient by last name, select the checkbox next to **Last name starts with** and then use the up and down arrows to specify the first letter.
    b. To search for a patient by ID, select the checkbox next to **ID starts with** and then use the up and down arrows to specify the first number.

2. Select **Search**. The patients meeting the search parameters are displayed. If you have more patients displayed than fit on the screen, use the UP and DOWN arrows to scroll to the desired patient test series. You can sort the list by any of the columns by pressing the button at the top of each column. The sort fields are: **[Name]**, **[ID]**, **[Series Date]**, **[Rx]** (post-drug tests done), and **[Prntd]** (tests have been printed). See the following example.

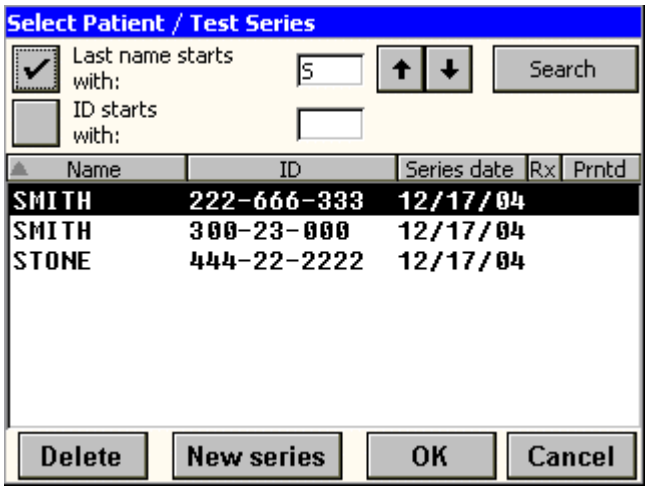


Figure 21 – Sample Search

3. Select the desired patient's test series.
4. Once the desired test series is highlighted, choose one of the following buttons:
    a. **[Delete]** Deletes the highlighted series. A prompt to confirm this choice will be presented.
    b. **[New Series]** Creates a new test series for the highlighted patient. Pressing **[OK]** will load this new test series for testing.
    c. **[OK]** Loads the highlighted test series for continued testing, reviewing, or printing.
    d. **[Cancel]** Exits the screen without making any choice.

6 Performing Tests

With the KoKo Legend, you can perform FVC and SVC tests.

6.1 FVC Test (Pre-Rx)

After creating a new patient or selecting an existing patient, you are now ready to perform the test.

6.1.1 Objective of the FVC Test

The primary spirometry test is also commonly called the FVC or Forced Vital Capacity test. Refer to "Appendix B - Glossary" for explanation of each value measured by the KoKo Legend. The object of the test is to measure the volume and flow of air from a patient after they have taken the largest and most forceful exhalation (expiration) they are capable of. To ensure good effort, and to gain insight into the flow and volume during the inspiration, have the patient take another deep breath in after performing the maximum expiration.

It is very important to perform more than one effort to ensure that the patient actually has done his or her best. The ATS recommendation is to perform at least two consistent error-free efforts within 5% or .15L variation, whichever is higher (using the FEV1 + FVC) out of three tests. In other words, spirometry should be repeated until two acceptable and matching maneuvers are obtained. The ATS also recommends discontinuing testing after eight maneuvers if the variability, reproducibility, and quality criteria still have not been met.

6.1.2 Performing the FVC Test

1. Enter or recall a patient. The FVC test screen is displayed.
2. Press the **[START]** button. Follow the on-screen prompts to perform the maneuver.

   In some cases, a prompt will appear to first wait until the flow sensor has zeroed. This will be indicated by a red message box. Then start relaxed tidal breathing through the filter mouthpiece. However, normally, after pressing **[START]**, the patient can begin relaxed tidal breathing immediately.
3. When the patient is ready, instruct him/her to take a deep breath in. During that deep breath, press the **[NEXT]** key. Then, the patient should blow out as hard and fast as possible, and continue blowing until no more air can be exhaled. Then, the patient should take another deep breath back in. When finished, the effort is complete. If a test is completed which does not meet the acceptability criteria a message will be displayed to assist in understanding what went wrong (see Table 3 for an explanation of the Messages Related to a Patient's Effort).

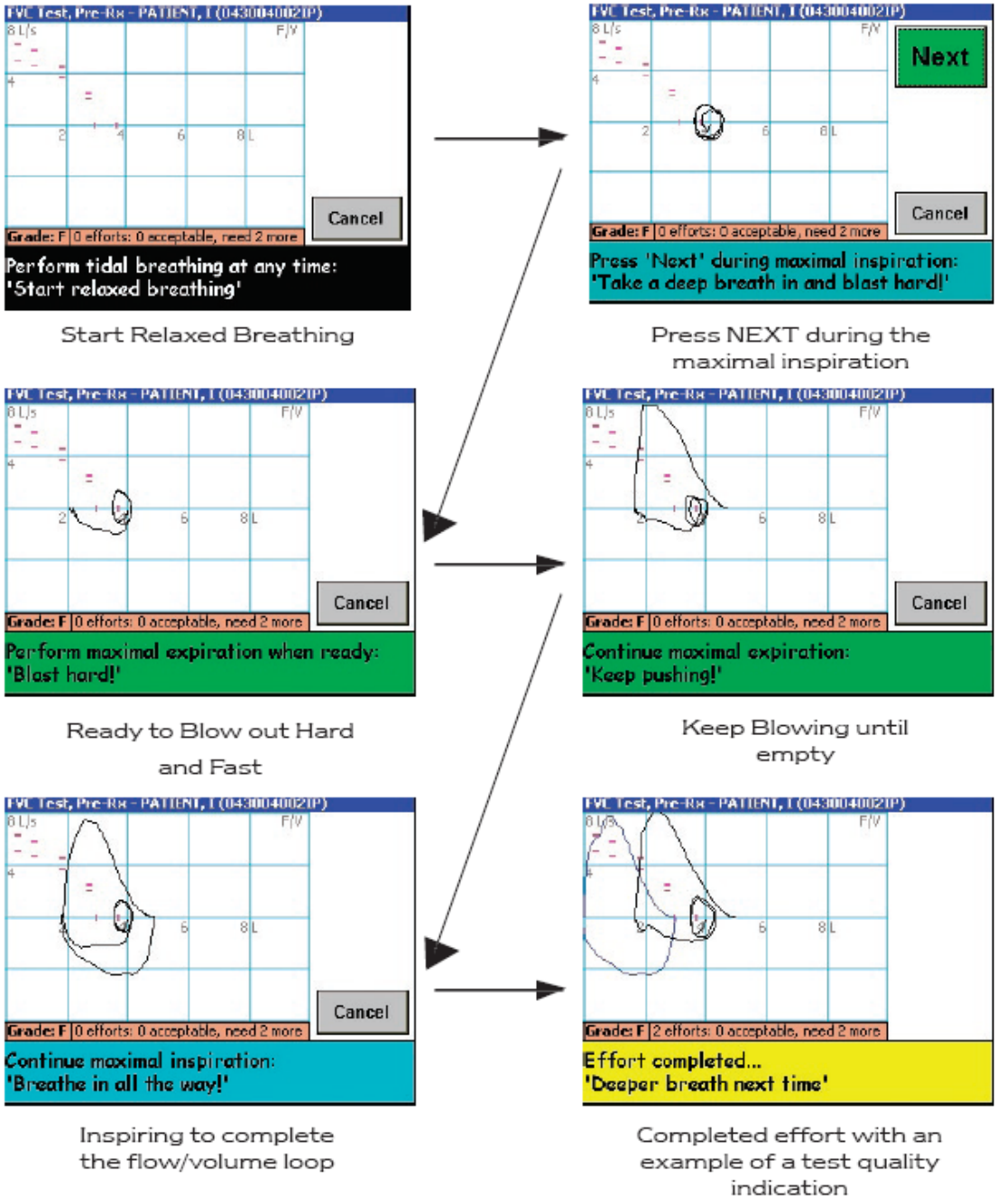


Figure 22 – FVC Test Screens

6.2 SVC Test

The SVC (Slow Vital Capacity) is the maximum amount of air expired from the point of maximum inspiration without attention to speed. However, a maximal effort is still required through the end-expiration. The primary diagnostic value of the SVC test is a relative measure of the effort dependence of the FVC value. Some patients can produce a higher vital capacity when the maximal expiration is done slowly (SVC) versus quickly and forcefully (FVC). When this is true, there is usually an indication of air trapping in the lung. The SVC test can also help uncover a poor effort

on the FVC test due to a misunderstanding of the test procedure. The SVC test also presents a breakdown of some of the standard classifications of lung volume (IRV, ERV, IC, TV).

6.2.1 Objective of the SVC Test

The object of the SVC test is to have the patient establish a steady tidal breathing rate for at least six breath cycles. The patient then fills his or her lungs maximally as in the FVC test, but then lets the air out slowly instead of forcefully. The patient should still continue the expiration until no more air can be exhaled. Refer to "Appendix B - Glossary" for explanation of each value measured by the KoKo Legend.

6.2.2 Performing the SVC Test

1. Explain the procedure to the patient.
2. Enter or recall a patient. The FVC test screen is displayed.
3. Press the **[Test>]** button to display the SVC Test button.
4. Select the **[SVC Test]** button. The SVC Test screen is displayed.

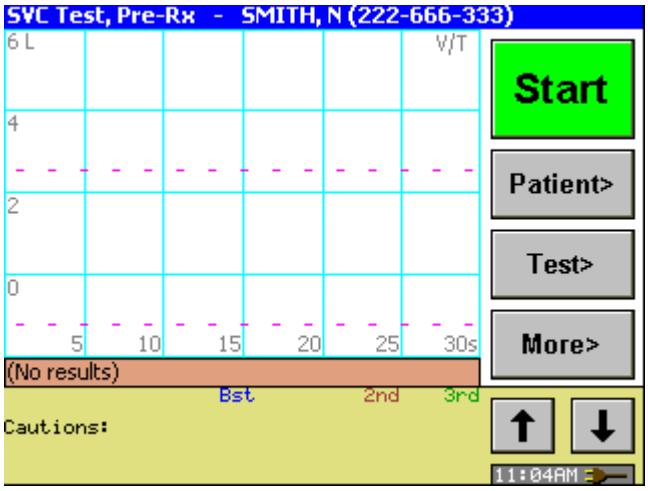


Figure 23 – SVC Test Start Screen

5. Attach a nose clip.
6. Connect the patient to the mouthpiece and direct him/her to breathe normally.
7. Press the **[START]** button. Follow the on-screen prompts to perform the maneuver. The following screens illustrate the maneuver.

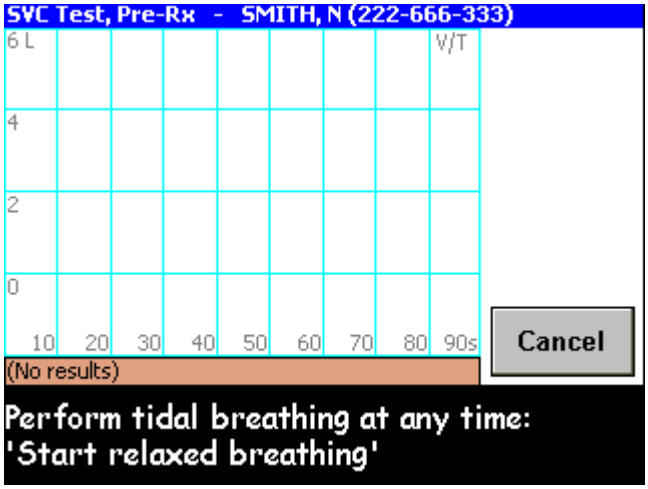


Figure 24 – Start of SVC Test

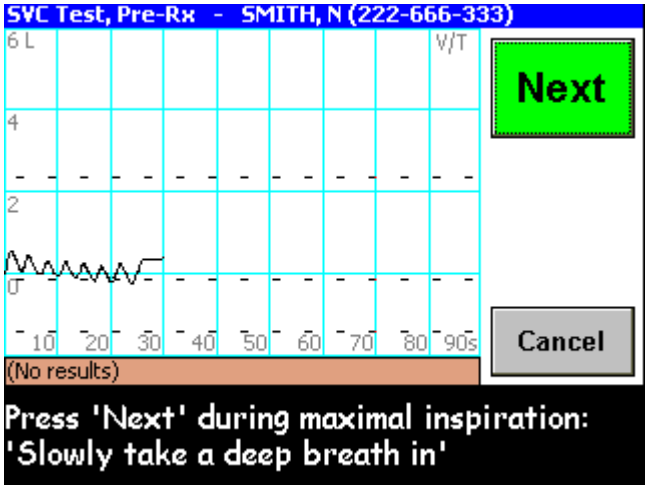


Figure 25 – SVC Prompt for Maximal Inspiration

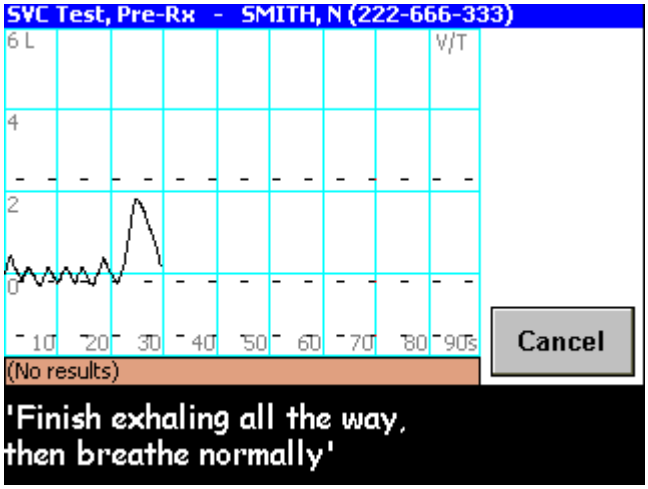


Figure 26 – SVC Prompt for Maximal Expiration

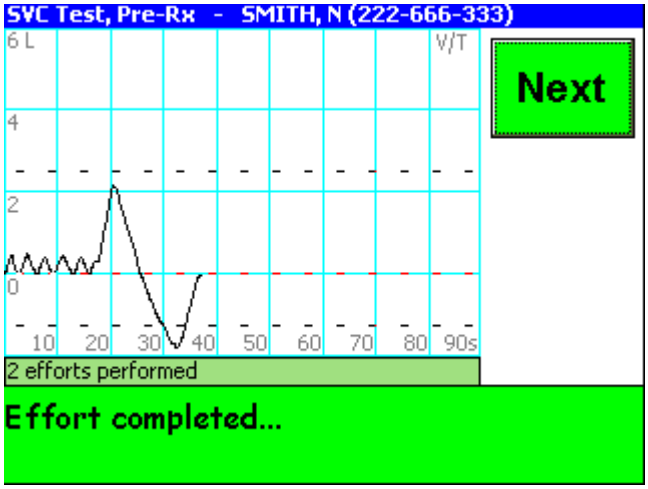


Figure 27 – SVC Effort Completed

6.3 Viewing Immediate Test Results

As soon as the patient has completed a maneuver, the display will change briefly to show the first page of calculated results. If the "Effort less than 1 second, try again" message is displayed, it means that the patient did not exceed 1 second of expiration for the test. The predicted value (Pred), results for the Best Test (Bst), and the percent of predicted (%Prd) are displayed. Results from the 2nd and 3rd best efforts are also shown on this screen. The overall test series grade and a countdown of acceptable and reproducible efforts are shown.

