

# KoKo Spirometer & KoKo DigiDoser

## Windows Operations Guide

September 2002



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 who played a prominent role in early Native American culture. He is often portrayed as the bearer of health and plenty.

For Pulmonary Data Services, KoKopelli represents new directions of excellence in pulmonary diagnostic testing.

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Contact your representative for:  
Sales and Marketing Information  
Technical Support



“Attention, consult accompanying documents.”  
This symbol indicates that the user must read and understand all instructions and warnings prior to use.



This symbol indicates that this device provides a certain level of safety because the patient applied part is floating.



This symbol indicates that this Class IIA equipment complies with the European Union Medical Device Directive.

0086

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# INTRODUCTION

Congratulations! You have purchased a quality instrument that will give you many years of excellent service. Your friends at Pulmonary Data Services, Inc are ready and anxious to help you in any way necessary to assure you are totally satisfied with your purchase.

Please take the time to:

- Inspect the contents of this package for completeness, by referring to the enclosed packing list.
- Read the statement regarding the software license for which you are assuming liability.
- Read the Essential Prescribing Information, especially the Precautions.
- Complete the enclosed warranty card.

## USING THE MANUAL

This manual is written with the understanding that the user is adequately familiar with standard Windows software operation. For example, the word **select** means choose a function either by clicking on the choice with the mouse or by using the Tab key to highlight the function and then pressing Enter. If you have questions regarding standard Windows functions please consult a Windows manual or Windows software representative.

All instructions in this manual refer to the KoKo Spirometer, KoKo USB Spirometer, KoKo DigiDoser Spirometer, and the KoKo USB DigiDoser Spirometer with Windows software, unless otherwise indicated. The terms KoKo Spirometer and KoKo DigiDoser Spirometer will apply to the serial versions as well as the USB versions unless noted.

## SOFTWARE LICENSE

Pulmonary Data Services, Inc. authorizes you to use ONE copy of the software product enclosed herein, included with your purchased product. The software may be copied to a computer system that is used in conjunction with that individual spirometer ONLY. Any use of Pulmonary Data Services Inc. software not included in your purchase, or any use by others of unauthorized copies of any Pulmonary Data Services, Inc. software traceable to your licensed copies violates United States copyright laws and international treaty provisions for which you agree to be held legally and financially responsible. Financial responsibility includes damages, punitive damages, injunctive relief, attorney's fees and court costs.

### *Multi User Version Only*

Each licensee must register the purchase of the software product with Pulmonary Data Services, Inc. within 21 days of software installation. Also, each printed report must contain the software licensee's name (or the licensee's site/facility name), clearly readable when printed. After registering the software product, this condition will be enforced by the software. Changing the licensee name after software registration requires purchase of a new software license.

# ESSENTIAL PRESCRIBING INFORMATION

## I. DEVICE DESCRIPTION AND SPECIFICATIONS

The KoKo Spirometer and KoKo DigiDoser Spirometer are manufactured by Pulmonary Data Services, Inc., as pulmonary function testing devices.

- Pneumotach Brass Fleisch-type
- Dimensions 18x10x6cm
- Weight .3kg Koko Spirometer  
.47kg Koko DigiDoser
- Data Sampling Rate 128/sec KoKo Spirometer KoKo DigiDoser Spirometer  
200/sec KoKo USB Spirometer KoKo USB DigiDoser Spirometer
- Volume Scaling 10mm/L, user variable
- Volume Range 0-19.9L
- Flow Scaling 5mm/L/sec, user variable
- Flow Range  $\pm 16$ L/sec
- Accuracy  $\pm 2\%$
- Power source Serial port – Koko Spirometer  
USB – Koko USB Spirometer, Koko USB DigiDoser  
AC power pack 110, 220, 240 VAC – Koko DigiDoser.
- Computer Requirements WINDOWS - Windows '95 or higher, Pentium or higher, minimum 100MHZ, minimum 32MB RAM, Minimum 60MB available space on hard drive, available COM or USB port. USB devices must use Windows 2000, Windows XP, or higher.
- Operating Environment 20°-35°C
- Safety EN 60601-1  
Class I power supply for Koko DigiDoser; all models connected to Class I type personal computers that provide Class III type I/O ports.  
Type BF patient applied part  
Ordinary equipment (not protected against harmful ingress of moisture)  
Not suitable for use with flammable anesthetics  
Suitable for continuous operation
- EMC EN 60601-1-2  
IEC 801-2 / EN 61000-4-2: 3kV CD, 8kV AD  
IEC 801-3 / EN 61000-4-3: 3V/m  
IEC 801-4 / EN 61000-4-4: .5 kV I/O, 1 kV AC mains  
IEC 801-5 / EN 61000-4-5: 1 kV DM, 2 kV CM

## II. INTENDED USE AND INDICATIONS

This device is intended to be used as a pulmonary function diagnostic testing device. It is to be connected to a customer-supplied personal computer that possess IEC 950 certification. Additionally, the Koko DigiDoser requires a Class I power supply that is supplied by the manufacture. The device is to connect via the signal input port/signal output port/DC power input to the serial or USB port of the computer. During testing it is to be connected to the KoKo Moe single patient use, viral/bacterial filter and used by trained medical personnel in hospitals, clinics and doctor's offices. The KoKo DigiDoser is to be used with the supplied nebulizer for the purpose of controlling the delivery of aerosolized substances. The operator must maintain a patient area of 1.5m horizontally and 2.5m vertically, and, at no time, bridge the patient and the personal computer/printer/specified power supply system. This device 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 allergies, asthma and respiratory diseases.

### III. CONFORMANCE TO STANDARDS

Pulmonary Data Services, Inc. and this device conform to the following standards:

- Industry Recommendations - ATS 1994, NIOSH, SSD, OSHA, ECCS
- Quality System Regulations - FDA QSR, ISO 9002, EN 46002
- Product Testing Regulations - IEC 601 series, 601-1, 601-1-1, 601-1-2
- European Directive - MDD 93/42/EEC

### IV. WARNINGS AND PRECAUTIONS

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

**WARNING:** During provocation testing, the patient's response to the challenge agent may require the suspension of testing. This procedure can be dangerous, and should only be performed with a physician and appropriate emergency equipment available. Always review the information provided with the challenge agent very carefully.

**CAUTION:** The computer (and specified power supply used with the KoKo DigiDoser Spirometer) must be located outside the patient environment.

**CAUTION:** Do not connect either end of the supplied cable to any telecom jack or outlet.

**CAUTION:** Always use the power pack that accompanied your Koko DigiDoser Spirometer. Using a different power pack can cause permanent damage to your system. Please ensure the power supply and all associated computer equipment are plugged into properly grounded power receptacles.

**CAUTION:** Always use the KoKo Filter with the KoKo Spirometer. Failure to use the filter could affect accuracy due to expectorated matter in the pneumotach.

**CAUTION:** The KoKo Filter is designed for single patient use only. Do not attempt to clean or sterilize.

**CAUTION:** Do not attempt to wash or submerge the KoKo Spirometer handle in water or cleaning fluid, as there are electronic components inside the handle that will be permanently damaged.

**CAUTION:** Never use the KoKo DigiDoser to administer emergency bronchodilator.

**CAUTION:** Only use compressed air with the KoKo DigiDoser. Use of compressed oxygen can be dangerous.

**CAUTION:** Do not use anti-static or electrically conductive hoses or tubing with this device.

**CAUTION:** This device complies with the minimum electromagnetic compatibility requirements of the MDD. However, electromagnetic interference may still be encountered. If the device is behaving erratically due to electromagnetic interference, contact our service department.

## **V. MAINTAINING DEVICE EFFECTIVENESS**

Pulmonary Data Services, Inc. recommends that the KoKo Spirometer be powered at all times, or that it be allowed to warm up for 15 minutes after power is applied, before calibration or testing is performed.

The recommended transport and storage conditions for the KoKo Spirometer are  $-40^{\circ}\text{C} - 70^{\circ}\text{C}$ , 0-100% relative humidity and 550-780 mmHg. The recommended operating and storage temperature range 24 hours prior to and during testing is  $20^{\circ} - 35^{\circ}\text{C}$ .

Daily calibration with a 3Liter syringe prior to testing is advisable. The syringe should also be validated yearly for accuracy.

A KoKo filter should be used during testing to reduce the need for cleaning and disinfecting. See Appendix A for Cleaning and Disinfecting instructions.

Circuit diagrams, component part lists and component descriptions are available upon request.

# GETTING STARTED

## CHAPTER 1 SETUP THE KOKO SYSTEM

After you have unpacked all items, prepare your KoKo Spirometer for use by following these instructions:

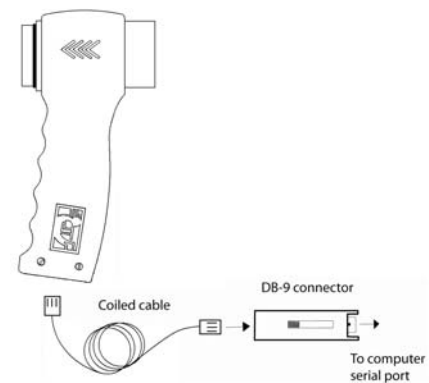
### 1.1 CONNECT THE CABLE

If you have the KoKo Spirometer:

1. Plug the “snap” connector end of the coiled serial cable into the bottom of the KoKo Spirometer.
2. Plug the DB 9 pin serial connector end of the coiled serial cable into the serial port of your computer.

If you have the Koko DigiDoser :

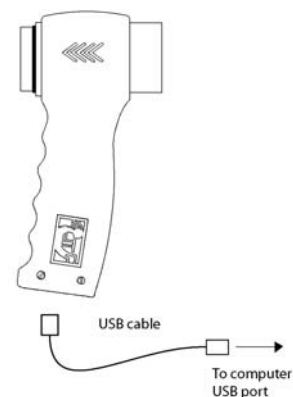
1. Follow steps 1 and 2 above.
2. Plug the power supply connector end of the serial cable into the included power supply cable and plug the power pack into a grounded outlet.



**NOTE: It is important to use the power pack supplied with your system. Use of a different power pack can cause permanent damage to your KoKo DigiDoser.**

If you have the KoKo USB Spirometer or Koko USB DigiDoser:

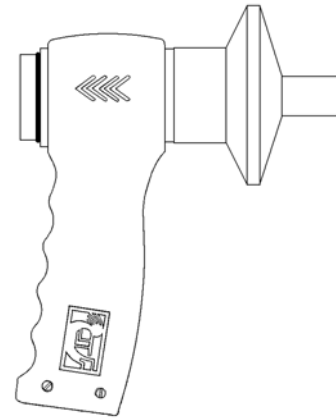
1. Plug the square end of the USB cable into the bottom of the KoKo Spirometer.
2. Plug the rectangle end of the USB cable into the USB port of your computer.



## 1.2 ATTACH THE KOKO FILTER

1. Locate the arrow indentations on the sides of the spirometer handle.
2. Place the KoKo Filter on the side of the handle which is opposite the direction that the arrows point.
3. Make sure that the filter is fitted snugly on the spirometer.