The standard list of FVC parameters shown on this first screen of test results are FVC, FEV1, FEV1/FVC, PEFR, and FEF25-75. Other parameters can be revealed by pressing the DOWN arrow key.

The standard list of SVC parameters shown on this first screen of test results are SVC, IC, ERV, Vt, and RR.

Pressing the DOWN arrow will show the results for effort number 4 through 8 along with a quality statement abbreviation for the effort (see Table 4). A preliminary interpretive statement based upon the best result achieved so far in this session is also displayed (if a complete session is completed with at least 2 acceptable and 2 reproducible efforts).

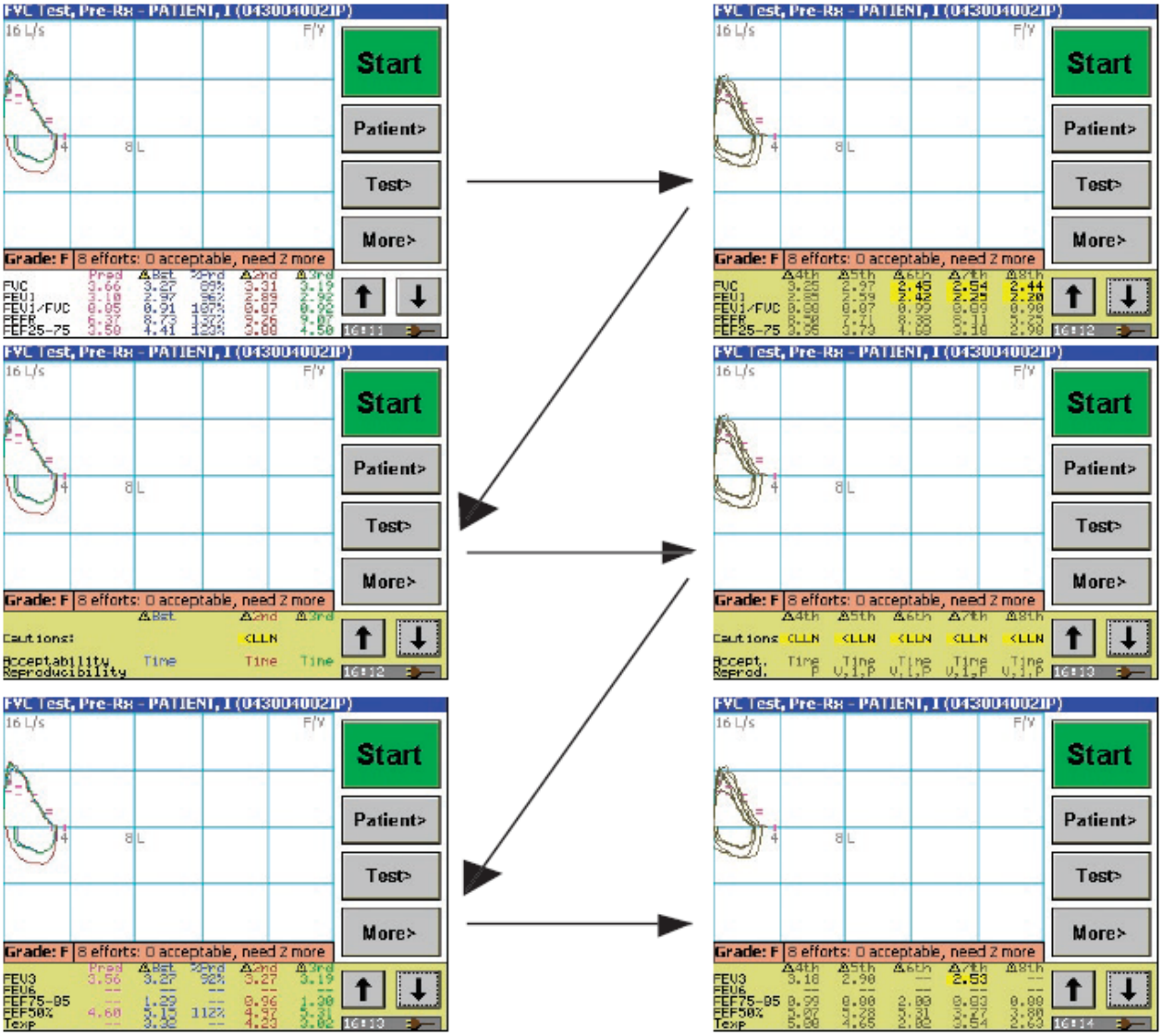


Figure 28 – Scrolling Through Test Results Screen

Table 3 – Messages Related to Patient's Effort			
Message	**Criteria**	**Explanation**	**Abbreviation**
Don't Hesitate	BEV>150ml	Patient hesitated after beginning the expiration.	
Blast Out Faster	PEFT>120ms	The effort to produce a maximal peak flow was insufficient.	Time
Blow Out Longer	FET<6.0 sec and EOTV>100ml	The patient stopped blowing before 6 seconds even though at least 0.1L of exhalable air was in their lungs.	

Table 3 – Messages Related to Patient's Effort			
Message	**Criteria**	**Explanation**	**Abbreviation**
Blast Out Harder	PEF values do not match within 1.0 L/sec.	If several tests were done and the peak flow variability is too high, it indicates that the effort was insufficient.	
Deeper Breath	FEV6 values do match within 0.150 L.	If several tests were done and the FEV6 variability is too high, it indicates that the patient is taking inconsistent deep breaths before each effort.	
BEV - Back Extrapolated Volume in ml. EOTV - End of test volume - change in volume during the last 0.5 seconds of the maneuver. PEFT - Time to peak flow in msec. FET - Forced Expiratory Time in seconds. Only one QC message is displayed, in order of top to bottom priority shown in the table above. After 2 acceptable maneuvers that match, the QC message is GOOD TEST SESSION.			

6.3.1 QC GRADE

The overall session interpretation and QC Grade is based upon this Composite Best data. Composite Best is the best data from the test session, mixing "best" values from different efforts within the series.

Table 4 – Quality Grades Related to Patient's Effort	
QC Grade	**Explanation**
A	At least 2 acceptable maneuvers with the largest two FEV1 values matching within 100 ml, with the largest 2 FEV6 values matching better that 100 ml.
B	At least 2 acceptable maneuvers with FEV 1 values matching between 101 and 150 ml.
C	At least 2 acceptable maneuvers with FEV1 values matching between 151 and 200 ml.
D	Only one acceptable maneuver, or more than one, but the FEV1 values match >200 ml (with no interpretation).
F	No acceptable maneuvers (with no interpretation).

6.3.2 Interpretation Statement

The KoKo Legend interprets the spirometry data following the recommendations in the publication "McKay, R. Airway Obstruction Severity, AARD, 1991." The FEV1 percent of predicted is the primary defining value used in categorizing the severity of the abnormality. It is advisable to report the FEV1 to the patient as a percentage of predicted. This is "the number" the patient should remember. A flow chart showing the interpretive is shown in "D.1 McKay Interpretation Flow Chart."

6.4 Performing the Next Test

Press the **[START]** button to begin the next patient effort. Up to eight efforts will be allowed.

6.5 Performing Post-Rx Tests

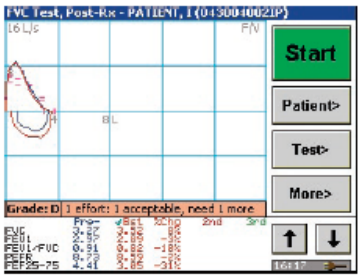
After selecting the same patient or an existing patient, you are now ready to perform the Post-Rx test. It is possible to test new patients while the previous patient is being administered the bronchodilator. Simply enter and test a new patient, then re-select the ID number of the patient currently waiting for the bronchodilator to take effect.

6.5.1 Object of the Test

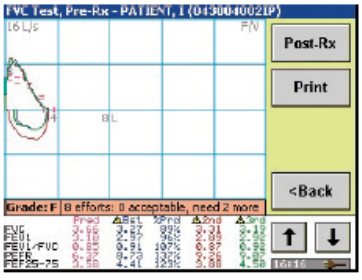
This spirometry test is also commonly called the Post-BD FVC or Post-BD Forced Vital Capacity test (often referred to as Post-Rx). Some clinicians refer to this as Bronchospasm evaluation. Refer to the "Appendix B - Glossary" for an explanation of each value measured by the KoKo Legend. The object and procedure of this test is identical to the Pre-Rx tests, except the final results are compared numerically to the pre-Rx test and a percentage change is calculated. If a patient responds to the administration of a bronchodilator, there is typically a significant (>20%) increase in FEV from the Pre-Rx value to the Post-Rx value.

6.5.2 Performing the Test and Viewing Results

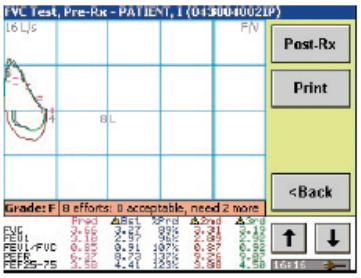
To perform the Post-Rx FVC test, press **[Test]** and then **[Post-Rx]**. Follow the exact same procedures described in the section on pre-Rx testing (refer to section 6.1.2 and 6.2).



Selecting Post-Rx Mode



A typical Post-Rx



(Post BD) Test

6.6 Printing Test Reports

1. To print patient reports, press the **[Test>]** button and then press **[Print]**. The Print Test Series screen is displayed.

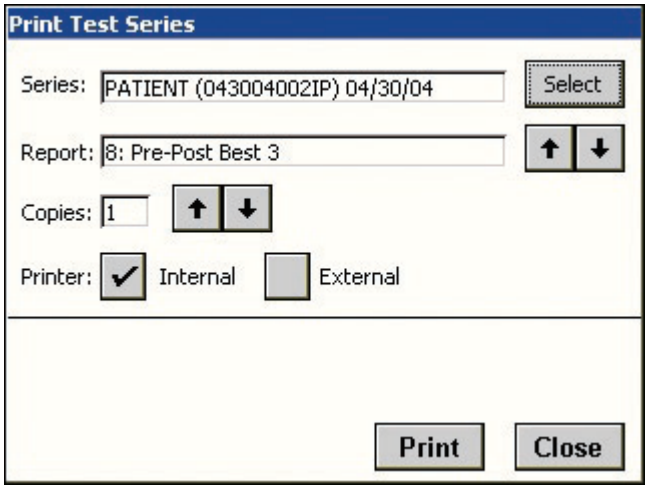


Figure 29 – Printing a Test Series

2. Perform the following to select a test to print:
    a. To select a different patient, press the **[Select]** button and then search for the desired patient (refer to section 5.3 for details).
    b. To select the desired report to print, use the up and down arrows ( ).
    c. To select the number of copies to print, use the up and down arrows ( ).
    d. To select the desired printer, press the appropriate checkbox.
3. To print the report, select the **[Print]** button.

6.6.1 Estimated MVV

The MVV is calculated from the best FEV1 reported from the FVC test. Estimated MVV is equal to the FEV1 multiplied by 37.5. It is reported as the MVVest parameter on the following printed reports:

- FV V/T Full Size (report #5)
- Pre-Post Best 3 (report #8)

7 Maintenance

Minimal maintenance is required for the KoKo Legend. Daily calibration and minor cleaning is recommended. Refer to sections 7.1.1, Calibration, and 7.2, Cleaning.

7.1.1 Calibration

The calibration procedure tests your KoKo Legend's ability to measure a known volume (3 Liters) as well as its ability to repeat the measurement.

ATS recommends calibration whenever you test. It is most convenient to perform calibration first thing in the morning. The KoKo Legend software will warn the user if calibration has not been completed in the last 24 hours.

The following calibration techniques are available to calibrate the flow sensor:

- One-Push Calibration (refer to section 7.1.1.1)
- Three-Push Calibration (refer to section 7.1.1.2)

A 3-liter syringe is required for all calibration techniques.

Before performing a calibration, verify the following have been performed:

- Selected the desired calibration technique in the Setup screens (see Figure 13).
- Entered the current temperature, barometric pressures, and relative humidity in the Options screens (see Figure 17).

Caution: It is critical that the station barometric pressure be entered, not an altitude correct barometric pressure.