**NOTE: The KoKo Spirometer is designed to be used with the KoKo Filter. If the filter is not used during testing, accuracy may be affected due to expectorated matter in the pneumotach.**



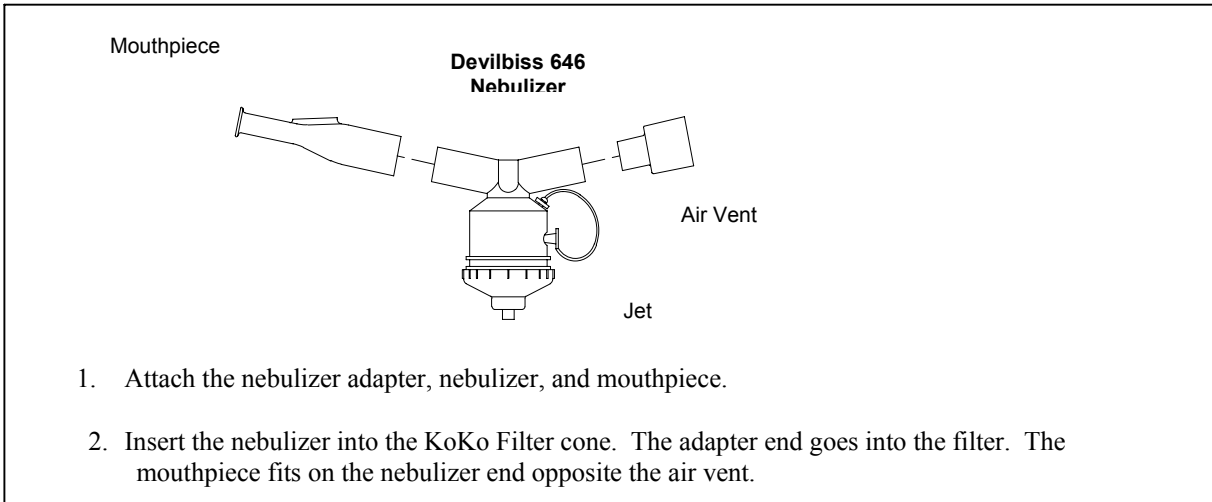
## 1.3 ASSEMBLE THE NEBULIZER (CHALLENGE TESTING ONLY)

Perform the following steps if you have purchased the KoKo DigiDoser.

If the Devilbiss 646 nebulizer is included with your KoKo DigiDoser, it is recommended that you use this nebulizer for bronchial challenge testing, in order to follow the standardized protocol recommended in the package insert for Provocholine. When using this nebulizer with the KoKo Dosimeter and a driving air pressure of 30 PSI, the output aerosol will closely duplicate that of the aerosol output during the original standardization study. Any variation in this configuration may significantly alter the amount of drug delivered and render the testing inconsistent with the standards established.

**Note: The KoKo DigiDoser may be used with a variety of nebulizers. The choice of a nebulizer for use with the DigiDoser is left to the discretion of the user. However, the nebulizer MUST be designed so that ALL air passes through a single port during inspiration as well as expiration (see example below). Nebulizers that “entrain” air through openings or other air sources such as one way valves are not appropriate for use with the KoKo DigiDoser.**

Read the assembly instructions included with your nebulizer to prepare the nebulizer for use.

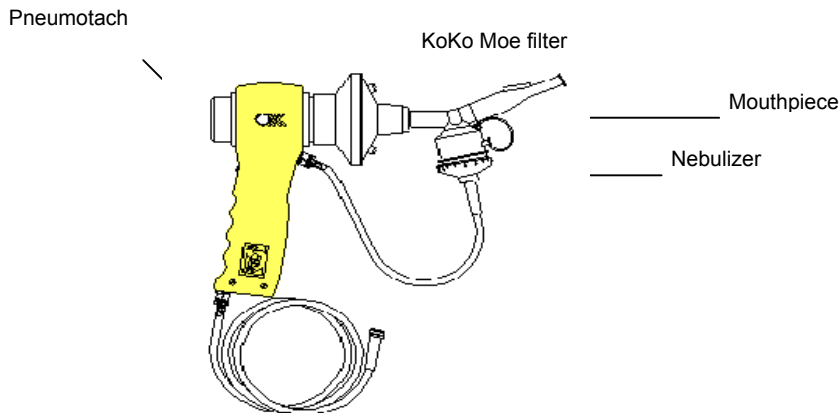


**Note: Refer to the ATS Guidelines for Methacholine and Exercise Challenge Testing – 1999 for further information on choosing a nebulizer and preparing solutions.**

#### 1.4 CONNECT THE KOKO DIGIDOSER (CHALLENGE TESTING ONLY)

Perform the steps in this section if you have purchased the KoKo DigiDoser.

1. Connect the pressure line outlet on the front of the KoKo DigiDoser handle to the pressure line inlet on the bottom of the supplied nebulizer with the short piece of supplied tubing.
2. Adjust your pressurized air source for 30 pounds per square inch (PSI).
3. Connect the pressurized air source to the bottom of the DigiDoser with the long piece of tubing.



**Note: For best results, the air source should be pressure regulated, not flow regulated. Use compressed "air" only. Use of oxygen is not recommended.**

## **1.5 PREPARE THE SOLUTIONS (CHALLENGE TESTING ONLY)**

Prepare the solutions as recommended by the instructions on the solution packaging. Place the solution into the nebulizer to prepare for Challenge testing. It is recommended that you always use the same amount of solution for each stage, to further ensure accuracy and consistency. Do not rinse the nebulizer between stages, rather, simply shake dry and fill with the next indicated solution.

## CHAPTER 2 START THE KOKO SYSTEM

### 2.1 INSTALL THE SOFTWARE

Prior to opening the package containing the diskettes or the CD, read the Software License Agreement.

1. Place the CD in your CD-ROM drive.
2. If installation does not start automatically; click **Start**, then **Run**. Type D:\Setup (where D: is your CD-ROM drive).
3. Follow on screen instructions.

Pulmonary Data Services recommends that you accept all default choices during installation by clicking **Next**.

### 2.2 CONFIGURE THE MULTI-USER SYSTEM

IF THIS IS AN UPDATE OF A USER WHO HAS BEEN PREVIOUSLY USING THE KOKO-PFT IN SINGLE USER MODE, PLEASE FIRST REFER TO THE NOTES SECTION AT THE END OF THIS DOCUMENT.

After first-time installation of the multi-user version of the KoKo PFT System on all workstations, perform the following additional steps:

- 1) Create a "shared database directory": on the system that will be used as the network server, create a directory that will be used to store the database files. Use an obvious name such as *KOKODATA*

If you are not clear on how to create this directory (folder) on the server, please ask the account's computer person to do this.

- 2) Set the database location at each workstation: After performing the standard installation on a workstation, and with the network connection to the shared database directory functional, start up the KoKo PFT System. **The first time the program is run after installation**, you will be prompted to select the shared directory for the database.
  - a. Select the directory created in the previous step. **OR**
  - b. **Click on NETWORK and type in the proper UNC designation of the data location as follows:** [\\servername\shreddirectory\KOKODATA\](#) Make sure you include the \ (backslash) at the end of the line. Using this method is better than simply choosing the shared network drive letter because it avoids the possibility that a user will change the drive mapping letters at the workstation.
- 3) **ADMINISTRATOR** - Designate a "system administrator": One person must be designated as responsible for setting up and maintaining the KoKo PFT System multi-user version. Set the database administration and maintenance options at each workstation: The first time the program is run after

installation, you will be asked if you want the database administration and maintenance functions accessible on that workstation. Answer "Yes" if you want to be able to perform both types of tasks from this workstation. We recommend that the administrative functions not be available to a typical testing workstation, since improper use can cause errors.

If you answer "No" to the administration question, you will be asked if you want only the database maintenance tasks accessible from this workstation. Answer "Yes" if the workstation has an adequately high-speed connection to the server, since performing a local backup or restore of the database requires copying of the entire database file set over the network. If you answer "Yes", the technician will periodically be prompted at exit from the program to perform automatic local backups. The "system administrator" has the ability to perform some routine operations such as:

- Backup/restore database
- Compressing database
- Determining which users are logged on
- Logging off all users in case of abnormal workstation termination (network/server crash, workstation reboot, task termination, cabling problem, etc.)
- Unlocking a patient that was in use when a connected workstation terminated abnormally
- Designing and relocating shared report designs to a common location (described below)

If possible, the system designated as the "administrator's" should be the same as the network server. This will dramatically speed up backup/restore/compress, since these file operations will be performed "locally" instead of "over the network".

At first startup of the administrator's system, answer "Yes" to the system administrator prompt. This change enables the `File|Database|Administrator` menu at the main window.

**Nothing prevents more than one system being an administrator's system, if desired (caution is required, however: some functions (log-off all users, unlock current patient), when misapplied, will cause errors).**

- 4) **REGISTRATION** - Register the KoKo PFT software: After installing the KoKo PFT System multi-user version (or upgrading to a larger maximum number of simultaneous users), a registration reminder is shown at each startup until the program is registered with PDS. The purpose of registration is to allow PDS to know who the ultimate licensee of the program is, and to prevent unauthorized use by others. The system will run for 21 days after installation and first-run, with the registration reminder being shown at each startup, and the registration dialog being shown at each startup when only 7 days are remaining. After the 21-day period, the PFT System will not continue until registration is performed. To register the PFT System, start up the KoKo PFT System (preferably on the administrator's system). follow the instructions on the registration dialog, accessible from `Help|Register`. Registration only needs to be performed on one workstation to be effective for all workstations. **CALL PULMONARY DATA SERVICES CUSTOMER SUPPORT AT (800-574-7374 or 303-666-5555) TO FINALIZE THE REGISTRATION. YOU MUST BE IN FRONT OF THE COMPUTER AT THE TIME. PLEASE NOTE that the license name, once entered, cannot be changed. It appears on the top left of each report so it should be something appropriate (ie. Hospital's or Clinic's or Office's name)**
- 5) **Adding the license name to each report:** As a condition of the KoKo PFT software license, each printed report (therefore each report design) used must contain the software licensee's name (facility name). After registering the KoKo PFT System, this condition is enforced. When necessary, the Report Design function will suggest a suitable text item for this purpose, which the administrator should place on the page, where

desired. The location of where the license name is placed is the same as the facility name. Therefore, it is advisable to leave the facility name prompt blank when it is offered by the KoKo software. If it has already been entered, it is easy to remove the facility name by choosing System|Preferences|Facility Name / Location from the main KoKo menu. On some reports, it may be necessary to slightly rearrange the location of some report items to allow the new license name to be placed and the report design saved.

- 6) **Set up shared report designs (optional):** The system administrator may decide that designs for all reports need to be stored in a common location on the network so that all connected systems can use a uniform report style, and so that any changes to report designs can be effective on all systems without the necessity of copying the design files to each system.

Make sure no systems are running the PFT System while performing the following procedure.

The system administrator must **first move the set of existing report designs (\*.DES files, installed in the local C:\Program Files\KoKo PFT System application directory by default) to the database directory, set previously by the procedure in "Select the database location", described above.**

Next, delete all local \*.DES files from all other workstations, so there can be no confusion over which report designs are actually in use. The .DES files are located on the hard drive under Program Files\KoKo PFT System.

Finally, using a text editor such as Wordpad or Notepad, add the following to the KoKoPFT.INI file at each connected system (the .INI file is located at Program Files\KoKo PFT System\Bin\KoKo PFT.ini):

```
[Database]

NetworkReportDesigns=True
```

From this point on, all systems should share the same report design files. Verify this by selecting Report|Read/Interpret/Print on each system, and checking that all of the common designs are available.

The administrator should edit all report designs to meet the physician/facility requirements, being sure to include the software licensee (i.e.: facility) name on each page of each report *absolutely exactly* as it was reported to PDS during software registration. This condition is enforced after the software is registered with PDS (see Software License). When necessary, the Report Design function will suggest a suitable text item for this purpose, which the administrator should place on the page, where desired.

Please note that changing the licensee name *after* registration requires purchase of a new software license, so it is very important to get this right "the first time".

Finally, after software registration has been completed and the printed reports are tested and correct, if so desired, a system administrator can set the "read-only" file attribute for each .DES file, using the Properties dialog that comes up by right-clicking on the file in Windows Explorer. *This can be important*, since there is no "file locking" mechanism for simultaneous editing of the .DES files. From this point on, all users (including the administrator) who attempt to edit a read-only report design will see a message saying that editing can't be performed on that design. The system administrator may, of course, clear the read-only attribute for any .DES file that needs further editing, resetting the attribute when editing is completed.

- 7) **Start up and test each workstation:**

At this point, start up each workstation, up to the maximum number of simultaneous users allowed. Check Help|About for the proper description of the database path and user name/ID.

If each workstation is set up correctly, proceed with normal PF testing functions, as described in this

document.

**Notes and Special Situations:**

The following are the relevant statements in the KOKOPFT.INI file located on each workstation in the C:\Program Files\KoKo PFT System\BIN directory.

Use a text editor such as Wordpad or Notepad to edit these statements, if necessary.

**Database Location** - edit the following section in the KoKoPFT.INI file on each system:

```
[Database]

NetworkDbPath=\\server\shared\kokodata
```

**where the expression following NetworkDbPath= is a valid DOS or UNC path to the shared database directory on the server system. Obviously, all workstations must be configured to have read/write/create access to all files in this shared server path.**

**Administrator Status** - To change the designation of a particular system as the "administrator's", make the following changes to the KoKoPFT.INI file on that system:

```
[Database]

DbAdmin=True

DbMaintenance=True
```

**Workstation Location Identifiers** - When each workstation starts up the KoKo PFT System multi-user version *for the first time*, a random unique name and unique ID are assigned to each workstation (and written to the KoKoPFT.INI file). These can be checked by choosing Help|About from the main KoKoPFT menu.

If desired, the administrator may change the name and ID to something more descriptive by editing the KoKoPFT.INI file at each workstation (each ID and name **must** be unique, or errors **will** occur):

```
[Database]

MultiUserImageId=32768

MultiUserImageName=KoKo32768
```

MultiUserImageName is used to identify each site, and appears as the name of the 'Site' as part of the data for all tests performed.

*Only change these values **before** performing any PF testing on a KoKo PFT System.*

---

**UPGRADING FROM PREVIOUS SINGLE-USER VERSION**

**Converting KoKo-DOS patient data** - It is advisable to first do the full multi-user installation and configuration prior to importing any old KoKo-DOS patient data. This avoids any additional delays which can occur in converting the patient files. This also can be done at any time without impacting on day to day

operations.

**Updating Files and Compressing Database** - If the previous version was of an older generation (ie. earlier releases were versions 4.0.34 or 4.1.139 or 4.1.180 or 4.2.24.4) and you are now upgrading to the Multi-User Version 4.2.120 or higher, it is likely that the database itself will need to be converted (updated and compressed) to be compatible with new fields in the newer version. This is accomplished automatically the first time the application is started after the new version is installed. However, this conversion process may take a very long time to complete (approximately 200-400 test series per hour), and should be performed only when the system will not be required for other uses for a period of time. To accomplish this, install the new version on the workstation. If a previous single user version existed, it will not prompt for a network location of the database. After the conversion is complete, move ALL the database files from the C:\Program Files\KoKo PFT System\PtData directory to the new shared directory on the file server. Then use a text editor such as Wordpad or Notepad to edit the NetworkDBPath statement in the [Database] section of the KoKoPFT.INI file to now reflect the location of the data on the file server.

```
[Database]

NetworkDbPath=\\server\shared\kokodata
```

where the expression following NetworkDbPath= is a valid DOS or UNC path to the shared database directory on the server system. Obviously, all workstations must be configured to have read/write/create access to all files in this shared server path.

#### **Merging Existing Single-User Databases -**

```
[Database]

MergeDB=True
```

After adding this command to the KoKoPFT.INI file, at next startup, the system will automatically merge the local single-user database created by a previous single-user installation (if any) into the multi-user shared database. After the merge has been successfully completed, the local database and directory will be deleted and the MergeDB statement will be changed to False. Note that this is not a normal operating situation- it is intended only for if a single-user version was installed (and PF testing was previously performed) **Also note that this process may take a very long time to complete (approximately 200-400 test series per hour), and should be performed only when the system will not be required for other uses for a period of time. This action does not require exclusive access to the database, so other users may proceed as usual.**

## **2.3 CONFIGURE THE CLIENT-SERVER SYSTEM**

Complete the following steps if you purchased the client and server versions of KoKo software.

**Note:** The bi-directional transfer of files between the KoKo PFT Client and Server systems, occurs using standard Windows TCP/IP protocol over a direct dial-up or Internet connection. **The Server version must be installed at a location with a FIXED IP Address or Domain name.** Many Internet providers (such as AOL and MSN) do not routinely provide fixed IP addresses unless specifically requested.

1. Install the server version on a system that has a fixed IP address. If it was installed on a network, designate a location for the database when prompted. It will also prompt for administrator functions from this location. It is advisable to always answer Yes to this prompt unless the Server version is only being set up as a workstation on a Multi-User installation.

2. Start up the server version for the first time and call the PDS Instrumentation Sales Department to register the server software.
3. Install the client version on a system that has a IP access to the server via Dial-Up Networking or via a live Internet connection
4. If not already running, activate the Dial-Up connection to the server from the client locations. It is important that the dial-up clients have access to the location on the network.
5. Start up the client version for the first time and call the PDS Instrumentation Sales Department to register each installed client software set.
6. Select `Transmit Test Series` or `Receive Test Series` from `File|Communications` on the main KoKo PFT menu.
7. If not already entered into the [Client-Server] section of KOKOPFT.INI, you will be prompted to enter the IP address (in numerical format such as 198.129.34.29) or the domain name (in .com format such as mydomain.com) of the server.

The following are the text changes to the KoKoPFT.INI file (located in the C:\Program Files\KoKo PFT System\BIN directory) which could be added with a text editor (i.e. Notepad) manually, if necessary. If the installation is performed as noted above, these changes should be automatically completed.

[ClientServer]

Role=Client

ServerDomainName=mycompany.com Set to the domain name (in '.com' domain-name format or '127.100.0.10' dotted-address format) where the KoKo server program is expected to be listening. Default is not meaningful.

## 2.4 RUN KOKO PFT

Before you begin, you should check the system time and date. To do this:

- Double-click on the time in the taskbar at the bottom right corner of your screen.
- Check that the time is set to the correct time.
- Check that your time zone is set correctly. If not, daylight savings time may not be adjusted correctly by Windows.
- PDS recommends that you designate a date format that requires 4-digit years.

To run KoKo PFT, after connecting your spirometer:

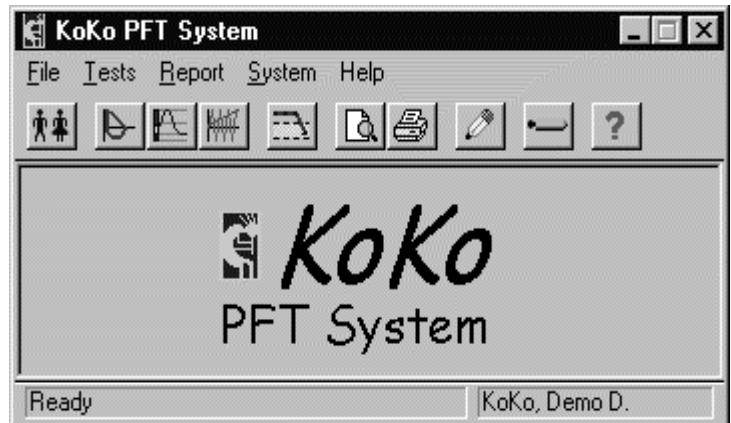
1. Click on **Start** at the bottom left of the desktop.
2. Click on **Programs | PDS**.
3. Click on **KoKo PF Testing**.

Or:

Double click the KoKo icon on the Windows desktop.



The Main Menu as shown will appear.



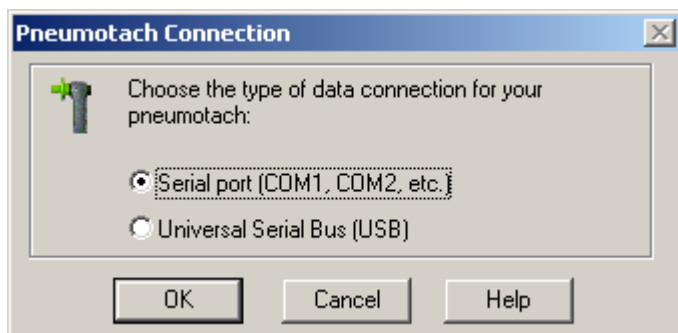
## 2.5 CHOOSE COMMUNICATION PORT

The first time the KoKo PFT System starts up, you will be asked if you would like to have the spirometer port detected automatically, or if you would like to manually enter a port setting. We recommend you choose automatically. If in the rare event KoKo PFT is unable to automatically detect your spirometer, you can manually assign the port.

## 2.6 INSTALLING PNEUMOTACH DRIVER

The "pneumotach driver" is the system software that enables the pneumotach to use one of your computer's serial ports or the Universal Serial Bus (USB) port. This driver is a separate program, and is installed separately from the KoKo program, using Windows.

The first time you start the KoKo program, this dialog may appear:



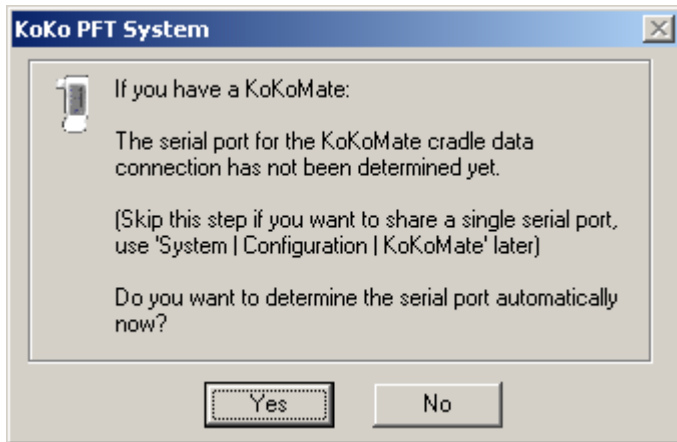
If you see this dialog, you need to determine *which type* of pneumotach you have, either *serial port* or *USB*.

If you select 'Serial Port', instructions for installing the driver that are specific to your system will be displayed.

If you select 'Universal Serial Bus (USB)', instructions for installing the USB driver specific to your system will be displayed.

## 2.7 SETUP KOKOMATE CRADLE

The first time you start up the KoKo PFT System, you will be asked if you have any KoKoMate spirometer(s).



If you do not have a KokoMate Spirometer answer NO and continue, otherwise answer Yes to this prompt.

Alternatively, at any time you want to set up the KoKo PFT System for use with a KoKoMate, from the main window, select System|Configuration|KoKoMate|Data connection...

In the dialog that appears, we suggest that you select the Automatic serial port detection method, then click OK.

If you know the number of the serial port (COMx, where x is typically a number from 1 to 4), you may select Manual, then click OK. Select the serial port number, then click OK.

Connect the cradle's data connector to a serial port on your system, then turn the KoKoMate on by pressing the I/O button, then place the KoKoMate in the cradle. Click on OK.

The KoKo program will now attempt to communicate with the KoKoMate, using an infrared (wireless) data link.

If the KoKoMate is successfully detected, a dialog box will prompt you to place the KoKoMate back in the cradle when you have completed patient testing and are ready to import the data.

If the KoKoMate could not be detected, make sure that the KoKoMate is turned on, placed in its cradle, and the data connector is connected to a serial port.

If you do not see anything on the KoKoMate screen after turning it on, check that a battery is installed. If a battery is installed, and you see nothing on the screen after turning the KoKoMate on, install a fresh battery and try again.

Click on Retry until the KoKoMate is successfully detected.