7.1.1.1 One-Push Calibration

If you have selected the one-push calibration on the setup screen, perform the following to calibrate your flow sensor:

1. Select the **[Cal]** button. The calibration parameters screen is displayed.

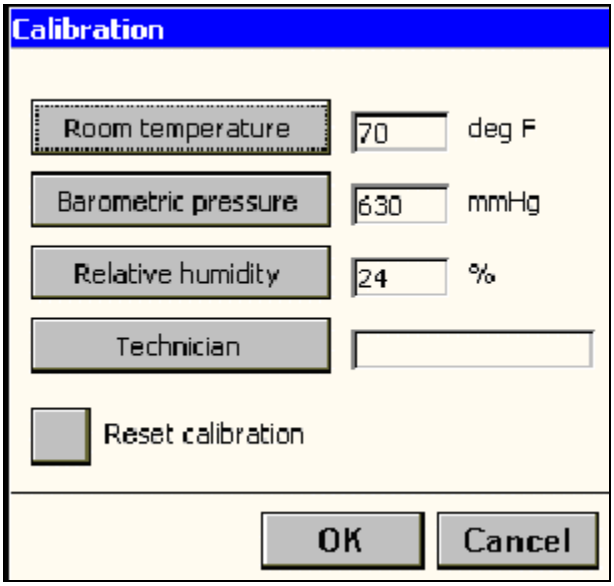


Figure 30 – Calibration Parameters

2. Review the displayed temperature, barometric pressure, and relative humidity; modify if needed. To delete any existing calibration factors, select the Reset Calibration checkbox. Select the **[OK]** button. The start calibration screen is displayed.

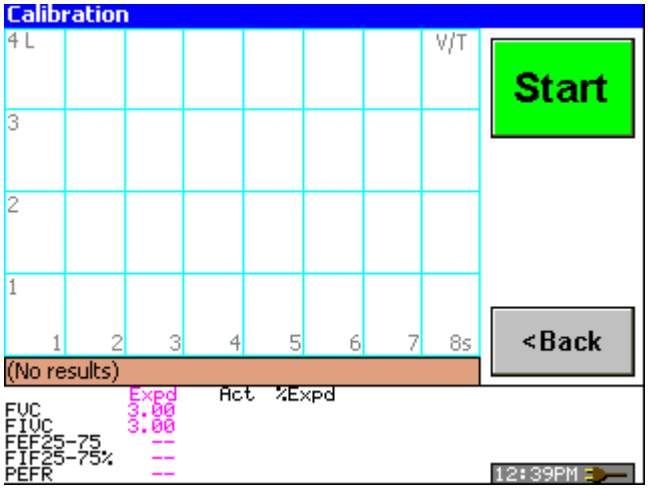


Figure 31 – Start Calibration Screen

3. Select the **[Start]** button. Connect the flow sensor assembly to the calibration syringe using the filter as a coupler. Pull out the syringe handle.
4. Press the **[Next]** button.

Note: The filter needs to be attached to the flow sensor assembly to perform a calibration.

5. Push the syringe handle all the way in quickly (within one second) and then back out (following the flow guide displayed on the screen). If calibration was successful, the following screen is displayed:

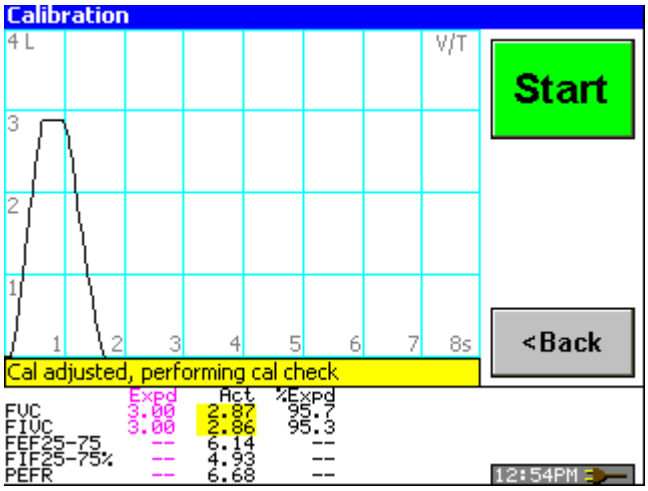


Figure 32 – Calibration Successful

6. Press the **[Start]** button to perform the calibration (cal) check.
7. Pull out the syringe handle and press the **[Next]** button.
8. Push the syringe handle all the way in quickly (within one second) and then back out (following the flow guide displayed on the screen). If the calibration (cal) check is successful, the following screen is displayed and calibration is complete.

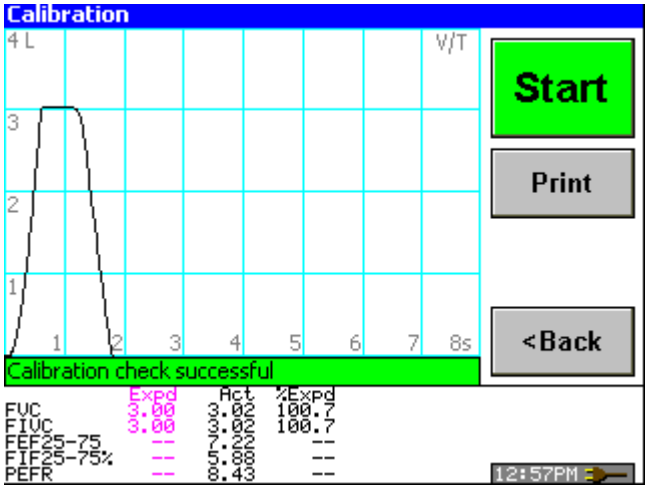


Figure 33 – Calibration (Cal) Check Successful

7.1.1.2 Three-Push Calibration

If you have selected the three-push calibration on the setup screen, perform the following to calibrate your flow sensor:

1. Select the **[Cal]** button. The calibration parameters screen is displayed (see Figure 30).
2. Review the displayed temperature, barometric pressure, and relative humidity; modify if needed. Select the **[OK]** button. The start calibration screen is displayed (see Figure 31).
3. Select the **[Start]** button. Connect the flow sensor assembly to the calibration syringe using the filter as a coupler. Pull out the syringe handle. Press the **[Next]** button.

   Note: The filter needs to be attached to the flow sensor assembly to perform a calibration.

4. Push the syringe handle all the way in and back out (following the flow guide displayed on the screen).
5. If calibration was successful, the following message is displayed:
   Cal adjusted, performing cal check
6. Press the **[Start]** button to perform the cal check.
7. Push the syringe handle all the way in and back out (following the flow guide displayed on the screen). If the calibration (cal) check is successful, the following message is displayed:
   Cal adjusted, performing cal check
8. Press the **[Start]** button to perform the second calibration check.
9. Pull out the syringe handle and press the **[Next]** button.
10. Push the syringe handle all the way in and back out (following the flow guide displayed on the screen). If the calibration (cal) check is successful, the following message is displayed:
    Calibration check successful
11. Press the **[Start]** button to perform the third cal check.
12. Pull out the syringe handle and press the **[Next]** button.
13. Push the syringe handle all the way in and back out (following the flow guide displayed on the screen). If the calibration (cal) check is successful, the following message is displayed:
    Calibration check successful

7.1.2 Barometric Pressure

Weather centers report an altitude corrected barometric pressure, which will be close to 760 mmHg no matter the altitude. For example, the station barometric pressure in Denver, Colorado, is typically 630 mmHg, but the weather news reports 760 mmHg. You need to enter the 630 mmHg value into the device. Table 5 shows an estimated barometric versus altitude.

Table 5 – Estimated Barometric Pressure vs. Altitude

(Smithsonian 1963, Irbarne 1973)

Feet ↓→	0	100	200	300	400	500	600	700	800	900
0	760	757	755	752	749	746	744	741	738	736
1000	733	730	728	725	722	720	717	714	712	709
2000	707	704	702	699	696	694	691	689	686	684
3000	681	679	676	674	671	669	666	664	661	659
4000	656	654	652	649	647	644	642	640	637	635
5000	632	630	628	625	623	621	618	616	614	611
6000	609	607	605	602	600	598	595	593	591	589
7000	586	584	582	580	578	575	573	571	569	567
8000	565	562	560	558	556	554	552	550	548	545
9000	543	541	539	537	535	533	531	529	527	525

The above values are estimates only. Weather can change these values by +20 mmHg. Thus, this table does not replace a barometer. (1 ft = 0.3048m; 1 m = 3.281 ft)

The values previously entered are retained for the next calibration for the user's convenience since minor variations in these entries do not substantially affect the performance of the device.

7.1.3 Printing a Calibration Report

After calibration has completed successfully, you can print the calibration report.

1. To print a calibration report, perform a calibration. After a successful calibration, the following screen is displayed:

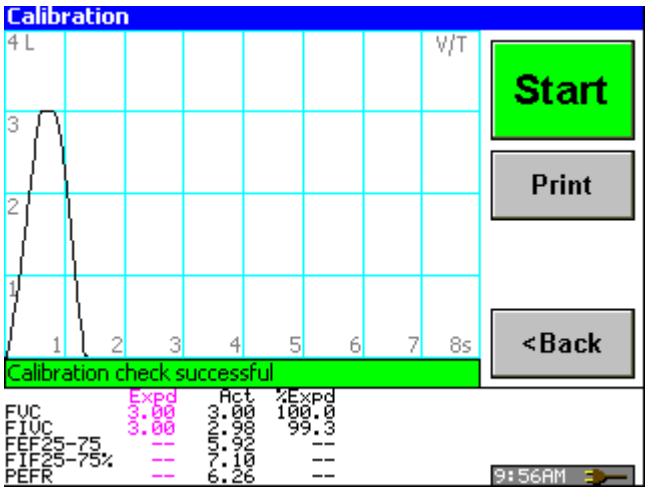


Figure 34 – Example of a Successful Calibration

2. Select the **[Print]** button. The following screen is displayed:

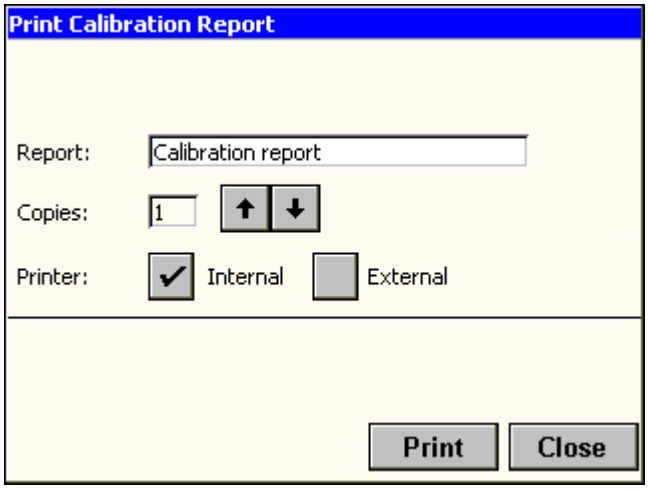
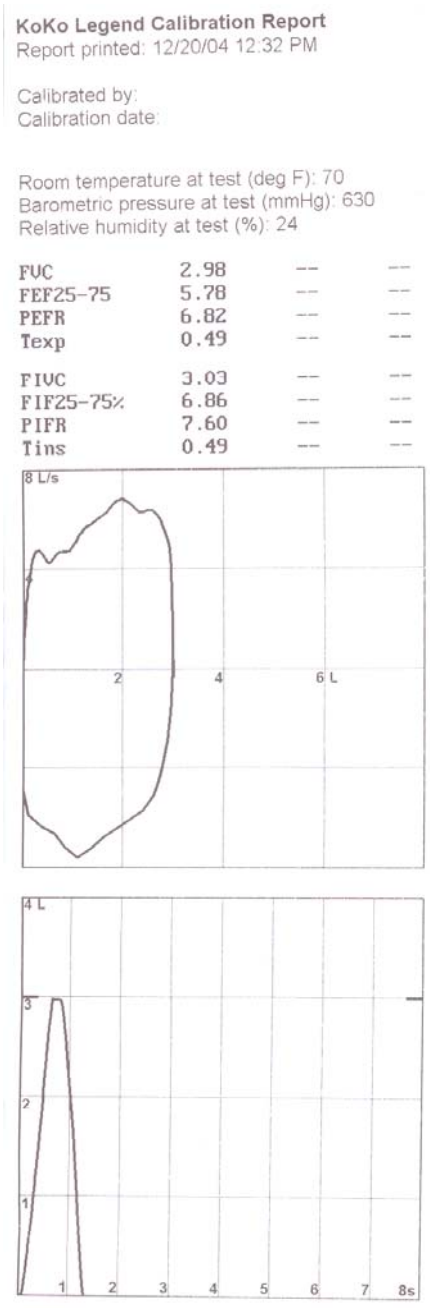


Figure 35 – Example of a Successful Calibration

3. Select the number of copies you want to print and select the printer you want to use.
4. Select the **[Print]** button. An example of the calibration report is shown below.



7.2 Cleaning

Equipment cleaning and contamination control are serious concerns of all clinicians involved in spirometry or pulmonary function testing.

In addition to the information provided in this section, you should refer to your local hygiene or infection control board for their guidelines on cleaning the medical equipment and/or accessories

described in this manual. Other sources of information on cleaning are the American Association of Respiratory Care AARC[1] and ATS[2] clinical practice guidelines.[3]

7.2.1 Cleaning the Main Unit

Use a non-abrasive mild cleanser with very little moisture on a soft cloth to clean the outside of the KoKo Legend. Do not disassemble the device for any cleaning.

Caution: Do not attempt to wash or submerge the KoKo Legend in water or cleaning fluid. There are electronic components inside the unit that will be permanently damaged.

7.2.2 Cleaning the Touch Screen

Use a soft cloth to remove fingerprints and dust from the touch screen. Do not press hard on the screen or depress with any sharp edged objects. If exceptionally soiled, use a mild non-abrasive cleanser with very little moisture on a soft cloth.

7.2.3 Cleaning the Flow Sensor Assembly

As needed, clean the outside of the flow sensor assembly with soapy water on a soft cloth with very little moisture. Do not disassemble the device assembly for any cleaning or submerge the entire flow sensor assembly.

To clean the pnuemotach tube, refer to section 7.2.6.

Note: After disassembly, disinfecting, and reassembly, you must re-calibrate the spirometer prior to patient testing. Always calibrate with a filter in place.

Caution: Do not attempt to wash or submerge the spirometer handle in water or cleaning fluid. There are electronic components inside the handle that will be permanently damaged.

7.2.4 Cleaning the Print Head

Cautions: Do not clean the thermal head immediately after printing because it may be hot after printing.

Do not use sandpaper or any sharp or pointed instruments when cleaning. This will damage the heat elements.

1. Remove the printer cover door by pressing the button to the right of the printer.
2. Clean the heat elements using ethyl alcohol or isopropyl alcohol (ethanol or isopropanol) and a cotton swab.
3. Wait until the alcohol dries and replace the printer cover.

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[1] AARC Clinical Practice Guideline – Spirometry, 1996 Update, reprinted from Respiratory Care, Vol 41, No. 7, pp. 629-636, 1996.

[2] American Journal of Respiratory and Critical Care Medicine, Vol 152, No. 6, pp 2188-2189, December 1995.

[3] Disinfection instructions from John Hopkins Cleaning and Disinfection website: http://hopkins-heic.org/prevention/clean_dis.html.

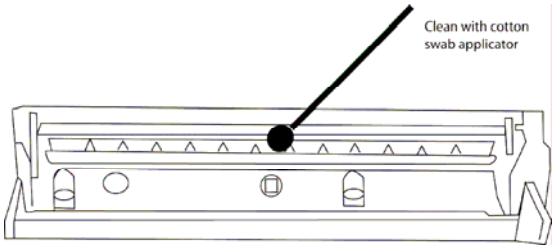


Figure 36 – Cleaning the Print Head

7.2.5 Removing the Pneumotach Tube

The pneumotach tube can be removed from the flow sensor assembly for replacement purposes or for cleaning.

To remove the tube, perform the following:

1. If attached, remove the disposable filter from the flow sensor.
2. Using a retainer ring pliers or a thin, blunt tool (never use a sharp or pointy tool), remove the “O” ring from the end of the pneumotach tube.
3. Pull the pneumotach tube from the casing.
4. Perform the desired maintenance.
5. Before reassembly, gently lubricate the three rubber "O" rings in the outer core with a very small amount of "O" ring grease. If you do not have Ferraris Respiratory "O" ring lubricant, gently rub a very small amount of stop-cock grease on the "O" rings.
6. Reinsert the tube or insert a new one in the casing.
7. Replace the “O” ring at the end of the casing.
8. After re-assembly, recalibrate the flow sensor to ensure that it functions properly. Refer to section 4.2.

7.2.6 Cleaning the Pneumotach Tube

The pneumotach tube should be cleaned every three months. To remove the flow sensor from the assembly for cleaning, remove the O-ring at the back of the flow sensor opening and slide the flow sensor to the front (refer to section 7.2.5 for additional details). Once removed, it is acceptable to clean the flow sensor in mild soapy water. Rinse and dry thoroughly before reassembling the flow sensor assembly. DO NOT insert anything inside the flow sensor to avoid damage.

As with all sanitation procedures, the hospital infection and control committee should be the final authority for approval of sanitation procedures, in order that they meet with their specific needs and requirements.

CAUTION	Do not autoclave any of the parts.

7.3 Managing Data on the Memory Card

If your KoKo Legend is connected to a PC with the KoKo PFT software, you can transfer patient demographics and test studies between the two devices.

You can also delete data from the memory card (refer to section 7.3.2) or erase all the contents from the card (refer to section 7.3.3).

7.3.1 Checking the Status of the Memory Card

To check the memory card's status (space available, version, and serial number), perform the following:

1. From the Setup (4/4) screen, select the Memory Card **[Information…]** button. The following screen is displayed.

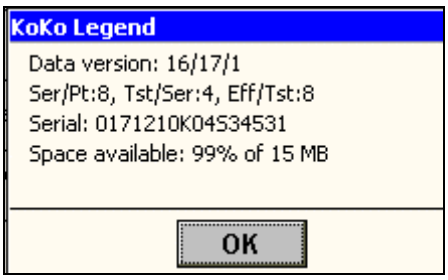


Figure 37 – Memory Card Information

2. Select **OK** to dismiss the screen.

7.3.2 Deleting Data from the Memory Card

To delete data from the memory card, perform the following:

1. Recall the desired patient.
2. Highlight the desired test series.
3. Select the **[Delete]** key. The following screen is displayed.

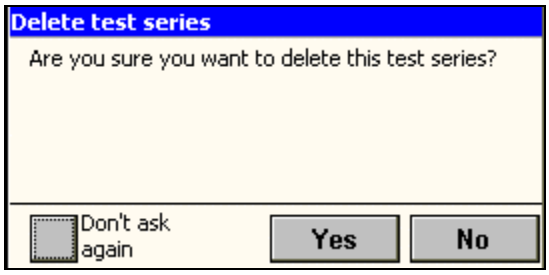


Figure 38 – Delete Test Series Screen

4. To delete the selected test series, select the **Yes** button.
5. To delete another test series for the same patient, repeat steps 1-4.
6. When you have deleted all of the test series associated with a patient, the following screen is displayed:

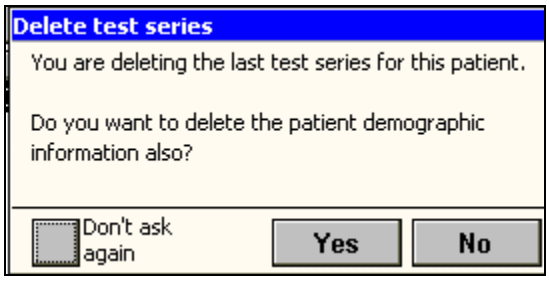


Figure 39 – Delete Patient Demographics Screen

7. Perform one of the following:

a. To delete the patient's demographic information, select the **Yes** button.
b. To cancel the action, select the **No** button.

7.3.3 Erasing the Memory Card

To erase the patient data from the memory card, perform the following:

1. On the KoKo Legend, select the **[More]** button.
2. Select the **[Setup]** button.
3. Press the **[Next]** button until the Setup (4/4) screen is displayed.
4. Select the **[Erase…]** button. The following screen is displayed.

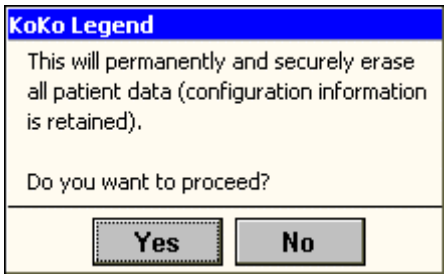


Figure 40 – Warning Message

Caution: If you select the Yes button, all patient data will be erased from the memory card and you will not be able to retrieve it.

5. Perform one of the following:
   a. To erase the patient data, select the **Yes** button.
   b. To cancel the action, select the **No** button.

7.3.3.1 Replacing the Memory Card

You may have to replace the memory card if it becomes faulty or reaches its maximum storage capacity and you do not want to delete any stored information.

To replace the memory card, perform the following:

1. Grasp the card and pull it out of the slot.

Note: Do not force the card in to the slot. The slot is designed so the memory card can only be installed in the proper orientation.

2. Insert the replacement card, inserting the connector end first. If the card does not slide in to the slot without using force, remove the card and turn it in the other direction.

8 PC Interface

8.1 Extended Configuration using the Configurator Program

For complete instructions on loading the KoKo Legend USB driver and operating the Configurator program, refer to the Help system on the Configurator or KoKoPFT disk. To install the Configurator program, insert the CD into the computer's CD drive and wait for the auto-installation to complete. Figure 42 shows which features can be edited using the Configurator program. This software will also be available for download from www.ferrarisrespiratory.com.

Note: The Configurator program or the KoKoPFT software is also required to perform an internal software (firmware) upgrade on the KoKo Legend.

8.1.1 Accessing the Extended Configuration Options

To access the extended configuration options using the Configurator software, perform the following:

1. Start the Configurator software by double clicking on the Configurator icon:  . The following window is displayed:
2. Connect the Legend to the PC via the USB cable.
3. Power on the Legend.

Note: When you are configuring the Legend, it will be unavailable for use. A *Communicating with host message* will be displayed on the Legend. When configuration is complete, you should restart the Legend.

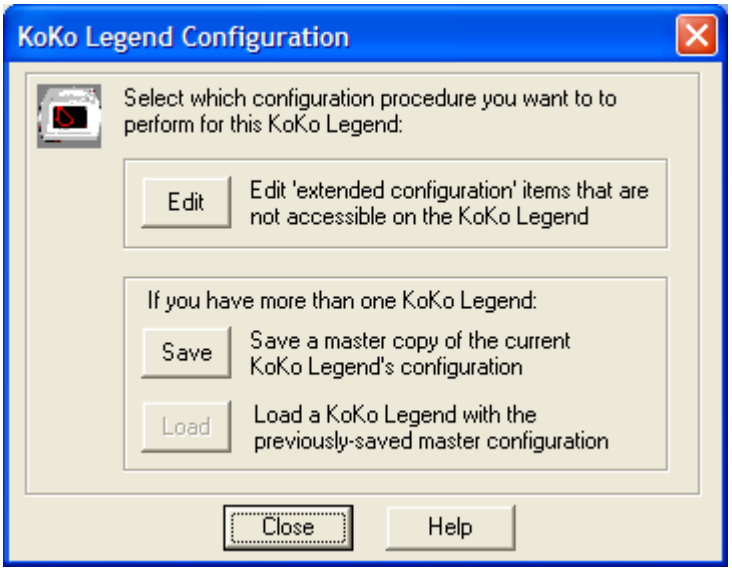


Figure 41 – KoKo Legend Configuration Options

4. Perform one of the following:
    a. Select the **Edit** button to access additional configuration items. The extended configuration screen is displayed (see Figure 42). Set the parameters as desired. Select the **OK** button.

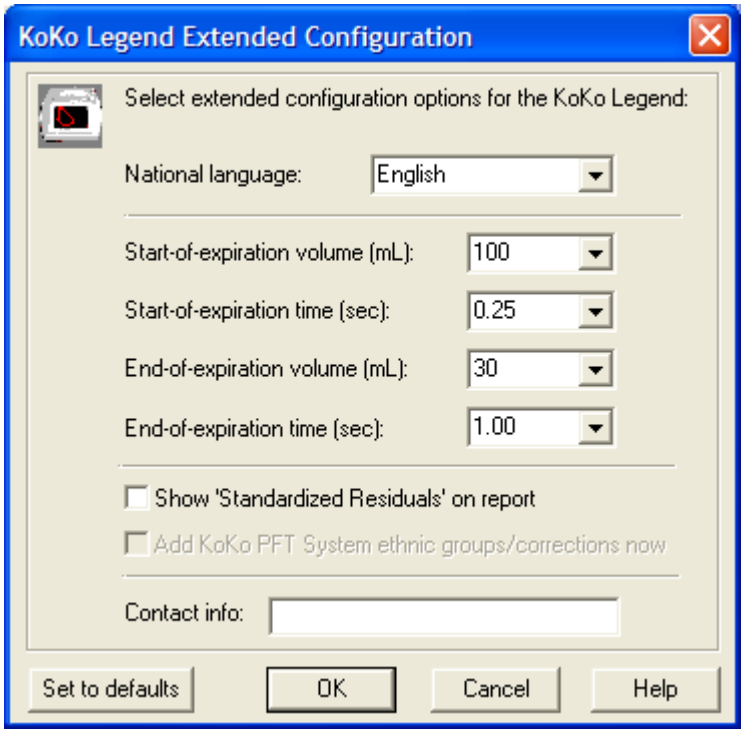


Figure 42 – Extended Configuration Options

This screen enables you to change the extended configuration options for the connected Legend device. The default values for the testing parameters are set to the ATS recommendations. The available options include:

National language: Selects the desired language for the Legend. This selection will override any selection made during the setup of the Legend (see Setup 4/4 screen).

Start-of-expiration volume (ml): Sets the minimum detectable volume (in milliliters) where volume begins accumulating for the start of expiration.

Start-of-expiration time (sec.): Sets the minimum time (in seconds) where volume begins accumulating for the start of expiration.

End-of-expiration volume (ml): Sets the minimum detectable volume that marks the end of expiration.

End-of-expiration time (sec): Sets the time for the plateau to determine the end of test.

Show 'Standardized Residuals' on report: If checked, includes the standardized residuals on the patient report.

Add KoKo PFT System ethnic groups/corrections now: If selected, adds any defined ethnic groups or corrections defined in the Configurator software to the Legend.

Contact Info: Sets the contact information that is displayed on the Legend's startup screen.

Set to defaults: Sets all the options to the default settings.

b. If you have more than one Legend and want to configure them the same as the one that is currently connected to the PC, select the **Save** button. The configuration parameters are saved and a message indicating the progress of the save is displayed.

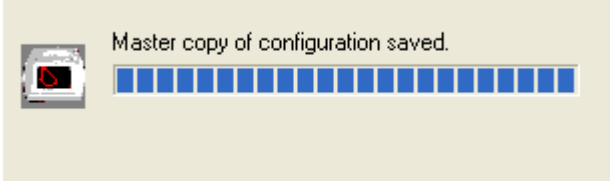


Figure 43 – Saving Master Configuration Screen

c. If you have a Legend connected to the PC that you want to configure with the configuration parameters you have previously saved, select the **Load** button. The stored configuration parameters are downloaded to the connected unit and a message indicating the progress of the save is displayed.

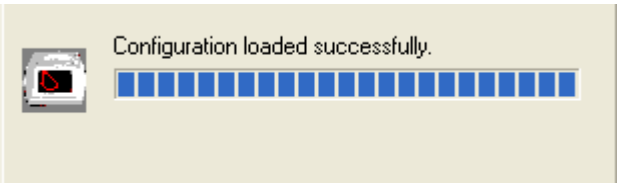


Figure 44 – Loading Configuration Screen

5. Select the **Close** button to close the window. The Legend is automatically powered off.
6. From the Configurator software, select Exit from the File menu.
7. Disconnect the Legend from the PC.
8. Restart the Legend.

8.2 Transferring Data to the KoKo PFT Spirometry Software

The KoKo Legend can transfer the stored tests to Ferraris Respiratory's spirometry software, the KoKo PFT. Users can choose to use the KoKo PC-based spirometer and also transfer data from both the KoKo Legend and the handheld portable KoKoMate screening model. For complete instructions on transferring patient test data from the KoKo Legend to the KoKo PFT spirometry software via the standard USB cable, please refer to the KoKo PFT User's Guide, and Help screens.

Connect the USB cable from the inlet on the back of the KoKo Legend to the USB inlet jack on your computer. The jack is labeled:

Note: To transfer patient test data from the KoKo Legend to the KoKo PFT Software, it is necessary to have the KoKo PFT software installed on a computer using the Windows XP or Windows 2000 operating system.