If the setup process completed successfully, you will see a green status indicator flashing in the lower right of the main window, indicating "ready to accept KoKoMate data". Proceed with the next section, "Set KoKoMate options".

**NOTE: If the serial port used by the KoKoMate cradle ever becomes unavailable, the status indicator in the lower right of the main window will show a red "X" when the KoKo program starts up. Before importing KoKoMate data, you should close any program that may be using that serial port, and restart the KoKo program. Alternatively, repeat the setup procedure above, selecting and connecting to a different serial port.**

**NOTE: If you discontinue use of the KoKoMate, you should select select System|Configuration|KoKoMate|Data connection... , then Manual, then None to free the serial port for other programs to use.**

## 2.8 ENTER THE FACILITY / LOCATION NAME

After installing KoKo PFT, you will be asked to enter a facility and location name to appear on your reports. Refer to System|Preferences to change this entry at a later time.

## 2.9 ENTER THE ID / LIN NUMBER (#)

Once you have opened the PFT File, you must enter the identification/linearization # of the pneumotach into the software. This # contains all of the pneumotach linearization and calibration information particular to your individual pneumotach. For this process you will need the pneumotach ID/Lin# printed on the documents that accompanied the software.

1. From the PFT Master Menu, click on System|Calibrate.
2. If you are entering pneumotach information for the first time, the "Add Pneumotach" dialog appears automatically.
  - ◆ Enter a description. We recommend the pneumotach serial number. (Depending upon your software and hardware version, the serial number may be recognized automatically).
  - ◆ Enter the ID/Lin# for the pneumotach **exactly** as it appears on the accompanying document. The ID # has 43 alphabetic and numeric characters, with dashes separating the groups. If incorrectly entered, the # may not be accepted. **Depending on your spirometer, you may need to enter an additional four digit code to activate the linearization.** If so, this code will be provided to you by PDS.
3. Click on OK to finish. You should now complete a calibration. See Chapter 6 for instructions.

## 2.10 QUICK GUIDE

Here is the typical sequence of tasks for performing an FVC test and reporting the results:

1. Calibrate the pneumotach.



2. Select the FVC test.



3. Enter a new patient, or create a new test series for a returning patient.



4. Start the FVC test.



5. Save the test, open a Read/Interpret /Print window.



6. Interpret the results (optional).



7. Print the results (optional).



## 2.11 SOFTWARE FEATURES

### 2.11.1 HELP FILE

The Help File is always available to provide information about a particular topic. To access, click on the icon or select Alt+H or F4 (if function keys are activated). Choose **How To** in order to see a list of topics.



### 2.11.2 RESETTING THE SYSTEM

Occasionally it is necessary to reset the system after it is already turned on. To reset the system, simultaneously press Ctrl, Alt, Del, or turn the computer off, wait 15 seconds and turn it back on. If “rebooting” in this manner, please wait for Windows to complete any self-scanning processes and when the KoKo-PFT is restarted you will get a warning message regarding turning the computer off without first exiting the KoKo-PFT software.

### 2.11.3 BACKING UP YOUR WORK

Periodically, when you exit the KoKo PFT system, a question will appear asking if you would like to backup the KoKo PFT data. We recommend that you take this opportunity to create a backup. The process creates a “local” copy of all data that can be quickly restored in case the database becomes corrupted. (The backup files are located on your hard drive at Program Files\KoKo PFT System\Ptdata\\*.bot, \*.bs1, \*.bs2, \*.bs9 and \*.bxn).

Files can also be backed up onto removable media, such as Zip disks or CD-R/RW, by copying all files from the destination folder chosen for the KoKo PFT system during installation.

### 2.11.4 SYSTEM DATE FORMATS

PDS recommends that you designate a date format in your Windows operating system that requires 4 digit years.

To change the date and time format, open the Control Panel (either from the "My Computer" icon on the desktop, or from the Start menu "Settings" item), then double-click on the "Regional Settings" icon. Make adjustments to the date and/or time formats using the tabs of the same name. The PFT System will respond by updating open report windows when you close this dialog box.

### 2.11.5 SELECTING OPTIONS FROM MENUS

The KoKo Windows program offers standard Windows menus. There are several ways to make selections:

1. Use the mouse and left click on the menu or selection desired.
2. Use the function key or the “Cntrl + letter” expression listed beside the items to make your selection.
3. If a menu heading has an underlined letter, hold the Alt key + underlined letter to make the selection. If a menu option has an underlined letter, press the letter to make the selection.
4. Sometimes you will be able to use the tab key or arrow keys to highlight an item and then you can select the highlighted item by pressing the “Enter” key.

### 2.11.6 ADJUSTING WINDOWS



Use your mouse to close the window.



Use your mouse to minimize the window.



Use your mouse to maximize the window.

### 2.11.7 USEFUL KEYS

The tab key allows you to move around in Windows. For example, in the patient entry screen, use the tab key to move from field to field.

The space bar starts tests when you are in a testing screen. Instead of clicking on the green button icon, simply press the space bar. The space bar also allows you to step through the calibration prompts and start a calibration.

Menu key accelerators are available for your convenience. The default condition is the Ctrl-key or combination. To activate the F keys, select *System|Preferences|F-key Menu Accelerator*.

<b>Ctrl key combination</b>	<b>Function</b>	<b>F-key equivalent</b>
-----------------------------	-----------------	-------------------------

**(Main window)**

*File:*

Ctrl+T	Patient information	F2
Alt+F4	Exit	F9

*Test:*

Ctrl+F	FVC Test	F3
Ctrl+V	SVC Test	F11
Ctrl+M	MVV Test	F12
Ctrl+C	Challenge	

*Report:*

Ctrl+R	Read/Interpret/Print	
Ctrl+P	Print multiple...	
Ctrl+D	Design	

*System:*

Ctrl+B	Calibrate
Ctrl+L	Calibration log

**(Testing)**

*File:*

Ctrl+T	Select patient and test series	F2
Ctrl+S	Save efforts	F5
Ctrl+P	Display/interpret/print results	F6
Alt+F4	Exit	F9

*Test:*

Ctrl+E	Start effort	F4 (or SPACE BAR)
Ctrl+C	Cancel effort	
Ctrl+F	FVC Test	F3
Ctrl+V	SVC Test	F11
Ctrl+M	MVV Test	F12

*Stage:*

Ctrl+G	Next stage
Ctrl+D	Administer dosage
Ctrl+C	Cancel dosage
Ctrl+W	Edit worksheet

*Effort:*

Ctrl+B	Best effort
Del	Drop effort

*Mode:*

Ctrl+R	Post-Bronchodilator	F7
Ctrl+I	Incentive	

*Setup:*

Ctrl+O	Ptach Environment	
Ctrl+N	Test Information	F8

**(Report)**

*File:*

Ctrl+T	Select patient and test series	
Ctrl+D	Select design	
Ctrl+I	Interpret	
Ctrl+R	Mark as reviewed	
Ctrl+P	Print	F6

*View:*

Ctrl+E	Reduced
Ctrl+A	Actual

**(Design)**

*File:*

Ctrl+O	Open
Ctrl+S	Save
Ctrl+P	Print

*Edit:*

Ctrl+U	Attributes
Ctrl+X	Cut
Ctrl+C	Copy
Ctrl+V	Paste
Del	Delete
Ctrl+L	Select all
Ctrl+N	Select none
Ctrl+F	Bring to front
Ctrl +	Move forward
Ctrl -	Move backward
Ctrl+B	Send to back

*Mode:*

Ctrl+M	Select
Ctrl+D	Draw

*View:*

Ctrl+W	Preview
Ctrl+E	Reduced size
Ctrl+A	Actual size
Ctrl+Z	Zoom in
PgDn	Next page
PgUp	Previous page

*Add:*

Ctrl+P	Pt/Series/Protocol info
Ctrl+N	Numeric result
Ctrl+G	Add graphic result

*Style:*

Alt+T	Font
-------	------



# KOKO PFT SOFTWARE

## CHAPTER 3 FILE

To perform database functions, select the word `File` on the PFT Main Menu or type `Alt, F`.

### 3.1 PATIENT INFORMATION

Enter the Patient Information database by selecting `File|Patient Information`. The database allows you to enter new patient information, edit, recall or update existing patient information, establish or delete test groups, and obtain lists of patients arranged either by name, identification #, test date, test type, test group or various test series statuses. **You may also perform the same functions under the testing or reporting screens.**



There are two patient dialogs available for your use. The Basic patient dialog automatically appears upon installation. This dialog should be sufficient for most of your needs. However, if you need to complete functions such as delete a patient or test series, or view a specific test series, the Advanced patient dialog will simplify those tasks. To activate the Advanced dialog, select `System | Preferences` from the Main Menu, and click on `Basic dialogs` to uncheck it. You can return to using Basic dialogs by clicking on it again to check it.

#### 3.1.1 NEW PATIENT

To enter a new patient, select “Entering a new patient” (Basic dialog) or click on `New` (Advanced dialog) on the “Enter/Edit Patient Information” dialog. Selecting this option allows you to enter patient information for the first time, and causes the subsequent test results to be saved under this patient's name.

On the patient information screen, enter the appropriate information in each of the boxes. The following items are required: *Last name, First name, ID, Date of Birth, Sex, Height*.

**Note:** Date of birth must be entered as a four digit year. It is not necessary to enter slashes (“/”) or dashes (“-”). Simply enter the date as a number string (12151954 = Dec. 15, 1954; 04031958 = April 3, 1958) and press the `Tab` key or click in the next mouse field.

The screenshot shows the "Enter Patient Information" dialog box with the following data entered:

- Last name: KoKo
- First name: Demo
- ID: 123456789
- DOB: 9/3/1991
- Sex: Male (selected)
- Height: 36 in (selected)
- Weight: (empty)
- Smoking history: (empty)
- Predicteds: Crapo 1981, Polgar (P) (selected)
- Ethnic group: Other (selected), American Indian (selected)
- Ethnic correction: (empty)
- Diagnosis: Healthy (selected)
- Group: PDSI (selected)
- Comments: (empty)

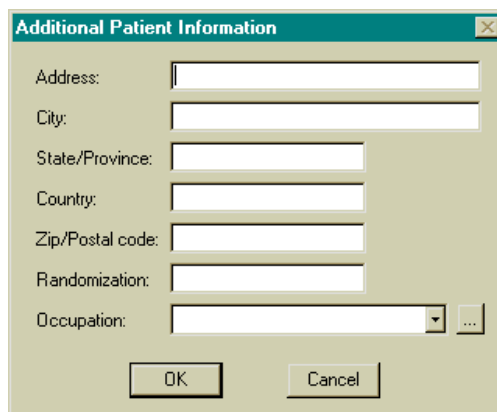
You may designate the following information:

- ◆ A set of predicted values for the patient. The default is Crapo, Polgar.
- ◆ An ethnic group and correction factor. Select either one of the standard groups, *Caucasian*, *African-American*, *Mexican-American*, or select *Other* and enter a different group. If you would like a correction factor to be used, enter that in the appropriate field. Each group entry with its associated correction factor, if applicable, will be saved in a list and can be accessed by the dropdown bar.

**Note: The Hankinson (NHANES III Study) predicted values use a separate set of equations for the Caucasian, African-American and Mexican-American races. Any correction factor entered with these races will be overridden when Hankinson predicted values are used. A correction factor can be added for Other ethnic groups. This will use the equations for Caucasians and reduce the values by the entered percentage.**

- ◆ A diagnosis. Each diagnosis entered will be saved in a list and can be accessed by the dropdown bar. The list has a convenient maintenance capability that allows items to be added, edited or deleted by clicking on the box to the right of the field.
- ◆ A group. Each group entered will be saved in a list and can be accessed by the dropdown bar. The list has a convenient maintenance capability that allows items to be added, edited or deleted by clicking on the box to the right of the field.
- ◆ Comments pertaining to the patient.
- ◆ More. Additional information, including patient address, randomization and occupation, can be added.