Appendix A - Troubleshooting

Table 6 – Troubleshooting Scenarios	
Problem	**Possible Solution**
Paper Jam	Remove paper cover and pull forward on paper release lever. Be sure to carefully remove any pieces of paper remaining in the printer mechanism. Be careful not to damage the print head or rollers.
Lock Up	Power the KoKo Legend down and restart. If the KoKo Legend will not turn off, press the Reset button on the back of the unit. If the problem persists, contact Technical Support.
Short Battery Life	Allow unit to completely discharge. Then fully recharge for 24 hours. If the problem persists, contact Technical Support.

Appendix B - Glossary

Table 7 – Glossary	
TERM	**DEFINITION**
ATS	Abbreviation for the American Thoracic Society. The most recent set of ATS standards were published in 1994.
Back Extrapolation	The method recommended by ATS/ECCS to determine "time-zero" when measuring the FEV-1 and other timed volumes. If a hesitant or slow start of the FVC test occurs, this can lead to a starting volume greater than the ATS/ERS recommended 5% of the total FVC (or 100 ml, whichever is greater), thereby introducing some inaccuracy into the measurement of all timed FEVs.
BTPS	Body Temperature and Pressure, fully Saturated with water.
ECCS	European Community for Coal and Steel. The ECCS published predicted values of lung indices that are almost universally applied in Europe.
ERS	European Respiratory Society.
ERV	Expiratory Reserve Volume (mean end tidal volume to end maximal expiratory volume) ERV = SVC – IC.
FEF 25-75%	The averaged FEF between the expiration of 25% and 75% of the FVC, expressed in liters per second. Also known as MMEF (Mid-Maximal Expiratory Flow), MEF (Mid-Expiratory Flow) or Midflow. This average of the middle portion of the expiratory curve has been thought to be a more sensitive measure of small airways obstruction.
FEV-1	Forced Expiratory Capacity at 1 second into the expiratory maneuver.
FEV1/FEV6 %	The ratio of FEV-1 to FEV-6, expressed as a percentage.
FEV-3	Forced Expiratory Capacity at 3 seconds into the expiratory maneuver.
FEV-6	Forced Expiratory Capacity at 6 seconds into the expiratory maneuver. Categorized as a replacement for FVC when evaluating obstruction.
Flow sensor	An airflow-measuring device, which measures pressure drop through a known resistive material. Also called "flow sensor" for the KoKo Legend.

Table 7 – Glossary	
TERM	**DEFINITION**
Flow sensor assembly	The hand-held device that contains the flow sensor and the circuitry that measures the pressure differential of the flow sensor.
FVC	Forced Vital Capacity – the maximal volume obtained in one forced expiratory maneuver. Substituted with FEV-6 in spirometers designed to meet the NLHEP specifications.
IC	Inspiratory Capacity (mean end tidal volume to end maximal inspiratory volume) IC = IRV +TV.
LLN	Lower limit of normal; the lowest value expected for a person of the same age, gender, and height with normal lung function.
MVVest	Estimated Maximum Voluntary Ventilation - this is calculated by the actual FEV1 multiplied by 37.5.
NLHEP	National Lung Health Education Program. This organization, comprised of some of the leaders in pulmonary medicine in the USA, has launched an education program to encourage primary care physicians to perform screening spirometry in the office in an effort to increase early detection of COPD. The operation and performance of the KoKo Legend has also been designed in accordance to the details outlined in the publication "Office Spirometry for Lung Health Assessment in Adults – A Consensus Statement From the National Lung Health Education Program" (Chest 117(4): 1146-1161).
Patient Demographics	Information about a patient, which includes height, age, sex, race, etc. Used to calculate the predicted values.
PEFR	Peak Expiratory Flow Rate – the highest flow registered during the forced expiratory maneuver.
RR	Respiratory Rate – average rate of breathing of the tidal breaths during the SVC maneuver, expressed as breaths per minute.
Rx	Prescription drug, such as a bronchodilator, used in post drug testing.
SVC	Slow Vital Capacity

Table 7 – Glossary	
TERM	**DEFINITION**
SVC/FVC	Slow Vital Capacity divided by Forced Vital Capacity, expressed as a ratio. Often, a patient with significant obstruction can expire more air in a slow maneuver than a forced (fast) maneuver. The amount over a ratio of 1.00 is often called the “air trapping index.”
Texp	Expiratory Time - the time from beginning to end of expiration, expressed in seconds.
Vext%	Extrapolate Volume, expressed as a percentage of the FVC value. This is the amount of volume that has not been collected, due to a hesitation on the start of the expiration in a forced expiratory maneuver. If it exceeds 5% of the FVC value, it is considered an unacceptable maneuver.
Vt	Tidal Volume

Appendix C - Predicted Normal Equations

C.1 Hankinson (NHANES III) Predicted Values

C.1.1 Caucasian male ≥ 8 years <20 years

FEV1 = -0.7453 + (-0.04106*A) + (0.004477*A^2) + (x = 0.00014098*H^2)	CI = x - (0.00011607*H^2)
FEV6 = -0.3119 + (-0.18612*A) + (0.009717*A^2) + (x = 0.00018188*H^2)	CI = x - (0.00015323*H^2)
PEFR = -0.5962 + (-0.12357*A) + (0.013135*A^2) + (x = 0.00024962*H^2)	CI = x - (0.00017635*H^2)
FEF25-75 = -1.0863 + (0.13939*A) + (x = 0.00010345*H^2).	CI = x - (0.00005294*H^2)
FEV1/FEV6 = (x = 87.340) + (-0.1382*A) / 100	CI = x - 78.372 / 100

C.1.2 Caucasian male ≥20 years

FEV1 = 0.5536 + (-0.01303*A) + (-0.000172*A^2) + (x = 0.00014098*H^2)	CI = x - (0.00011607*H^2)
FEV6 = 0.1102 + (-0.00842*A) + (-0.000223*A^2) + (x = 0.00018188*H^2)	CI = x - (0.00015323*H^2)
PEFR = 1.0523 + (0.08272*A) + (-0.001301*A^2) + (x = 0.00024962*H^2)	CI = x - (0.00017635*H^2)
FEF25-75 = 2.7006 + (-0.04995*A) + (x = 0.00010345*H^2)	CI = x - (0.00005294*H^2)
FEV1/FEV6 = (x = 87.340) + (-0.1382*A) / 100	CI = x - 78.372 / 100

C.1.3 Caucasian female ≥ 8 years <18 years

FEV1 = -0.8710 + (0.06537*A) + (x = 0.00011496*H^2)	CI = x - (0.00009283*H^2)
FEV6 = -1.1925 + (0.06544*A) + (x = 0.00014395*H^2)	CI = x - (0.00011827*H^2)
PEFR = -3.6181 + (0.60644*A) + (-0.016846*A^2) + (x = 0.00018623*H^2)	CI = x - (0.00012148*H^2)
FEF25-75 = -2.5284 + (0.52490*A) + (-0.015309*A^2) + (x = 0.00006982*H^2)	CI = x - (0.00002302*H^2)
FEV1/FEV6 = (x = 90.107) + (-0.1563*A) / 100	CI = x - 81.307 / 100

C.1.4 Caucasian female ≥18 years

FEV1 = 0.4333 + (-0.00361*A) + (-0.000194*A^2) + (x = 0.00011496*H^2)	CI = x - (0.00009283*H^2)
FEV6 = -0.1373 + (0.01317*A) + (-0.000352*A^2) + (x = 0.00014395*H^2)	CI = x - (0.00011827*H^2)
PEFR = 0.9267 + (0.06929*A) + (-0.001031*A^2) + (x = 0.00018623*H^2)	CI = x - (0.00012148*H^2)
FEF25-75 = 2.3670 + (-0.01904*A) + (-0.000200*A^2) + (x = 0.00006982*H^2)	CI = x - (0.00002302*H^2)
FEV1/FEV6 = (x = 90.107) + (-0.1563*A) / 100	CI = x - 81.307 / 100

C.1.5 African-American male <20 years

FEV1 = -0.7048 + (-0.05711*A) + (0.004316*A^2) + (x = 0.00013194*H^2)	CI = x - (0.00010561*H^2)
FEV6 = -0.5525 + (-0.14107*A) + (0.007241*A^2) + (x = 0.00016429*H^2)	CI = x - (0.00013499*H^2)
PEFR = -0.2684 + (-0.28016*A) + (0.018202*A^2) + (x = 0.00027333*H^2)	CI = x - (0.00018938*H^2)
FEF25-75 = -1.1627 + (0.12314*A) + (x = 0.00010461*H^2)	CI = x - (0.00004819*H^2)
FEV1/FEV6 = (x = 88.841) + (-0.1305*A) / 100	CI = x - 78.979 / 100

C.1.6 African-American male ≥20 years

FEV1 = 0.3411 + (-0.02309*A) + (x = 0.00013194*H^2)	CI = x - (0.00010561*H^2)
FEV6 = -0.0547 + (-0.024*A) + (x = 0.00016429*H^2)	CI = x - (0.00013499*H^2)
PEFR = 2.2257 + (-0.04082*A) + (x = 0.00027333*H^2)	CI = x - (0.00018938*H^2)
FEF25-75 = 2.1477 + (-0.04238*A) + (x = 0.00010461*H^2)	CI = x - (0.00004819*H^2)
FEV1/FEV6 = (x = 88.841) + (-0.1305*A) / 100	CI = x - 78.979 / 100

C.1.7 African-American female <18 years

FEV1 = -0.9630 + (0.05799*A) + (x = 0.00010846*H^2)	CI = x - (0.00008546*H^2)
FEV6 = -0.6370 + (-0.04243*A) + (0.003508*A^2) + (x = 0.00013497*H^2)	CI = x - (0.00010848*H^2)
PEFR = -1.2398 + (0.16375*A) + (x = 0.00019746*H^2)	CI = x - (0.00012160*H^2)
FEF25-75 = -2.5379 + (0.43755*A) + (-0.012154*A^2) + (x = 0.00008572*H^2)	CI = x - (0.00003380*H^2)
FEV1/FEV6 = (x = 91.229) + (-0.1558*A) / 100	CI = x - 81.396 / 100

C.1.8 African-American female ≥18 years

FEV1 = 0.3433 + (-0.01283*A) + (-0.000097*A^2) + (x = 0.00010846*H^2)	CI = x - (0.00008546*H^2)
FEV6 = -0.1981 + (0.00047*A) + (-0.000230*A^2) + (x = 0.00013497*H^2)	CI = x - (0.00010848*H^2)
PEFR = 1.3597 + (0.03458*A) + (-0.000847*A^2) + (x = 0.00019746*H^2)	CI = x - (0.00012160*H^2)
FEF25-75 = 2.0828 + (-0.03793*A) + (x = 0.00008572*H^2)	CI = x - (0.00003380*H^2)
FEV1/FEV6 = (x = 91.229) + (-0.1558*A) / 100	CI = x - 81.396 / 100

C.1.9 Mexican-American male <20 years

FEV1 = -0.8218 + (-0.04248*A) + (0.004291*A^2) + (x = 0.00015104*H^2)	CI = x - (0.00012670*H^2)
FEV6 = -0.6646 + (-0.11270*A) + (0.007306*A^2) + (x = 0.00017840*H^2)	CI = x - (0.00015029*H^2)
PEFR = -0.9537 + (-0.19602*A) + (0.014497*A^2) + (x = 0.00030243*H^2)	CI = x - (0.00021833*H^2)
FEF25-75 = -1.3592 + (0.10529*A) + (x = 0.00014473*H^2)	CI = x - (0.00009020*H^2)
FEV1/FEV6 = (x = 89.388) + (-0.1534*A) / 100	CI = x - 80.810 / 100

C.1.10 Mexican-American male ≥20 years

FEV1 = 0.6306 + (-0.02928*A) + (x = 0.00015104*H^2)	CI = x - (0.00012670*H^2)
FEV6 = 0.5757 + (-0.02860*A) + (x = 0.00017840*H^2)	CI = x - (0.00015029*H^2)
PEFR= 0.0870 + (0.06580*A) + (-0.001195*A^2) + (x = 0.00030243*H^2)	CI = x - (0.00021833*H^2)
FEF25-75 = 1.7503 + (-0.05018*A) + (x = 0.00014473*H^2)	CI = x - (0.00009020*H^2)
FEV1/FEV6= (x = 89.388) + (-0.1534*A) / 100	CI = x - 80.810 / 100

C.1.11 Mexican-American female <18 years

FEV1 = -0.9641 + (0.06490*A) + (x = 0.00012154*H^2)	CI = x - (0.00009890*H^2)
FEV6 = -1.2410 + (0.07625*A) + (x = 0.00014106*H^2)	CI = x - (0.00011480*H^2)
PEFR = -3.2549 + (0.47495*A) + (-0.013193*A^2) + (x = 0.00022203*H^2)	CI = x - (0.00014611*H^2)
FEF25-75 = -2.1825 + (0.42451*A) + (-0.012415*A^2) + (x = 0.00009610*H^2)	CI = x - (0.00004594*H^2)
FEV1/FEV6 = (x = 91.664) + (-0.1670*A) / 100	CI = x - 83.034 / 100

C.1.12 Mexican-American female ≥18 years

FEV1 = 0.4529 + (-0.01178*A) + (-0.000113*A^2) + (x = 0.00012154*H^2)	CI = x - (0.00009890*H^2)
FEV6 = 0.2033 + (0.00020*A) + (-0.000232*A^2) + (x = 0.00014106*H^2)	CI = x - (0.00011480*H^2)
PEFR = 0.2401 + (0.06174*A) + (-0.001023*A^2) + (x = 0.00022203*H^2)	CI = x - (0.00014611*H^2)
FEF25-75 = 1.7456 + (-0.01195*A) + (-0.000291*A^2) + (x = 0.00009610*H^2)	CI = x - (0.00004594*H^2)
FEV1/FEV6 = (x = 91.664) + (-0.1670*A) / 100	CI = x - 83.034 / 100

C.2 CRAPO 1981

(Polgar predicted equations are used for all ages under 18.)