Click **OK** when you are done. The system will automatically save the information and create the first test series for this patient.



The screenshot shows a dialog box titled "Additional Patient Information". It contains the following fields:

- Address: [text input]
- City: [text input]
- State/Province: [text input]
- Country: [text input]
- Zip/Postal code: [text input]
- Randomization: [text input]
- Occupation: [dropdown menu with a small box containing three dots]

At the bottom of the dialog are "OK" and "Cancel" buttons.

### 3.1.2 RECALL PATIENT / TEST SERIES

To recall a patient and test series:

- In Basic dialog, you must enter the test screen to recall a patient. Select `File|Select patient & test series` from the test screen. Choose "Recalling a previously entered patient", and click `Next`. Choose to search by either last name or identification number and click on `Next`. Enter the patient information and click `Next`. Highlight the patient and click `Next`. Choose "Select an existing test series" and click `Next`. Highlight the desired test series and click `Next` then `Finish`.
- In Advanced dialog, use the search options to locate the patient. For example, choose to search by "last name" and "starts with" to search for a last name by the starting letter. Type the letter that the name starts with in the white box and click on `Show all matches`.

### 3.1.3 EDIT PATIENT

To change or update any patient information, except for the identification #:

- In Basic dialog, select “Editing previously-entered patient information” and click on **Next**. Choose to search by either last name or identification number, click on **Next**. Enter the patient information and click on **Next**. Highlight the desired selection and click **Next**. Edit the patient information as needed and click **Ok** then **Finish**.
- In Advanced dialog, locate and highlight the desired patient as described in 3.1.2. Once the desired patient is highlighted, click on **Edit** at the bottom of the dialog. Update the information and click on **OK**.

See 3.1.1 NEW PATIENT for a description of the fields in the patient entry screen.

### 3.1.4 NEW TEST SERIES

To create a new test series for an existing patient:

- In Basic dialog, follow the instructions in 3.1.2 and then instead of choosing to select an existing test series, choose “Creating a new test series”. Click on **Next** then **Finish**.
- In Advanced dialog, locate and highlight the desired patient as described in 3.1.2. Click on **New** under the “Test Series” heading at the bottom of the "Enter/Edit Patient Information" dialog. A new test series is automatically generated.

### 3.1.5 EDIT TEST SERIES

To edit a test series, you must be using the Advanced dialogs.

To add further information to a test series such as medications, work shift, exposures and exercise levels, click on **Edit** under the "Test Series" heading at the bottom of the "Enter/Edit Patient Information" dialog. This is also the best way to update the height and weight of an existing patient at the time of a new test session.

### 3.1.6 DELETE TEST SERIES

To delete a test series, you must be using the Advanced dialogs. Locate and highlight the desired test series as described in 3.1.2. Click on **Delete** under the "Test Series" heading at the bottom of the "Enter/Edit Patient Information" dialog. A window will appear asking, "Are you sure you want to delete the selected test series?" Click on **Yes**.

Multiple tests can be deleted by choosing **File|Delete test series**. Simply search for the patients and test series you would like to delete, highlight the specific tests and choose **Delete**.

## 3.2 IMPORT/EXPORT

Perform import and export functions by selecting **File|Import/Export**.

### 3.2.1 IMPORT DOS KOKO TESTS

If the DOS-KoKo is not on the same computer as the new KoKo PFT for Windows, you must first transport the DOS-KoKo files to the computer with the Windows-KoKo software installed.

1. Use a computer-to-computer file transfer program with a serial port cable, or
2. Save the DOS files onto removable disks (preferable high-capacity disks such as "Zip" disks)
3. Move the files from each A-Z directory in the \KoKo directories on the DOS-KoKo system, to the same directories on the new system.

**Note: The system can be set to import only patient demographics form KoKo-DOS. This setting is described in the Help system, but should be modified only under the direction of your representative or the PDS Technical Support department.**

Once all DOS-KoKo files are on the same system as the KoKo PFT for Windows program, select File|Import/Export|Import all DOS-KoKo tests. All existing data will be transferred to the new PFT System. Importing all results is a one-time process only. Any new results added after this in the DOS-KoKo program can be added to the Windows version by selecting Import New DOS-KoKo Tests.

**Note: If an effort does not include an FEV1 value, that effort will not be imported.**

### 3.2.2 IMPORT TESTS FROM OTHER SYSTEMS

#### *MSSX Tests*

This function allows the import of patient data and test data from the MultiSpiro-SX spirometer. It will import the three best FVC tests without graphics into the KoKo-PFT database. It requires that the user first run the Export to ASCII function in the MultiSpiro-SX software. This creates a file in the C:\SX directory called SXEXPORT.TXT. It is this file that the KoKo-PFT software looks for in the C:\SX directory. If the file is present, it will import into the KoKo-PFT database. The MultiSPIRO-SX does not include patient last name or first name in its export file. As a result, when the data is imported, it uses "Unknown, Unknown" as the patient name. The user can search by ID number in the KoKo-PFT and then edit the name field with the proper name, if desired.

**Note: It is necessary for the MultiSpiro to have ID numbers present in order to allow a successful import into the KoKo-PFT database.**

#### *OHM Patients*

This function allows the import of patient demographic data from the Occupational Health Manager (OHM) software designed by Unique Software Solutions, Inc. The purpose of this import function is to eliminate the need for double entry of patient demographics in these two databases located on the same computer (or network). The KoKo-PFT will (by default) look in the directory C:\Program Files\KoKo PFT System for a file called OHM\_PTS.TXT. If the file is present, it will import the records into the KoKo-PFT database. These records consist of basic patient demographics only, no test data. It is possible to change the location and name of this file by editing the following line in the [Database] section of the KOKOPFT.INI file (located in C:\Program Files\KoKo PFT System\BIN directory):

ImportOHMFile=<filename.ext>

Add this item to specify the name of the file that contains the OHM patient information to be imported. The default is OHM\_PTS.TXT.

ImportOHMDirectory=<path>

Add this item to specify the path to the file that contains the OHM patient information to be imported. The default is C:\Program Files\KoKo PFT System.

### ***Rosetta Patients***

This function allows the import of patient demographic data from the Rosetta Medical Records software from NextGen, Inc. The purpose of this import function is to eliminate the need for double entry of patient demographics in these two databases located on the same computer (or network). The KoKo-PFT will (by default) look in the directory C:\Program Files\KoKo PFT System for a file called NGR\_PTS.TXT. If the file is present, it will import the records into the KoKo-PFT database. Once the records are imported, the patient will have to be edited to add Height, which is not included in Rosetta's record, but is required by the KoKo-PFT to be able to calculate predicted values. These records consist of basic patient demographics only, no test data. It is possible to change the location and name of this file by editing the following line in the [Database] section of the KOKOPFT.INI file (located in . C:\Program Files\KoKo PFT System\BIN directory):

ImportNGRFile=<filename.ext>

Add this item to specify the name of the file that contains the NextGen/Rosetta patient information to be imported. The default is NGR\_PTS.TXT.

ImportNGRDirectory=<path>

Add this item to specify the path to the file that contains the NextGen/Rosetta patient information to be imported. The default is C:\Program Files\KoKo PFT System.

**Note: The NextGen/Rosetta patient file does not contain patient height data, which must be entered manually before predicted values can be calculated.**

## **3.2.3 EXPORT**

Test information can be exported to a database such as Microsoft Access by selecting File|Import/Export|Export Test Series. From the "Export Test Series" dialog, you can select the series you would like to export, or you can click on *Select All*, and all test series will be exported. Click on "Log" to print the list of test series to be exported.

See the Help system for more detailed information and instructions.

## **3.3 COMMUNICATION**

### **3.3.1 RECEIVE TEST SERIES**

If you have the multi-user version installed, use this function to receive tests from the master database.

### **3.3.2 TRANSMIT TEST SERIES**

If you have the multi-user version installed, use this function to transmit tests to the master database.

### 3.3.3 READ TEST SERIES

Use this function to transfer individual patient files from external media, such as a floppy disk or a zip disk, to the KoKo PFT program.

### 3.3.4 WRITE TEST SERIES

Use this function to transfer patient files from the KoKo PFT program to external media, such as a floppy disk or a zip disk.

## 3.4 DATABASE

By selecting `File|Database` in the Main Menu, you can backup, compress or restore your data. If you have the Multi-User version and have been designated as a system Administrator, you can also complete administration functions from this location.

### 3.4.1 BACKUP

To protect your patient data from loss, select `Database|Backup`. This makes a local copy of all patient and test data that you can quickly restore in case the database becomes corrupted. It is also recommended to frequently save all patient and test data to a removable medium.

Backup is especially important for users of the Multi-User version, as the quantity of data is often greater. Local backup can be performed as indicated above by any workstation that has exclusive database access. Backup to removable storage should be performed by the system administrator.

### 3.4.2 COMPRESS

If your database is taking up too much hard drive space, you can compress it, using `Database|Compress database`.

**Note: Before you start compression, make a database backup.**

### 3.4.3 RESTORE

In the unlikely event that your hard drive crashes or your database becomes corrupted, you will need to restore your backed up files to your replacement system.

For a total hard drive failure, once the drive is replaced or repaired, restore the backed up information.

If your database has become corrupted, select `Database|Restore database`, and the database will be restored from the local copy on the hard drive.

### 3.4.4 ADMINISTRATION

The Administration function is only available to the designated system administrator for the Multi-User version.

#### *Delete Test Series*

If the database size becomes larger than desired, you may delete selected test series, then compress the database to recover free disk space.

The procedure is:

- Arrange for a time when no workstations will be accessing the database (night, weekend)
- Make sure all users are logged of (i.e.: the KoKo program is closed at all connected workstations)
- If the size of the database, backup, and transaction log files added together are more than one-third of free disk space: Backup the database locally using File|Database|Backup database to empty the transaction log
- Delete test series (usually older test series, selected by specifying date range) by selecting File|Database|Administrator|Delete test series
- Compress the database using File|Database|Compress database
- Backup the database locally to empty the transaction log one more time
- Allow users to log on

### ***Show Current Users***

At any time, the system administrator may see which workstations are currently connected to the database.

To do this, select File|Database|Administrator|Show current users.

If users are shown who are known to not be currently running the PFT System, the administrator should force a log-off of the user(s) with Log off other users.

### ***Log off Other Users***

Occasionally, the system administrator may need to "log off" from the database, workstations which have terminated abnormally, but are still "connected to the database" due to the absence of the (automatic) log-off at normal program exit.

This condition would occur if all users (except the administrator) were known to not be running the KoKo PFT System, but a message to the effect "exclusive access required" persists when selecting a certain function.

Select File|Database|Administrator|Log off other users. This should only be done when all other users are known to not be running the PFT System, since serious errors will occur if any other users are still connected.

### ***Unlock the Current Patient***

In the event of an abnormal termination of the KoKo PFT program (due to network/server crash, workstation reboot, task termination, cabling problem, etc.), the current patient for that workstation may remain "locked", and unable to be accessed by other workstations.

To correct this, the system administrator should:

1. Make sure all other workstations are logged off
2. Make sure "basic dialogs" are not in use (System|Preferences|Basic dialogs)
3. Select the locked patient, using File|Patient information
4. Select File|Database|Administrator|Unlock current patient.

### ***Unlock all Patients***

When several patients are locked, this selection can be made to unlock all at the same time. Follow the instructions indicated for the `Unlock Current Patient` function.

### ***Rebuild Database Keys***

This function provides for database rebuilding if a data corruption has occurred.

### ***Listen on TCP/IP Port***

**Only available to users of the Server version.** This selection serves as a manual method of returning to the server mode when a user has exited to the standard KoKo program.

# CHAPTER 4 TESTS

To begin a test, click on the appropriate icon or select the word `Tests` on the PFT Main Menu or type `Alt T`.

## 4.1 FVC TEST

This test directly measures inspiratory and expiratory flows and volumes. Select the FVC test option by selecting `Tests | FVC`.



### 4.1.1 PATIENT SELECTION

By default, the KoKo PFT system will open the last active patient and test series, if that test series was created within the last day. If you wish to add to the current test series, simply confirm and proceed to testing.



If the last active test series was created more than one day ago, a dialog will appear providing the option to continue with the current test series or select a different patient or test series. If you wish to select a different patient, add a new patient, or edit a patient, you may do so within the testing screen by following the instructions in 3.1.

### 4.1.2 TEST PREPARATION

#### *Incentive Screen:*

Turn on the incentive screen option, if desired, by selecting `Mode | Incentive` in the FVC window. (To turn the incentive off, click `Incentive` a second time.)

The KoKo FVC test includes four incentive screens: Candles, Kite, 3 Pigs and Wall. The graphic effect is proportional to the percentage of normal FVC that the patient attains.

You can change the incentive screen selection by clicking `Setup | Incentive`. Use the arrow keys to select the desired screen. Click on `OK`.



#### *Post/Rx:*

Choose the Post/Rx designation if desired by selecting `Mode | PostRx`. When new patient information is entered, the tests are automatically designated pre-bronchodilator. Changing the test designation to post-bronchodilator will change the designation of all subsequent efforts in the test group to post-bronchodilator.




To display the best pre-bronchodilator results in the post-bronchodilator screen, select `View | Pre-Rx effort` so that this option is checked. To display the predicted values, uncheck the option.

To enter the type of bronchodilator used, select `Setup | Test Information`. In Post-Rx there is an extra line for the bronchodilator name.


To return to pre-bronchodilator, select `Mode | PreRx`.

## View

Choose the following options under `View` in order to customize the screen display.

- **Scale:** Choose a different scale for the graph, if desired, by clicking on `View`, then the desired scale 8L, 4L, or 2L. 
- **Numeric Results:** Highlight the results that should show on the screen. Note that all possible results will be available for display on reports even if all are not selected to show on the screen.
- **Reference Effort:** Check this option to show the best historical effort (FVC+FEV1) for the specified patient. The Reference Effort data will be shown in the leftmost column. The graphs of Reference Efforts will be displayed in a light green color.
- **Tidal Phase:** Check this option to show the graphic tidal phase on the screen.
- **Best 3 Efforts Only:** Check this option to show only the best 3 efforts on the screen. Uncheck the option to show the number of efforts selected to be retained in the protocol. Note that if this option is selected, the number of efforts retained and available to display on reports is not affected.
- **All Efforts:** Select this option to show all efforts. Note that this selection has no affect on the number of efforts retained.

## ***Pneumotach Setup Information:***

Verify, and change if necessary, the pneumotach setup information, including room temperature,  barometric pressure and current relative humidity, by selecting `Setup|Pneumotach|Environment`. Enter any data changes then click `OK`.

If more than one pneumotach is entered on the system you must select the one that you will be using by selecting `Setup|Pneumotach|Selection`. Choose the desired pneumotach then click `OK`.

## ***Protocol:***

Choose the desired protocol for the tidal and end expiratory phases of the test by selecting `Setup|Effort Protocol`. Click on `OK` when finished.

### 1. Tidal

- ◆ Auto - Four tidal breaths must be performed before the test begins (default)
- ◆ Manual - Prompt for tidal breaths will appear, however, they may be skipped by pressing “Enter”
- ◆ Skip - No prompt will appear for tidal breaths

### 2. End Expiratory

- ◆ ATS 1987 – The test is terminated after the volume accumulation drops below .040L in two seconds
- ◆ Manual – The test is ended by pressing the space bar
- ◆ ATS 1994– The test is terminated after the volume accumulation drops below .030L in one second (default)

### 3. Quality Check

The **quality checks** performed (and the corresponding **codes**) are:

- **Start of expiration (code: S):** If extrapolated volume as a percent of FVC ( $V_{ext}\%$ ) is greater than 5.0, there may be a problem with the patient hesitating at the start of the expiratory effort.
- **Cough (code: C):** If there is a flow transient of greater than 10% of peak flow (measured peak-to-valley) in the first second of expiration, the patient may have coughed.
- **Expiratory Time (code: T):** If expiratory time is less than 6 seconds, the patient may not be exhaling completely.
- **End of expiration (code: E):** If the volume accumulated in the last 2 seconds of expiration is greater than 30 cc (ATS protocol) or 40 cc (Auto protocol), or if expiratory flow drops from 1.0 L/sec to zero in less than 0.2 seconds, the patient may have come off of the mouthpiece too soon, not given a full effort, or had a glottis closure.
- **No Inspiration (code: I):** If no inspiration is performed, the reliability of the end-of-test volume ( $V_{ext}\%$ ) is suspect, since in a well-performed maneuver it cannot be determined if and when the patient actually came off of the mouthpiece (since there is zero flow in each case).


### 4. Variability Check

The variability checks consist of testing whether an effort's FVC, FEV1, or PEFV variation from the best effort exceeds -0.200L, -0.200L, and -15%, respectively.


### 5. Maximum # of efforts

The maximum # of efforts value is the number of efforts that are kept from all efforts performed. Any efforts performed after this maximum number is reached are ranked with existing efforts, and the new "worst effort" is discarded.

#### ***Predicted Equation Set:***

Choose the desired predicted equation set by selecting `Setup|Predicteds`. Use the arrow  key to select the desired equation set (refer to the Help File - Normal Equations). Click `OK`. The predicted set for a particular patient will be displayed on the screen numerically and graphically. If ITS is chosen, the graphic display on the spirogram (Volume/Time graph) will be in the form of a confidence range. The upper border of this range is "Normal", while the lower border is the "Lower limit of normal." On a report, measured results outside of the confidence range are flagged, either in the form of magenta print or an asterisk.

#### ***Test Information:***

Enter or edit the test information, including the physician's name, technician's name, test site, patient position and comments for the test by selecting `Setup|Test Information`. 

The physician, technician, test site and comment entries will be saved in a list and can be accessed by the dropdown bar. The list has a convenient maintenance capability that allow items to be added, edited or deleted by clicking on the box to the right of the field.

Enter or edit the information, then click `OK`.

**Note: The test site for Multi-User version systems is automatically recorded as the individual work station i.d.#.**

### 4.1.3 TEST EFFORT

During the test effort, pediatric patients should be standing, while adult patients may be seated or standing. Place nose clips on the patient's nose.

#### *Start Effort*

To begin an effort,



- ◆ click on Test|Start Effort, or
- ◆ click on the green circle icon, or
- ◆ press F4, if the function keys are activated, or
- ◆ press the space bar.

(If this is the first test since turning on the system, you will need to verify the environmental conditions.) To stop an effort at any time, click on Test|Cancel Effort or the red circle icon.

Occlude the pneumotach opening so that there is no flow.

#### *Tidal / Inspiratory Phase:*

If the protocol includes "auto tidal", the patient must perform four breaths.

If the protocol for tidal is manual, the patient may perform tidal breaths or they can be skipped by pressing "Enter."

If the protocol skips tidal breathing, the patient performs an inspiration (with or without the mouthpiece) to begin the effort.

**NOTE: If the effort does not begin within one and a half minutes from the prompt, a "problem" message will appear and the pneumotach will need to be re-zeroed.**

#### *Expiratory / Inspiratory Phase:*

For the auto and ATS end-expiratory protocol, the patient exhales until prompted to inhale.

For the manual end-expiratory protocol, the patient exhales as much as possible and the technician presses the space bar to end.

### 4.1.4 EVALUATE EFFORT

Following the completion of the effort, a screen appears with the test results, and asks if you want to keep this effort. The screen may also contain cautions explaining a potential problem with the effort. If a caution appears, coach the patient for better effort. If you do not think the patient will be able to produce better results, be sure to retain each effort performed.

Click on Yes or No to keep or drop the effort. If you elect to keep the effort, the results, compared to the predicted, are shown at the bottom of the screen. As you complete and save more efforts, the results of the three best are displayed. The best of the three is displayed in the far left column, labeled "Best." The best effort is determined by the sum of FVC and FEV<sub>1</sub>. Additional effort results are displayed in the columns to the right of

the best and labeled "Cons" or "Incn" (consistent or inconsistent) depending upon whether the FVC and FEV<sub>1</sub> for those efforts are within 5% of the best results.

### Quality Cautions

After an effort is performed, you may see some **effort quality** statements. If the effort is retained, the quality statements for each effort are saved as letter codes visible in the numeric results pane during testing (and available for reports). See the protocol section in 4.1.2 above for a description of the quality checks.

	Pred	Best %Prd	Cons %Prd	Incn %Prd
		#6	#4	#5
FVC (L)	4.44	4.40 99%	4.24 95%	4.02 90%
FEV1 (L)	3.72	3.57 96%	3.65 98%	2.89 78%
FEV1/FVC	0.83	0.81 97%	0.86 103%	0.72 86%
PEFR (L/s)	8.67	9.28 107%	9.14 105%	7.97 92%
FEF25-75% (L/s)	4.06	3.42 84%	3.30 81%	2.16 53%
Quality cautions: T S,C,T,E,I S,C,T,E				
(Key: C=Cough, E=End exp, I=No insp, S=Start exp, I=Exp time)				

### Variability Cautions

After the effort is retained, **effort variability** for efforts other than the best (outlined in red below) is also shown in the numeric results pane. See the protocol section in 4.1.2 above for a description.

Variability cautions: F,P,U  
 (Key: P=PEFR var>15%, F=FEV1 var>0.2L, U=FVC var>0.2L)

### 4.1.5 CHANGE EFFORT

You may change the **best effort** selection, if desired, by selecting **Effort|Best Effort**.  
 Select a new best effort and click OK.



You may **drop an effort** completely, if desired, by clicking **Effort|Drop Effort**. Select the effort(s) to drop and click OK.



### 4.1.6 SAVE EFFORTS

Save the efforts by clicking **File|Save Efforts**. If you choose to exit the FVC window before you have saved the efforts, a window will appear asking if you wish to save the modified test.



## 4.2 SVC TEST

Slow Vital Capacity test results provide vital capacity, expiratory reserve volume, and inspiratory capacity results by sampling tidal breathing, establishing a resting expiratory level, then measuring slow vital capacity.



Select the SVC test option by selecting **Test|SVC**. As most of the options and features for SVC testing are similar to those for FVC testing, please refer to 4.1 for general test instructions.

## 4.2.1 PATIENT SELECTION

See 4.1.1.

## 4.2.2 TEST PREPARATION

The default protocol for the SVC test mode requires four stable tidal breaths prior to performing the maximal inspiratory/expiratory maneuver. You have the option, however, to change the effort protocol to not require stable tidal breathing and to allow the maximal inspiratory/expiratory maneuvers to be completed in any order.

Select Setup|Effort Protocol from the SVC test screen. Place a checkmark in the box that appears and click OK.

**Note: No IC or ERV values will be calculated when using this mode.**

## 4.2.3 TEST EFFORT

### *Start Effort*

See 4.1.3

### *Complete Manuever*

At the prompt, the patient should begin relaxed tidal breathing. The breathing is monitored on the display.

If the protocol requires stable breathing, the patient will need to complete four stable breaths before being prompted to begin the slow, maximal inspiration. Press the space bar to indicate the start of the maximal inspiration. After completing the inspiration, the patient should complete the slow maximal expiration and then return to relaxed tidal breathing.

If the protocol does not require stable tidal breathing, the patient will be prompted to perform the maximal inspiration and expiration in any order. Press the space bar when the test is complete.