Polgar Predicted Equations

C.2.1 Male <18 years

FVC = .0000044*(2.67H)

FEV1 = .0000021*(2.8H)

FEV1/FVC = .86

PEFR = 8.74*(10^{-2})*H-7.093

FEF25-75% = (2.621*H-207.7)/60.0

C.2.2 Female <18 years

FVC = .0000033*(2.72H)

FEV1 = .0000021*(2.8H)

FEV1/FVC = .86

PEFR = 8.74*(10^{-2})*H-7.093

FEF25-75% = (2.621*H-207.7)/60.0

C.2.3 Male ≥18 years

FVC = .06*H-.0214*A-4.65
FEV.5 = .0327*H-.0152*A-1.914
FEV1 = .0414*H-.0244*A-2.19
FEV1/FVC = -.0013*H-.00152*A+1.1049
FEV3 = .0535*H-.0271*A-3.512
FEV3/FVC = -.000627*H-.00145*A+1.1209
FEF25-75% = .0204*H-.038*A+2.133
PEFR = .14393*Hin-.02403*A+. 22544
FEF25% = 9.03*(10^{-2})*Hin-.01987*A+2.72554
FEF50% = .06526*Hin-.03049*A+2.40337
FEF75% = .03583*Hin-.04142*A+1.98361
SVC = FVC
ERV = FRC-RV
IC = TLC-FRC

C.2.4 Female ≥18 years

FVC = .0491*H-.0216*A-3.59
FEV.5 = .0238*H-.0185*A-.809
FEV1 = .0342*H-.0255*A-1.578
FEV1/FVC = -.00202*H-.00252*A+1.2658
FEV3 = .0442*H-.0257*A-2.745
FEV3/FVC = -.000937*H-.00163*A+1.1816
FEF25-75% = .0154*H-.046*A+2.683
PEFR = 9.13*(10^{-2})*Hin-.01776*A+1.1316
FEF25% = .06876*Hin-.01926*A+2.14653
FEF50% = .0622*Hin-.02344*A+1.4264
FEF75% = .02334*Hin-.0345*A+2.21596
SVC = FVC
ERV = FRC-RV
IC = TLC-FRC

C.3 ERS 93/ POLGAR

C.3.1 ECCS / ERS Predicted Values (European)

European Community for Coal and Steel Predicted Equations / adopted by the ERS (European Respiratory Society)

Polgar predicted equations are used for all ages under 18.

Persons age 18 - 24 should be entered into the equations as age 25.

FVC equations used for FEV6.

C.3.2 Polgar Predicted Equations

C.3.3 Male <18 years

FVC = (.0000044)*(2.67H)
FEV1 = .0000021*(2.8H)
FEV1/FVC = .86
PEFR = 8.74*(10^{-2})*H-7.093
FEF25-75% = (2.621*H-207.7)/60.0

C.3.4 Female <18 years

FVC = (.0000033)*(2.72H)

FEV1 = .0000021*(2.8H)
FEV1/FVC = .86
PEFR = 8.74*(10^{-2})*H-7.093
FEF25-75% = (2.621*H-207.7)/60.0

C.3.5 Male ≥18 years

FVC = .05757*H-.026*A-4.345
FEV1 = .04301*H-.029*A-2.492
FEV1/FVC = -.179*A+87.21
FEF25-75% = .01944*H-.043*A+2.699
PEFR = .06146*H-.043*A+. 154

C.3.6 Female ≥18 years

FVC = .04426*H-.026*A-2.887
FEV1 = .03953*H-.025*A-2.604
FEV1/FVC = -.192*A+89.10
FEF25-75% = .01252*H-.034*A+2.924
PEFR = .05501*H-.030*A-1.106

C.3.7 PERRIERA Predicted Values (Brazil)

Perreira 1996 (Brazil)
(Note: height in cm (H), age in years (A), weight in kg (W), logs are natural logs)
FVC equations used for FEV6.

C.3.8 Male, age 6 - 14 height 115 - 160 cm

FVC = ln-1[(lnH)(2.7093)-12.6205]	LLN= pred x 0.79
FEV1 = ln-1[(lnH)(2.5431)-11.8832]	LLN= pred x 0.8
FEV1/FVC = 93.0%	LLN= pred x 0.83
FEF25-75 = ln-1[(lnH)(1.8309) + (lnA)(0.1667)- 8.5219]	LLN= pred x 0.78
PEFR = (5.06H-360)/60	LLN= pred x 0.85

C.3.9 Female age 6 - 14 height 116 - 167 cm

FVC = (0.02417H)+ (0.0561A) + (0.010W) - 2.2197	LLN= pred - 0.477
FEV1 = (0.02336H)+ (0.0499A) + (0.008W) - 2.1240	LLN= pred - 0.429
FEV1/FVC = 91.0%	LLN= pred x 0.81
FEF25-75 = ln-1[(lnH)(2.0561) + (lnA)(0.2791)- 9.9287]	LLN= pred x 0.74
PEFR = (5.06H-360)/60	LLN= pred x 0.85

C.3.10 Male age 15 - 24 height 155 - 185 cm

FVC = ln-1[(lnH)(1.3100)+ (lnA)(0.3170)+ (lnW)(0.3529)- 7.6487]	LLN= pred x 0.81
FEV1 = ln-1[(lnH)(1.2158)+ (lnA)(0.1900) + (lnW)(0.3077)-6.683]	LLN= pred x 0.82
FEV1/FVC = 94.0%	LLN= pred x 0.82
FEF25-75 = ln-1[(lnH)(0.7513) + (lnW)(0.3303)- 3.6530]	LLN= pred x 0.68
PEFR = (5.06H-360)/60	LLN= pred x 0.85

C.3.11 Female age 15 - 19 height 144 - 174 cm

FVC = ln-1 [(lnH)(1.7374) + (lnA)(0.2823) + (lnW)(0.1491) - 9.0562]	LLN= pred x 0.87
FEV1 = ln-1 [(lnH)(1.9293)+ (lnA)(0.2255)+ (lnW)(0.1105W) - 9.8100]	LLN= pred x 0.87
FEV1/FVC = 94.0%	LLN= pred x 0.82
FEF25-75 = ln-1[(lnH)(2.0561) + (lnA)(0.2791)- 9.9287]	LLN= pred x 0.91
PEFR = (5.06H-360)/60	LLN= pred x 0.85

C.3.12 Male age 25 - 78 height 152 - 182 cm

FVC = (0.0590H)-(0.0229A) - 4.569	LLN= pred - 0.864

FEV1 = (0.0473H)-(0.0281A) - 3.145	LLN= pred - 0.79
FEV1/FVC = ln-1 [-(lnA)(0.1198) + 4.854]	LLN= pred x 0.9
FEF25-75 = ln-1 [(lnH)(2.0020) - (lnA)(0.6977)- 6.3279]	LLN= pred x 0.6
PEFR = (5.06H-360)/60	LLN= pred x 0.85

C.3.13 Female age 20 - 76 height 136 - 170 cm

FVC = (0.0433H)-(0.0164A) - 2.967	LLN= pred - 0.556
FEV1 = (0.0338H)-(0.0210A) - 1.782	LLN= pred - 0.433
FEV1/FVC = ln-1[-(lnA)(0.1212) + 4.8707]	LLN= pred x 0.9
FEF25-75 = ln-1[(lnH)(1.2843) - (lnA)(0.6546)- 3.0208]	LLN= pred x 0.6
PEFR = (5.06H-360)/60	LLN= pred x 0.85

C.3.14 Gore Predicted Values (Australian)

Gore 1995 (Australia) Predicted Equations

(Note: Hm is height in meters)

FVC equations used for FEV6.

Polgar predicted equations are used for all ages under 18.

C.3.15 Polgar Predicted Equations

C.3.16 Male <18 years

FVC = .0000044*.67H^2

FEV1 = .0000021*.8H^2

FEV1/FVC =.86

PEFR = 8.74*(10^{-2})*H-7.093

FEF25-75% = (2.621*H-207.7)/60.0

C.3.17 Female <18 years

FVC = .0000033*.72H^2

FEV1 = .0000021*.8H^2

FEV1/FVC =.86

PEFR = 8.74*(10^{-2})*H-7.093

FEF25-75% = (2.621*H-207.7)/60.0

C.3.18 Male ≥ 18 years

FVC = 12.675 - 0.0002764 A^2 - 10.736 Hm^2 + 4.790 Hm^3	CI = 1.035
FEV1 = 2.081 + 0.5846 Hm^3 - 0.01599 AHm	CI = 0.798
FEV1/FVC = (92.963 + 0.002487 A^2 - 0.2260 AHm) / 100	CI = .0774
PEFR = -6.099 - 0.0003425 A^2 + 9.708 Hm	CI = 2.896
FEF25-75 = 0.5707 - 0.00005695 A^2 + 0.025818 Hm^3	CI = 0.180

C.3.19 Female ≥ 18 years

FVC = -3.598 - 0.0002525 A^2 + 4.680 Hm	CI = 0.629
FEV1 = 1.597 + 0.5552 Hm^3 - 0.01574 AHm	CI = 0.560
FEV1/FVC = (-4068.039 + 0.7137 A + 0.002234 A^2 +7675.039 Hm - 4719.018 Hm^2 + 967.776 Hm^3 - 0.6946 AHm) / 100	CI = .08016
PEFR = 3.364 - 0.02654 A + 1.036 Hm^3	CI = 2.230
FEF25-75 = -556.706 + 1036.012 Hm - 637.715 Hm^2 + 131.013 Hm^3 - 0.02708 AHm	CI = 1.271

C.4 Knudson 1976

H=height (cm), A=age (yrs)

C.4.1 Male <25 years

FVC = .05*H + .078*A - 5.508

FEV.5 = .03*H +.043*A - 3.054
FEV1 = .046*H +.045*A - 4.808
FEV1/FVC = (-.087*H-.14*A+103.64)/100
FEV3 = .052*H +.066*A - 5.531
FEF25-75% = .059*H - 5.334
PEFR = .078*H +.166*A - 8.06
FEF25% = .07*H +.147*A - 7.054
FEF50% = .051*H +.081*A - 4.975
FEF75% = .032*H - 2.455
SVC = FVC

C.4.2 Male ≥ 25 yrs

FVC = .065*H-.029*A - 5.459
FEV.5 = .037*H-.017*A - 2.746
FEV1 = .052*H-.027*A - 4.203
FEV1/FVC = (-.087*H - .14*A+103.64)/100
FEV3 = .063*H -.031*A - 5.245
FEF25-75% = .045*H - .031*A - 1.864
PEFR = .094*H - .035*A - 5.993
FEF25% = .088*H - .035*A - 5.618
FEF50% = .069*H - .015*A - 5.4
FEF75% = .044*H - .012*A - 4.143

C.4.3 Female <20 years

FVC = .033*H +.092*A - 3.469
FEV.5 = .019*H +.061*A - 1.738
FEV1 = .027*H +.085*A - 2.703
FEV1/FVC = (-.111*H -.109*A + 107.38)/100
FEV3 = .033*H +.086*A - 3.417
FEF25-75% = .025*H +.121*A - 1.893
PEFR = .049*H +.157*A - 3.916
FEF25% = .044*H +.144*A - 3.365
FEF50% = .034*H + .12*A - 2.531
FEF75% = .139*A + .692
SVC = FVC

C.4.4 Female ≥20 years

FVC = .037*H - .022*A - 1.774
FEV.5 = .019*H - .014*A - .406
FEV1 = .027*H - .021*A - .794
FEV1/FVC = (-.111*H - .109*A + 107.38)/100
FEV3 = .035*H - .023*A - 1.633
FEF25-75% = .021*H + .024*A + 1.171
PEFR = .049*H - .025*A - .735
FEF25% = .043*H - .025*A - .132
FEF50% = .035*H - .013*A -.444
FEF75% = -.014*A + 3.042
FIVC = FVC
SVC = FVC

C.5 Thai

H=height (cm), A=age (yrs)

C.5.1 Male

$FVC = 0.00023H^2 - 0.00046A^2 + 0.122A - 0.00061AH - 2.601$
$FEV1 = 0.067H - 0.00034A^2 + 0.123A - 0.0007AH - 7.697$
$FEF25\text{-}75 = -0.00039H^2 + 0.207H - 0.00042A^2 + 0.201A - 0.0012AH - 19.049$
$PEFR = 0.141H - 0.0018A^2 + 0.307A - 0.001AH - 16.859$
$FEV1/FVC = -0.0023H^2 + 0.829H + 0.49A - 0.0041AH + 19.362$

C.5.2 Female

$FVC = 0.056H - 0.0003A^2 + 0.088A - 0.0005AH - 5.914$
$FEV1 = -0.00022H^2 + 0.12H - 0.00019A^2 + 0.085A - 0.00056AH - 10.603$
$FEF25\text{-}75 = -0.0007H^2 + 0.272H - 0.00017A^2 + 0.11A - 0.00082AH - 21.528$
$PEFR = -0.00099H^2 + 0.391H - 0.00084A^2 + 0.162A - 0.00072AH - 31.355$
$FEV1/FVC = 0.08H + 0.0002A^2 + 0.243A - 0.0036AH + 83.126$

C.6 SEPAR (Spain)

H=height (cm), A=age (yrs), W=weight (kg)

C.6.1 Male 6-20

FVC	0.028*H + 0.03451*W + 0.05728*A - 3.21
FEV1	0.02483*H + 0.02266*W + 0.07148*A - 2.91
FEF25-75	(0.038*H) + (0.14*A) - 4.33
PEF	(0.075*H) + (0.275*A) - 9.08
FEF50	(0.017*H) + (0.157*A) + (0.029*W) - 2.17
FEF75	(0.024*H) + (0.066*A) - 2.61

C.6.2 Male 20-70

FVC	(0.0678*H) - (0.0147*A) - 6.05
FEV1	(0.0499*H) - (0.0211*A) - 3.84
FEF25-75	(0.0392*H) - (0.043*A) - 1.16
PEF	(0.0945*H) - (0.0209*A) - 5.77
FEF50	(0.0517*H) - (0.0397*A) - 2.4
FEF75	(0.019*H) - (0.0356*A) - 0.14