## 4.3 MVV TEST

The Maximum Voluntary Ventilation test calculates the maximum volume expired by maximum voluntary effort in a 3 to 15 second interval. Tidal volume excursions are shown on the small flow / volume axis. Accumulated excursions are shown to the right.



Select the MVV test option by selecting Test|MVV. As most of the options and features for MVV testing are similar to those for FVC testing, please refer to 4.1 for general test instructions.

### 4.3.1 TEST EFFORT

#### *Preparation*

When prompted, instruct the patient to breathe as rapidly and deeply as possible into the mouthpiece. Press the space bar when the patient is inhaling and exhaling satisfactorily. The breathing is monitored on the volume/time graph.

### *Maximum Ventilation*

The patient breathes rapidly and forcefully into the mouthpiece to obtain the MVV measurement. The breathing must continue for at least four seconds (as displayed on the screen) for a result to be calculated. After 15 seconds of the maneuver, or as much as the patient can complete, press the Space bar and remove the patient from the mouthpiece.

## **4.4 CHALLENGE TEST (INSTRUCTIONS FOR USE OF THE KOKO DIGIDOSER.)**

Challenge testing is used to determine a patient's response to a broncho-provocation agent, using increasing dosages of the agent, followed by an FVC effort to document the response at successive stages.



Select the Challenge test option by selecting `Tests | Challenge`.

### **4.4.1 GENERAL INFORMATION**

The KoKo Digi is shipped with a standard breath unit protocol (Rosenthal) preset. Using this protocol, the concentration of challenge agent is varied at each "stage." In this way, the cumulative dosage is increased until the patient shows a 20% and then a 35% decrease in FEV<sub>1</sub>. You may choose to design and use other challenge protocols for your specific application.

Up to 26 stages of testing can be performed and saved using one protocol. Stages include: baseline, control-saline, 23 test stages and a recovery effort. The results of up to three efforts can be viewed at each stage, with a best effort automatically or manually selected. Numeric and graphic results for the best effort are saved and a notation is made regarding the consistency of the effort.

You may leave the testing sequence at any time and save test results. Upon re-entering the test, you will automatically be returned to the next stage. This makes it possible to leave the testing sequence, have another patient perform a spirometry or challenge test and then return to continue the original challenge test.

**NOTE: Never use the KoKo DigiDoser to administer emergency bronchodilator.**

### **4.4.2 PATIENT SELECTION**

Refer to 4.1.1 for instructions.

### **4.4.3 TEST PREPARATION**

Refer to the instructions in 1.3-1.5 for assembly of the Challenge testing equipment, and to the instructions in 4.1 for information on test preparation.

#### ***Dosage Protocol:***

Edit or create a protocol for your challenge test sequence by selecting `Setup | Dosage Protocol`. Click on `Select` to choose a protocol. Click on `Edit` to view the protocol requirements and change them, if desired. Click on `Create` to design your own protocol.

For your convenience, the Rosenthal and Cockcroft protocols have been pre-entered as protocol selections. Using the Rosenthal protocol, the patient inhales a varying concentration of aerosolized agent. PDSI recommends the use of the Rosenthal New Standard Dosimeter, or the KoKo DigiDoser with the Rosenthal protocol.


To create a protocol, enter or change the following:

- Protocol Name
- Challenge agent
- Decision points #1 and #2 - expressed as a percent decrease from the selected baseline FEV<sub>1</sub>. This point is shown as a dotted line on the trend graph in reports. Click on the entry boxes to change the %s.
- Timers - establishes a time limit in minutes for the time lapsed between administration and test and for the time lapsed between one stage and the next stage. The time limit must be in positive integers, no decimals. Click on the entry boxes to enter the time.
- Stages - You may choose to designate the base, saline and recovery stages as either required, optional, or skipped. Click on the arrow at the side of each entry box and then highlight the desired designation.
- Efforts - You can define several features of the FVC efforts. Consistency between FVC efforts in a stage can be required, optional or skipped, by clicking on the arrow. The ranking of effort results can be based on the FVC value, the FEV<sub>1</sub> value or the Sum of both, by clicking on the arrow. The percent of consistency required for efforts to be labeled consistent can be changed by clicking on the entry box.
- Dosages - You can choose between two dosage stages to determine how to measure the number of administrations: *Breaths* or *Seconds*. If you choose the *Breaths* stage, you must then indicate the number of administration breaths required at each stage. If you choose the *Seconds* stage, you must then indicate the number of seconds the repeat administrations need to continue for each stage. Also indicate the concentrations of aerosolized agent in mg/ml for each stage.

Click on each of the entry windows and type in the desired numbers for as many stages as you wish. Note that the concentration numbers must always be increasing.

- Nebulizer - You should specify the nebulizer output in ml/min.
- DigiDoser - You can specify criteria for the DigiDoser's administrations, including the amount of agent released in Liters, the duration of the dose, and the target amount in Liters per second.

#### 4.4.4 WORKSHEET

A Challenge Test worksheet designed for recording dosage information, heart rate, blood pressure, and comments is accessible at any time during testing. The worksheet also shows the dosage protocol and the best results for each stage of testing. You may use the worksheet to change protocol for the current test. To view the worksheet, select `Stage|Edit worksheet`. 

The information for stages already performed is shown on the worksheet. Data regarding the blood pressure, heart rate and comments may be entered in the windows beside each stage. The dosage units, the best FEV<sub>1</sub>, and the % change from the reference is displayed beside each stage. You can specify the reference stage to be either the base or the saline stage, by clicking on the arrow beside the reference stage entry box. You can also change the specified Nebulizer output.

The results box at the bottom of the worksheet shows the following values:

- PD-20 du = Cumulative dosage units which causes a 20% fall in FEV<sub>1</sub>.
- PD-20 mg = Cumulative dose in mg which causes a 20% fall in FEV<sub>1</sub>.
- PC-20 mg/ml = Concentration being delivered when a 20% fall in FEV<sub>1</sub> occurs.
- PC-20 mg = Dose in mg being delivered when a 20% fall in FEV<sub>1</sub> occurs.
- Area under the curve = The area under the FEV<sub>1</sub> trend curve, bounded on the x-axis by the dosage for Stage 1 and the dosage for PD-20, and on the y-axis by the baseline FEV<sub>1</sub> value and the PD-20 FEV<sub>1</sub> value.

#### 4.4.5 BASE STAGE

If the protocol requires the completion of a baseline test, the base stage will be the first stage to appear on the screen. (The name of the current stage is noted at the bottom right of the Challenge Test window.)

Complete as many FVC baseline tests as desired according to the Test Effort instructions in 6.1. Typically, you will want to obtain three efforts.

#### 4.4.6 SALINE STAGE

Once the base stage is complete, select `Stage|Go to next stage`. If the protocol requires the completion of a control-saline test, the saline stage will appear as the only option in the "Go to Next Stage" window. Click on `OK`.



##### *Administration*

To administer the solution through the DigiDoser, first assemble the system as described in 1.3 - 1.5 then select `Stage|Administer dosage`. If you are not using the Digi, administer the Challenge agent for the current stage according to your standard practices.

Occlude the pneumotach so there is no airflow through the mouthpiece.

The prompt will instruct the patient to begin tidal breathing. The patient should inhale and exhale normally through the nebulizer mouthpiece.

Press the space bar during a patient exhalation when you are ready to begin the dose administrations. The KoKo DigiDoser will automatically discharge during the next inhalation. Repeat this process until the patient has inhaled the solution for the number of times designated in the protocol. (If using the Rosenthal Protocol, this will be five breaths). To stop the administration select `Test|Cancel Effort` or click on the red circle icon.

**Note: If you have chosen the *Seconds* option for the dosage stage in the protocol setup, you will only need to press the spacebar once. After the first administration, discharges will occur automatically at each inhalation for the number of seconds defined in the protocol.**

When the patient has completed all designated administrations, follow the prompt and remove the patient from the mouthpiece. A message will appear informing you that, "Dosage administration is completed for this stage." Click on `OK`.

If it is necessary to repeat the administration, select `Stage|Administer dosage`. A message will appear asking if you are sure that you want to re-perform the administration. Click on `OK`.

##### *Saline Effort*

Complete several FVC tests according to the instructions in 4.1.3.

#### 4.4.7 TEST STAGES

When the saline stage is completed, select `Stage|Go to next stage`. The "Go to Next Stage" window will show the options `Stage #(1-23)` and `Recovery stage`. Highlight the necessary stage and click on `OK`. To complete the Challenge test, the patient must complete the number of stages called for in the designated protocol prior to completing the Recovery stage. (If using the Rosenthal Protocol, this will be five stages.) Finally, the patient should complete the Recovery stage to finish the Challenge test.

### ***Administration***

After preparing the appropriate concentrations of broncho-provocation solution, administer the solution through the KoKo DigiDoser according to the instructions in "Administration" in 4.4.6.

### ***Stage Effort***

The spirometry test should begin as soon after administration as possible, especially if a timer has been entered into the protocol. Complete several FVC tests according to the instructions in 4.1.3.

### ***Conclusion***

Continue through the required test stages until the prescribed drop in FEV1 has been reached (the FEV1 trend has dropped into the yellow area). Select the Recovery stage, administer the recovery agent, and perform the recovery effort.

## **4.4.8 INCREASE REPRODUCIBILITY**

The following outlines important information regarding variables and how to enhance the reproducibility of Challenge testing:

### ***Nebulizers***

Always use the same nebulizer for each stage of a challenge. It is also important that when a patient return for continued testing, that the same nebulizer used for his/her previous tests is always used again. If a nebulizer should become defective, continue with another nebulizer with as similar characterization as possible.

### ***Solution***

Always use the same amount of solution in the nebulizer bowl for each stage (3cc's).

### ***Gas Pressure***

Maintain constant pressure from the air source. This should be 30 PSI **air** pressure.

### ***Nebulizer Position***

Hold the spirometer so that the nebulizer bowl is level during the administration procedure.

### ***Patient Coaching***

Coach the patient for consistent, strong inspiratory flow rate and consistent inspiration volumes.

By following the above guidelines, and through the use of the KoKo Spirometer, DigiDoser Dosimeter, and Characterized Nebulizers, the following variables are controlled:

- Onset of nebulization at a consistent point in the respiratory cycle.
- Precise duration of nebulization
- Consistent inspiratory flow rate
- Consistent characterized Nebulizer output

# CHAPTER 5 REPORTS

Reports can be generated in a couple ways; either from the individual test screens by selecting `File|Display/Interpret/Print results`, or from the Main Menu by selecting `Report` or typing `Alt R`.

## 5.1 READ / INTERPRET

Read and interpret results by selecting `Read/Interpret`. The screen will show the format of whichever report design is currently selected.



### 5.1.1 SELECT PATIENT AND TEST SERIES

To show the report of a particular test group, select `Read/Interpret|File|Select Patient & Test Series`. Select the desired group and click on `OK`. The chosen test group results will show on the current report design format.



### 5.1.2 SELECT REPORT DESIGN

To select a different report design format, select `Read/Interpret|File|Select Design`. In the "Open Report Design" dialog there is a list of saved report designs. Choose the desired design and then click `Open`. Use the icons or click on `View` to modify the size of the report and move from page to page. Information about each design follows:



#### ***Calibration Report***

The Calibration Report includes manufacturing information, calibration information, the specific test record, calibration Volume and Time graph, and a place for a review signature and date.

#### ***Screener Report:***

The Screener Report format shows the patient information, the interpretation, quality and variability codes, the numeric results of three FVC tests, and the FVC Flow vs. Volume and FVC Volume vs. Time graphs.