C.6.3 Female 6-20

FVC	0.03049*H + 0.0222*W + 0.0355*A - 3.04
FEV1	0.02866*H + 0.01713*W + 0.02955*A - 2.87
FEF25-75	(0.046*H) + (0.051*A) - 4.3
PEF	(0.073*H) + (0.134*A) - 7.57
FEF50	(0.046*H) + (0.067*A) - 4.17
FEF75	(0.027*H) + (0.032*A) - 2.68

C.6.4 Female 20-70

FVC	(0.0454*H) - (0.0211*A) - 2.83
FEV1	(0.0317*H) - (0.025*A) - 1.23
FEF25-75	(0.023*H) - (0.0456*A) + 1.11
PEF	(0.0448*H) - (0.0304*A) + 0.35

FEF50	(0.0242*H) - (0.0418*A) + 1.62
FEF75	(0.02*H) - (0.031*A) - (0.0062*W) - 0.21

C.7 Forche (Austria)

C.7.1 Male 5-18

FVC	$e^{(-1.142 + 1.259*H + 0.00407*A*(W^{1/2}))}$
FEV1	$e^{(-1.178 + 1.221*H + 0.003841*A*(W^{1/2}))}$
FEV1/FVC	$(101.99 + 1.191*H^2 - 3.962*LN(W))/100$
PEFR	$e^{(-0.214 + 0.921*H + 0.0467*A + 0.002*W)}$
FEF25	$e^{(-0.077 + 0.77*H + 0.0373*A + 0.0025*W)}$
FEF50	$e^{(-0.522 + 0.843*H + 0.03*A + 0.0035*W)}$
FEF75	$e^{(-1.576 + 1.166*H + 0.0219*A + 0.0021*W)}$

C.7.2 Male 18-90

FVC	(-11.606 + 8.172*H - 0.0339*AH + 1.2869*LN(A))
FEV1	(-8.125 + 6.212*H - 0.03*AH + 0.977*LN(A))
FEV1/FVC	$(101.99 - 1.191*H^2 - 3.962*LN(A))/100$
PEFR	$(1.798 + 2.311*LN(H) + 0.0159*A - 0.000248*(A^2))^2$
FEF25	$(1.581 + 1.854*LN(H) + 0.0213*A - 0.000283*(A^2))^2$
FEF50	$(1.49 + 1.29*LN(H) + 0.0125*A - 0.000218*(A^2))^2$
FEF75	$(1.314 + 0.898*LN(H) - 0.0083*A - 0.000026*(A^2))^2$

C.7.3 Female 5-16

FVC	$e^{(-3.842 + 4.1632*(H^{1/2}) + 0.1341*(A^{1/2}) - 1.614*(H/W^{1/3}))}$
FEV1	$e^{(-3.877 + 3.9809*(H^{1/2}) + 0.1485*(A^{1/2}) - 1.322*(H/W^{1/3}))}$
FEV1/FVC	0.923
PEFR	$e^{(0.411 + 1.793*LN(H) + 0.4251*LN(A) - 0.91*(H/W^{1/3}))}$
FEF25	$e^{(0.455 + 1.616*LN(H) + 0.3738*LN(A) - 0.861*(H/W^{1/3}))}$
FEF50	$e^{(0.256 + 1.643*LN(H) + 0.3481*LN(A) - 1.089*(H/W^{1/3}))}$
FEF75	$e^{(-0.772 + 2.002*LN(H) + 0.3063*LN(A) - 0.409*(H/W^{1/3}))}$

C.7.4 Female 16-90

FVC	(-10.815 + 6.64*H - 0.0408*AH + 1.7293*LN(A))
FEV1	(-6.995 + 5.174*H - 0.0314*AH + 1.0251*LN(A))
FEV1/FVC	$(118.993 - 3.032*H^2 - 6.9053*LN(A))/100$
PEFR	$(1.832 + 1.838*LN(H) + 0.0078*A - 0.000172*A^2)^2$
FEF25	$(1.779 + 1.421*LN(H) + 0.0096*A - 0.000179*A^2)^2$
FEF50	$(1.561 + 1.177*LN(H) + 0.0045*A - 0.00014*A^2)^2$
FEF75	$(1.372 + 0.938*LN(H) - 0.0152*A - 0.000036*A^2)^2$

C.8 Gulsvik (Norway)

H=height (m), A=age (yrs)

C.8.1 Male 18-34

FVC	$((A*0.0107) - (A^2)*(0.0002) + 1.306 + 0.285)*H^2$
FEV1	$((A*0.0074) - (A^2)*(0.00013) + 1.201 + 0.235)*H^2$
FIVC	$((A*0.011) + (A^2)*(0.0003) + 1.065)*H^2$
FIV1	$((A*0.0102) - (A^2)*(0.00021) + 1.138 + 0.307)*H^2$
FEV1/FVC	((H*-12.6) - (A*0.19) + (112.3))/100
FIV1/FIVC	((H*7.7) - (A*0.04) + 77.4)/100

C.8.2 Male 35-73

FVC	$((A*0.0107) - (A^2)*(0.0002) + 1.306 + 0.285)*H^2$
FEV1	$((A*0.0074) - (A^2)*(0.00013) + 1.201 + 0.235)*H^2$
FIVC	FIV1/(FIV1/FIVC)
FIV1	$((A*0.0102) - (A^2)*(0.00021) + 1.138 + 0.307)*H^2$
FEV1/FVC	((H*-28.3) - (A*0.09) + (137.7))/100
FIV1/FIVC	((H*-3.4) - (A*0.26) + 107.9)/100

C.8.3 Female 18-34

FVC	$((A*0.0107) - (A^2)*(0.0002) + 1.306)*H^2$
FEV1	$((A*0.0074) - (A^2)*(0.00013) + 1.201)*H^2$
FIVC	$((A*0.011) + (A^2)*(0.0003) + 1.065)*H^2$
FIV1	$((A*0.0102) - (A^2)*(0.00021) + 1.138)*H^2$
FEV1/FVC	((H*-26.5) - (A*0.18) + (134.8))/100
FIV1/FIVC	((H*20.6) - (A*0.28) + (60.8))/100

C.8.4 Female 35-73

FVC	$((A*0.0107) - (A^2)*(0.0002) + 1.306)*H^2$
FEV1	$((A*0.0074) - (A^2)*(0.00013) + 1.201)*H^2$
FIVC	$((A*0.011) + (A^2)*(0.0003) + 1.065)*H^2$
FIV1	$((A*0.0102) - (A^2)*(0.00021) + 1.138)*H^2$
FEV1/FVC	((H*-13.2) - (A*0.1) + 108.8)/100
FIV1/FIVC	((H*-14.1) - (A*0.29) + 121.6)/100

C.9 Viljanen (Finland)

H=height (cm), A=age (yrs)

C.9.1 Male <18

FVC	$(0.0000014253*H^{2.9092})$
FEV.5	$(0.0000019961*H^{2.7586})$
FEV.5/FVC	$(0.0000019961*H^{2.7586})/(0.0000014253*H^{2.9092})$
FEV1	$(0.0000020277*H^{2.8141})$

FEV1/FVC $(0.0000020277*H^{2.8141})/ (0.0000014253*H^{2.9092})$

FEF50 $0.0000055762*H^{2.6616}$

PEF $0.0000027423*H^{2.8864}$

C.9.2 Male 18-99

FVC $10^{(-0.00827*A - 144.68/H + 0.9461)}*A^{0.586}$

FEV1 $10^{(-0.00587*A - 116.55/H + 1.098)}*A^{0.2756}$

FEV1/FVC $(10^{(0.0024*A + 28.13/H + 2.1519)}*A^{-0.3104})/100$

FEF50 $10^{(-0.00041*A - 14.8/H + 1.3415)}*A^{-0.3087}$

PEF $10^{(-0.00211*A - 67.74/H + 1.3255)}*A^{0.1049}$

C.9.3 Female <18

FVC $(0.0000011451*H^{2.9423})$

FEV.5 $(0.0000010081*H^{2.8893})$

FEV.5/FVC $(0.0000010081*H^{2.8893})/(0.0000011451*H^{2.9423})$

FEV1 $(0.0000011317*H^{2.9229})$

FEV1/FVC $(0.0000011317*H^{2}.9229)/(0.0000011451*H^{2.9423})$

FEF50 $0.0000017804*H^{2.886}$

PEF $0.0000010397*H^{3.0746}$

C.9.4 Female 18-99

FVC $10^{(-0.00982*A - 141.37/H + 0.832)}*A^{0.6358}$

FEV1 $10^{(-0.0092*A - 132.84/H + 0.9296)}*A^{0.4772}$

FEV1/FVC $(10^{(0.00062*A + 8.53/H + 2.0975)}*A^{-0.1586}/100$

FEF50 $10^{(-0.00741*A - 85.81/H + 0.9336)}*A^{0.3471}$

PEF $10^{(-0.00677*A - 74.22/H + 0.9661)}*A^{0.4017}$

C.10 Hedenstrom (Sweden)

H=height (cm), A=age (yrs)

C.10.1 Male

FVC $(A*0.0467) + (H*0.0744) - 8.44 - (0.000705*A^{2})$

FEV1 $(A*0.0145) + (H*0.0509) - 4.67 - (0.000406*A^{2})$

FEF25 $(A*0.0193) + (H*0.0678) - 3.73 - (0.000508*A^{2})$

FEF50 $(A*0.0245) + (H*0.0375) - 1.71 - (0.000639*A^{2})$

FEF75 $0.000216*A^{2} - 0.0513*A + 0.0193*H + 0.19$

FEV1/FVC $(109.4 - (A*0.2251) - (H*0.1286))/100$

PEF $(A*0.0169) + (H*0.0885) - 5.8 - (0.000342*A^{2})$

C.10.2 Female

FVC $(-A*0.0143) + (H*0.0545) - 4.205 - (0.000118*A^{2})$

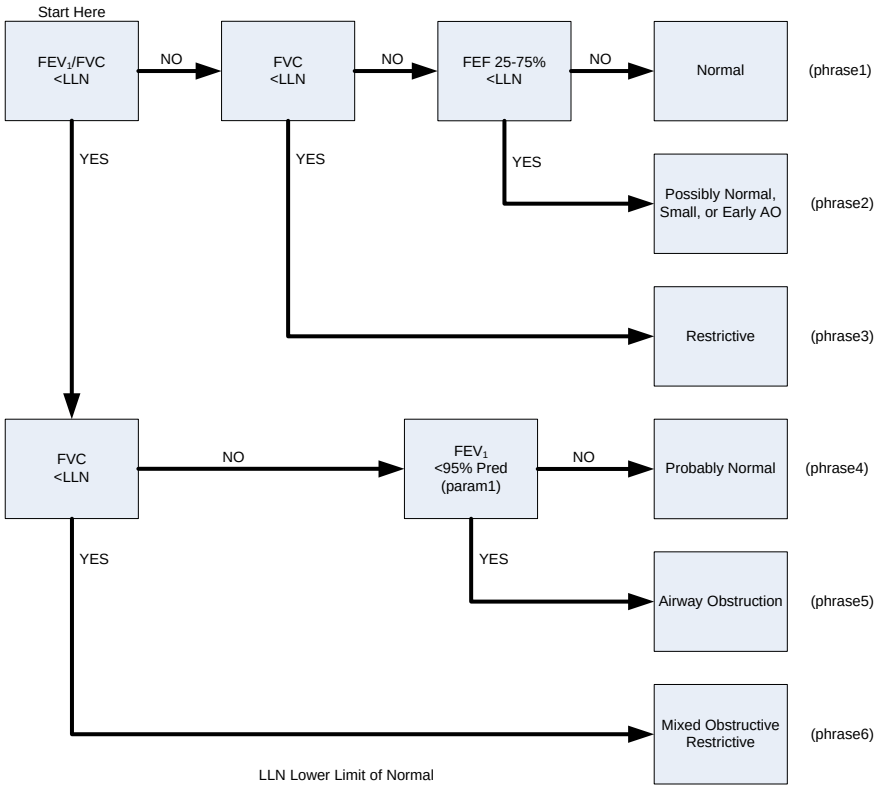
FEV1 $(-A*0.0281) + (H*0.0258) + 0.13$

FEF25 $(-0.001302*A^{2} + 0.0739*A + 0.0339*W + 4.088$

FEF50	$0.000132*A^2 - 0.0509*A + 0.0337*W + 4.073$
FEF75	$0.000768*A^2 - 0.1013*A + 0.0054*W + 3.97$
FEV1/FVC	$(136.4 - (A*0.2371) - (H*0.2809))/100$
PEF	$(-0.001206*A^2 + 0.0647*A + 0.0195*W + 6.544)$

Appendix D - Interpretation

D.1 McKay Interpretation Flow Chart



Severity of Airway Obstruction

		FEV_1 (% of Pred)
Mild (phrase8)		≥70 (param2)
Moderate (phrase9)	≥60 (param3)	& <70
Moderately Severe (p10)	≥50 (param4)	& <60
Severe (phrase11)	≥34 (param5)	& <50
Very Severe (phrase12)		<34

Severity of Chest Restriction*

	FVC (% of Pred)
Mild (phrase8)	≥70 (param6) but < LLN
Moderate (phrase9)	≥60 (param7) & <70
Moderately Severe (p10)	≥50 (param8) & <60
Severe (phrase11)	≥34 (param9) & <50
Very Severe (phrase12)	<34

*When TLC is not available

Source ATS, ARRD, 1991, Author: Dr. Roy McKay

Figure 45 – McKay Interpretive Algorithm

Appendix E - Sample Reports

Pulmonary Function Report
FERRARIS RESPIRATORY LAB
Name: SMITH, NANCY ID: 222-666-333
Sex: Female Age at test: 44
Height at test (in): 69
Weight at test (lb): 135
DOB: 01/22/1960

Interpretation: Normal expiratory flows and a normal FVC. This interpretation is valid only upon physician review and signature.

Test series created: 12/17/04 02:45 PM
Test series comment:
Physician:
Technician:
Number of efforts performed: 8

Pre-	Pred	Best	%Prd
FVC	4.05	3.79	94%
FEV1	3.29	3.00	91%
FEV1/FVC	0.80	0.79	99%
FEV6	--	--	--
FEV1/FEV6	--	--	--
PEFR	6.64	6.68	101%
FEF25-75	3.35	2.00	06%
Texp	--	4.97	--
Vext%	--	2.37	--
SVC	3.82	--	--

* below lower limit of normal (LLN)

FVC Flow vs. Volume Pre-

FVC Volume vs. Time Pre-

Patient position: Seated
Bronchodilator status: Pre-
Ethnic group: UNSPECIFIED
Predicteds: Crapo
Calibrated by:
Calibration date: 12/17/04 11:20 AM
Relative humidity at test (%): 24
Room temperature at test (deg F): 70
Barometric pressure at test (mmHg): 630
Report printed: 01/05/05 11:17 AM

Pulmonary Function Report
FERRARIS RESPIRATORY LAB
Name: SMITH, RANDY ID: 222123232
Sex: Male Age at test: 25
Height at test (in): 65
Weight at test (lb): 140
DOB: 04/05/1979

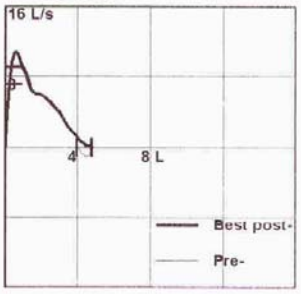
Interpretation: Normal expiratory flows and a normal FVC. This interpretation is valid only upon physician review and signature.

Test series created: 01/05/05 01:46 PM
Test series comment:
Physician:
Technician:
Number of efforts performed: 3

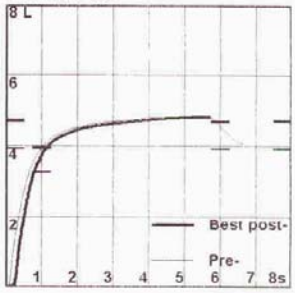
	Pred	Pre	%Prd	Post	%Prd	%Chg
FVC	4.73	4.84	102%	4.84	102%	0%
FEV1	3.96	4.06	103%	4.07	103%	0%
FEV1/FVC	0.83	0.84	101%	0.84	101%	0%
FEV6	4.71	--	--	--	--	--
FEV1/FEV6	0.84	--	--	--	--	--
PEFR	9.10	10.75	118%	10.84	119%	1%
FEF25-75	4.27	4.24	99%	4.32	101%	2%
Texp	--	5.49	--	5.48	--	0%
Vext%	--	1.88	--	2.18	--	16%
SVC	--	--	--	--	--	--

* below lower limit of normal (LLN)

FVC Flow vs. Volume
Pre vs. Post



FVC Volume vs. Time
Pre vs. Post



Patient position: Seated
Bronchodilator status: Pre-
Ethnic group: UNSPECIFIED
Predicteds: NHANES III
Calibrated by: BV
Calibration date: 12/30/04 03:18 PM
Relative humidity at test (%): 24
Room temperature at test (deg F): 70
Barometric pressure at test (mmHg): 630
Report printed: 01/05/05 01:52 PM

Figure 46 – Sample Internal Printer Reports

FERRARIS RESPIRATORY LAB

Pulmonary Function Report

Name: SMITH, NANCY
Height at test (in): 69
Weight at test (lb): 135
Ethnic group: UNSPECIFIED
Predicteds: Crapo
Predicted values extrapolated: No
Calibration date: 12/17/04 11:20 AM
Calibrated by:
Test series created: 12/17/04 02:45 PM

ID: 222-666-333
Sex: Female
Age at test: 44

DOB: 01/22/1960

Physician:
Technician:

Number of efforts performed: 8

Interpretation: Normal expiratory flows and a normal FVC. This interpretation is valid only upon physician review and signature.

Pre-	Pred	Best	%Prd	2nd	%Prd	3rd	%Prd
FVC	4.05	3.79	94%	3.80	94%	3.82	94%
FEV.5	2.54	2.26	89%	2.29	90%	2.25	88%
FEV.5/FVC	--	0.60	--	0.60	--	0.59	--
FEV1	3.29	3.00	91%	2.96	90%	2.94	89%
FEV1/FVC	0.80	0.79	99%	0.78	97%	0.77	96%
FEV3	3.86	3.64	94%	3.62	94%	3.61	94%
FEV3/FVC	0.95	0.96	102%	0.95	101%	0.95	100%
FEV6	--	--	--	--	--	3.82	--
FEV1/FEV6	--	--	--	--	--	0.77	--
FEV6/FVC	--	--	--	--	--	1.00	--
PEFR	6.64	6.68	101%	6.03	91%	6.23	94%
FEF25%	6.04	4.72*	78%	5.41	90%	4.94	82%
FEF50%	4.68	3.75	80%	3.93	84%	3.93	84%
FEF75%	2.31	1.09*	47%	0.98*	42%	0.95*	41%
FEF25-75	3.35	2.88	86%	2.75	82%	2.55*	76%
FEF75-85	--	0.68	--	0.62	--	0.63	--
FEF.1-1.2	--	5.33	--	4.65	--	5.02	--
Tpeakms	--	90.00	--	150.0	--	125.0	--
Vext%	--	2.37	--	5.03	--	3.82	--
MET	--	0.66	--	0.69	--	0.75	--
Veot	--	0.13	--	0.13	--	0.08	--

Pre-	Pred	Best	%Prd	2nd	%Prd	3rd	%Prd
FIVC	4.05	3.63	90%	3.59	89%	3.46	85%
FIV.5	--	2.59	--	2.25	--	1.78	--
FIV.5/FIVC	--	0.71	--	0.63	--	0.51	--
FIV1	--	3.55	--	3.55	--	3.18	--
FIV1/FIVC	--	0.98	--	0.99	--	0.92	--
FIV3	--	--	--	--	--	--	--
FIV3/FIVC	--	--	--	--	--	--	--
PIFR	--	5.56	--	4.52	--	3.59	--
FIF50%	--	5.20	--	4.51	--	3.45	--
FIF25-75%	--	4.78	--	4.26	--	3.30	--
FIF.1-1.2	--	4.26	--	3.36	--	2.94	--
FIF50/FEF50	--	1.39	--	1.15	--	0.88	--
MIT	--	0.38	--	0.42	--	0.52	--
Tins	--	2.41	--	1.15	--	1.30	--

Test series comment:

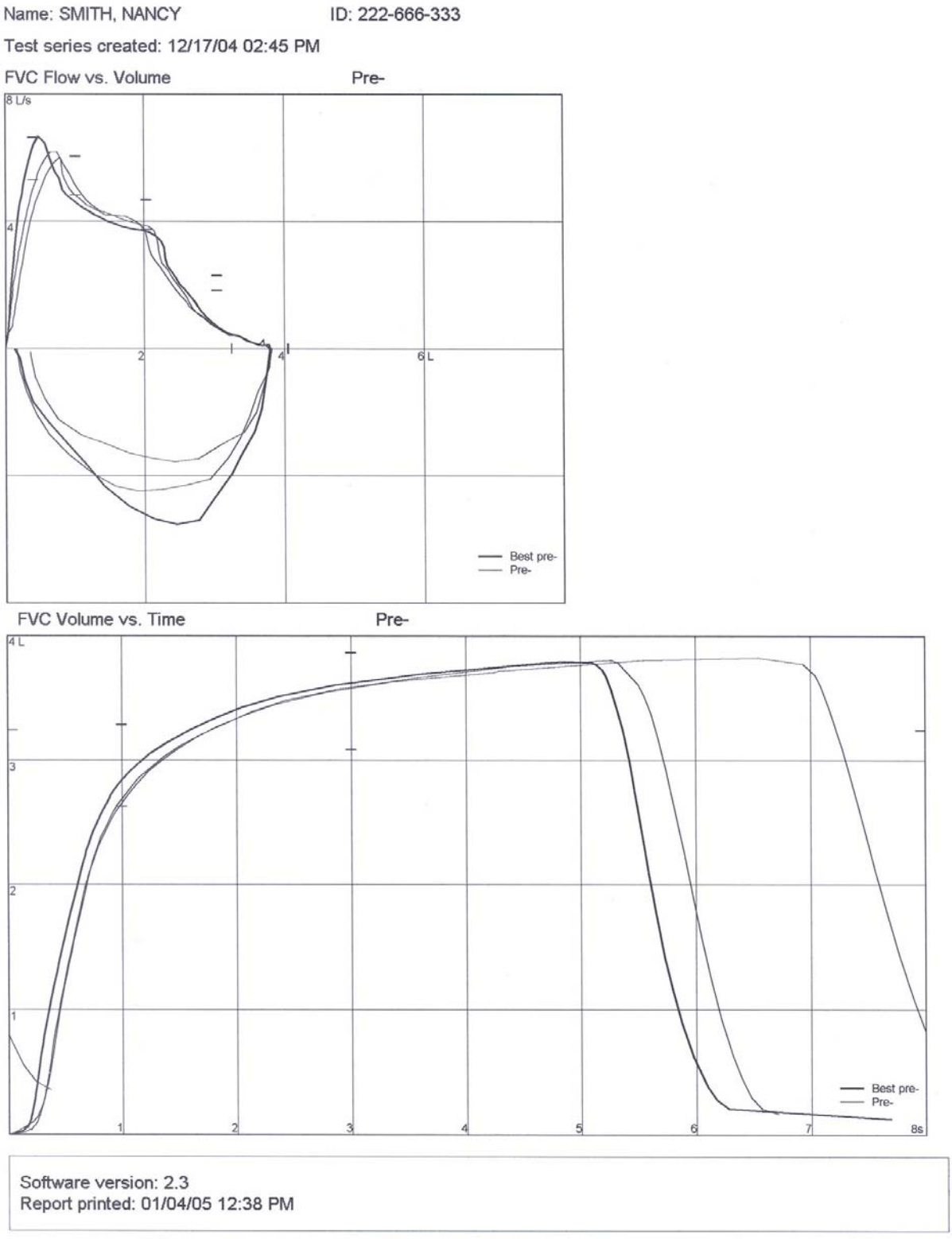


Figure 47 – Sample External Printer Report

Appendix F - References

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g. Pereira, C.A. I Consenso Brasileiro sobre Espirometria. Jornal de Pneumologia May/June 1996 Vol. 22 No.3: 130-136.

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Appendix G - Messages

The following table describes the messages that can be displayed if an unexpected condition is encountered. If you encounter a message, perform the following:

- Review the probable cause.
- Perform the suggested recovery procedure.
- If the condition is not resolved, call customer support.

Table 8 – Messages

Message	Probable Cause	Suggested Recovery
Age or height are outside the published range for the selected predicted set. Do you want to calculate predicteds for this patient using extrapolation?	Patient data is out of range of the predicted set.	Verify you have entered the correct patient age and height. Verify you have selected the desired predicted set. If *No* is selected, the predicted values will not be calculated. If *Yes* is selected, the predicted equation will be used even though it is out of the prescribed range for age or height.
Effort cancelled: Flow detected during zeroing.	During calibration, flow was detected through the flow sensor.	Pull the syringe handle all the way out and do not move it until the zeroing process is completed.
Effort cancelled: pneumotach not connected.	Attempted to perform a test or calibration, and the handset cable is not properly connected.	Verify the handset connections to the flow sensor assembly and the handset jack.
Effort rejected, invalid effort.	During calibration or testing, the flow through the flow sensor was out of the expected range; or the patient effort was under one second in length.	Verify there is an airtight connection between the filter and the syringe (for calibration) or the mouthpiece (for testing). Repeat the calibration procedure; or verify the patient understands the maneuver and repeat the test.
Flow was too low. Push/pull syringe handle faster next time.	During calibration, the flow through the flow sensor was too low.	Verify there is an airtight connection between the filter and the syringe. Repeat the calibration and attempt to follow the guidelines on the screen.
Formatting memory card...	A new unformatted memory card was installed.	No action required. The message will be cleared when formatting is complete.
Insufficient memory to add new effort	Attempted to store a new effort and sufficient memory is not available.	Delete obsolete data or insert a new memory card.
Insufficient memory to add new patient.	Attempt to store a new patient and sufficient memory is not available.	Delete obsolete data or insert a new memory card.
Insufficient memory to add new test.	Attempt to store a new test and sufficient memory is not available.	Delete obsolete data or insert a new memory card.
Insufficient memory to add new test series.	Attempt to store a new test series and sufficient memory is not available.	Delete obsolete data or insert a new memory card.
Memory card not formatted yet. Do you want to format the memory card now? (Caution: All data will be erased!).	A unformatted memory card has been installed.	Select Yes to format the card.
Memory card not usable.	The memory card may not be installed correctly.	Remove it and reinsert it. If message is still displayed, replace the card.
Memory card removed!	You attempted to store information and the memory card is not properly installed.	Reinsert the memory card and restart the unit. The information that you were attempting to store will be lost.

Table 8 – Messages		
Message	**Probable Cause**	**Suggested Recovery**
Printer error (temperature).	A high temperature has been detected for the printer.	Turn off the unit and open the printer cover. Wait 30 minutes before restarting.
Printer error (voltage).	Insufficient power has been detected.	Plug in the unit and recharge the battery.
Printer not on-line.	Printer cover may not be closed.	Verify the printer cover is closed and snapped in to position.
Printer not responding.	Possible problem with internal printer.	Check paper and verify the printer cover is closed.
Printer out of paper.	There is no paper in the printer.	Insert a new roll and press the OK button.
The pneumotach has not been calibrated yet.	An option has been selected that required calibration.	Perform a calibration.
The scheduled pneumotach calibration check is now due.	Calibration was performed more than 24 hours ago.	Advisable to recalibrate.
This effort is beyond the normal limits for use in calibration. Are you sure you want to use this effort?	Possible defective pneumotach.	Retry calibration.
This patient already has the maximum number of test series allowed.	Attempted to store a ninth test series for a patient. A maximum of eight test series can be stored for each patient.	Delete an obsolete test series or reenter the patient data.
Unable to read from the memory card.	Memory card is not installed correctly or faulty.	Power off the unit and remove and replace the card. If error continues, replace the card.
Unable to write to the memory card.	Memory card is not installed correctly or faulty.	Power off the unit and remove and replace the card. If error continues, replace the card.
You are deleting the last test series for this patient. Do you want to delete the patient demographic information also?	All the test series associated with this patient have been deleted.	Select Yes to delete the patient information. Select No to retain it.

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Notes