#### ***Pre-Rx Trend Report:***

The Pre-Rx Trend Report format shows the patient information, the interpretation, the numeric results of three FVC tests, the FVC Flow vs. Volume and FVC Volume vs. Time graphs; the spirometry history, trend results, and the Flow vs. Volume graphic history.

#### ***Pre-Rx Trend Extended:***

The Pre-Rx Trend Extended report shows patient information, interpretation, complete numeric results of the three best tests, the FVC Flow vs. Volume, Volume vs. Time and Flow vs. Time graphs, spirometry history, trend results, and the Flow vs. Volume graphic history.

### ***Pre-Rx Trend Report (FVC & SVC):***

Includes the features of the Pre-Rx Trend Report, plus includes SVC information.

### ***Pre vs. Post Report:***

The Pre vs. Post Report format shows patient information, the interpretation, the numeric values for the best pre and post trials along with the % change, the FVC Flow vs. Volume and FVC Volume vs. Time graph; lung subdivisions; and the spirometry history.

### ***Pre vs. Post Detailed***

Includes the features of the Pre vs. Post Report, plus includes numeric values and graphics for the best 3 pre-tests and the best 3 post-tests.

### ***Pre vs. Post (FVC & SVC) Report:***

Includes the features of the Pre vs. Post Report, plus includes SVC information.

### ***Challenge Report:***

The Challenge Report format shows patient information; the interpretation, numeric results of each of the stages, Dosage Unit Trend and Flow vs. Volume graphs; and a per stage summary and Flow vs. Volume.

### ***Exercise Challenge Report***

The Exercise Challenge Report format shows patient information; a manual interpretation, numeric results of each of the stages, Per-Stage Flow vs. Volume graphs; and a per stage summary with comments.

### ***Disability Report:***

The Disability Report format shows patient information; numeric results; calibration information; MVV results, SVC results; and Pre, Post and Pre vs. Post FVC with Flow/Volume, Volume/Time and Flow/Time graphs.

### ***Disability Short Report:***

The Disability Short Report represents a condensed version of the full report.

## **5.1.3 INTERPRET**

To obtain an interpretation of the selected test group results, select `File|Interpret` from the "Read/Interpret/Print Results" screen. In the interpretation window, you can type in your own interpretation or select one of the pre-set interpretations. The interpretation will appear, provided all necessary information has been obtained through testing, along with the statement, "This interpretation is valid only upon physician review and signature." The interpretation can then be edited and the name of the person reviewing the Interpretation can be entered in the "By:" window. To include the interpretation in the selected report, click on OK.



## **5.1.4 REVIEW**

The results of the selected test group can be marked as reviewed in the patient database by selecting `File|Mark as reviewed` from the "Read/Interpret/Print Results" screen.



### 5.1.5 REFERENCE EFFORT

To select a different FVC reference effort than the one chosen by the system:



- ◆ Open the test series that contains the FVC effort you want to reference.
- ◆ Select `File|Reference effort|Mark` from the "Read/Interpret/Print Results" screen.
- ◆ Choose the effort.

To revert to the automatic reference effort, select `File|Reference effort|Unmark` from the "Read/Interpret/Print Results" screen.

### 5.1.6 CAPTURE AREA

To copy an area or an individual page of a report to a bitmap file, select `Edit|Capture Area` from the "Read/Interpret/Print Results" screen. Drag your cursor to select the area to capture. Use the standard Windows functions to copy the selected area (Cntrl C) and then to paste it into another application (Cntrl V), such as a Word document.

## 5.2 PRINT REPORTS

### 5.2.1 SETTINGS

Before you print a report, make sure to indicate the settings you desire in `File|Print Setup` from the "Read/Interpret/Print Results" screen.

#### *Ink Saver Mode*

Select `File|Printer Mode` to change to an ink save mode. This mode automatically changes thick solid black lines to thin outlined borders. The report will still print in color if monochrome mode is not selected.

#### *Monochrome Mode*

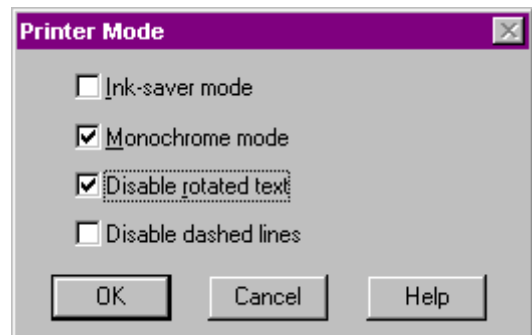
Select `File|Printer Mode` to change to a monochrome mode. In monochrome mode, the report displayed on the screen will be in color, however, the printed report will print in black and white.

#### *Disable Rotated Text*

If your printer does not have the ability to print the rotated text that appears on trend reports, Select `File|Printer Mode` to disable rotated text. With this option selected, the time/date stamp on the trend reports will appear horizontally instead of vertically.

#### *Disable Dashed Lines*

Result graphics for Post-Rx tests can optionally be shown as thick lines (instead of dashed lines), for printers that can't print dashed lines.



**Note: Post-tests print as a dashed line in the monochrome mode.**

## 5.2.2 PRINT

To print the one report on the screen, select `File|Print` from the "Read/Interpret/Print Results" screen.



To print a batch of reports:

1. Select `Report|Print Multiple` from the Main Menu.
2. Use the search options for Advanced dialogs, explained in 3.1.2, to locate the desired test series. Highlight one or more test series.
3. Select the desired design by clicking on `Select Report Design`.
4. Choose print options and properties by clicking on `Select Printer`.
5. Choose monochrome if desired.
6. When all modifications are complete, click on `Print`.

## 5.3 DESIGN

To design your own report format, select `Report|Design` from the Main Menu.

**Note: The design functions available in the KoKo PFT system are based on standard Windows functions and are fairly sophisticated. The following instructions are not detailed enough for a novice designer. For more complete instructions, refer to the Help system or contact your representative.**

### 5.3.1 AUTO-SELECT DESIGN

You may designate the default report design to appear for the following three types of tests:

- ◆ Pre- data only
- ◆ Pre-Post data available
- ◆ Challenge test

To set the defaults, complete the following steps:

1. From the Report design screen, open a report that you wish to set as one of the defaults.
2. Select `File|Auto-Select|Assign` from the Report Design screen.
3. Check the type of test you wish to default to the current design.
4. Repeat for each of the three types of tests.



You can view the current default settings by selecting `File|Auto-Select|Status`.

### 5.3.2 NEW DESIGN

To create a new design, select `File|New Design` from the "Report Design" Screen. A blank or grid screen will appear. You can remove or add the grid lines by clicking on `View|Guidelines`.

**Note: Before you begin creating a new design, read through the following instructions and experiment with the different functions, as there are many options with which you should be familiar.**

#### *File*

The File menu allows you to name and save a new design, to change page layout and print modes, to print a new design format and to exit back to the PFT Main Menu.





#### *Edit*

The Edit menu allows you to change the attributes of a selected item, cut or copy a selected item, paste a cut or copied item, delete a selected item, or select and move items. This explanation assumes that the reader is familiar with these very basic Windows functions, or, if not, will consult a Windows instruction manual.

#### *Mode*


The Mode you are in controls the functions you perform. To change the mode, click on `Mode` and then either `Draw` or `Select`. A checkmark will appear beside the selected mode.

- The Draw Mode allows you to add text or graphics to the screen. When you are in the draw mode, the cursor becomes a pointer. You can choose a line of text or a graphic to add (see `Add`). Once you have chosen the object to add, position the pointer at the desired location, click once and the object will appear on the screen. Several functions under `View` are useful for positioning the objects appropriately. It may also be helpful to have the grid lines visible on the screen. 
- The Select Mode allows you to click on an existing graphic or a line of text that was added in the Draw mode and select it, evidenced by a square at each corner of the object. When an object is selected, it can be moved by clicking on the selected object, holding down the left click button and using the mouse to move the object to the desired location. A selected object can be further edited by clicking on `Edit` then:
  - ⇒ To delete the object, `Delete`.
  - ⇒ To delete and copy the object to your clipboard, `Cut (Ctrl + X)`
  - ⇒ To copy the object to your clipboard, `Copy (Ctrl + C)`
  - ⇒ To paste at another location, `Paste (Ctrl + V)`
- The Select after Draw option simplifies the processes described above by automatically selecting each item that is added in Draw, to allow modification of the item.
- The Snap to Grid option allows three different forms of movement when moving selected objects, coarse, fine or smooth (off). A checkmark appears beside the current selection. If the "Coarse" option is check-marked, movement of a selected object will be in 4mm blocks in all directions. If the "Fine" option is check-marked, movement will be in 2mm blocks. If the Snap to grid option is "Off", movement will be smooth in all directions.

#### *View*

The View option selection, controls the view on the screen. To preview the page, change the page size, or move from page to page, click on `View` and then one of the options.




- *Zoom in* allows you to magnify and view a selected area. Once you have clicked on "Zoom in" the cursor becomes a magnifying glass and you are prompted at the bottom of the screen to "drag the 


cursor over the area to zoom in on.” To do this, position the glass at the upper left corner of the area to be magnified, then depress and hold the left click button while using the mouse to drag a dotted line around the area.


- *Guidelines* changes the screen from a blank screen to a grid screen. If there is a checkmark beside *Guidelines*, the grid screen is selected.


### Add


- The Add menu allows you to choose various types of text and graphics to the design. To choose an object to add, select *Add* and then one of the following options. (Make sure you are in the Draw Mode.) You can change any item to another by selecting the item, then selecting *Edit|Attributes*."


- *Pt/Test Series/Protocol info.* (Ctrl+P) adds pre-prepared lines of text including patient information, test series data and protocol data. Use the mouse to click on the desired category, then to select the item you wish to add to the design as well as the format. Click on *OK*. Position the cursor and click once to place the item on the screen. Repeat this process until all desired information has been added to the design. 


- *Numeric Result* (Ctrl+N) adds spirometric test results. Use the mouse to click on the Test type and then to select the item to be added as well as the format and any other desired options which can be checked or unchecked. Click on *OK*. Position the cursor and click once to place the item on the screen. Repeat this process until all desired results have been added to the design. 


- *Graphic Result* (Ctrl+G) adds a graphic test result to the screen. Use the mouse to select the desired graph and the format, either one stage only (click on the arrow to select), Pre and Post or Base to Recovery. Click on *Best Only* or *All* for the efforts to be shown on the graph. Check or uncheck the additional options, then click on *OK*. Position the cursor at the top left of the desired area for the graph then depress and hold the left click button while using the mouse to drag the striped box into the shape and size desired for the graph. 


- *Text* allows you to add arbitrary text to the page. Click on the location where you wish to add the text. Begin typing, then press "Enter" when finished. 


- *Line* allows you to add a line at any place in the design. Place the cursor at the desired location, depress and hold the left click button then use the mouse to drag the line in the desired direction. 

- *Border* allows you to add a border around a desired area. Place the cursor at the top left of the desired location then depress and hold the left click button while using the mouse to drag the border around the desired area. 

- *Rectangle* allows you to add a solid color rectangle at any location on the design. Place the cursor at the top left of the desired location then depress and hold down the left click button while using the mouse to drag the rectangle to the desired size and shape. 

- *Shadowed text box* allows you to add a box for text to the design. Follow the instructions above for creating a rectangle. 

- *Shadowed graphic box* allows you to add a box for graphs to the design. Follow the instructions above for creating a rectangle. 

- *Image* allows you to add a picture from another application. 

**Note: Edit the image to the desired size prior to importing it into the report. The KoKo PFT report**

- *New Page* allows you to add an additional page to the report.

## *Style*

Use the Style Menu to change the color of text, lines, borders and rectangles; the width of lines from very thick (5) to very thin (1); and the typeface, including font type, style and size.



### 5.3.3 MODIFY A DESIGN

To modify an existing design, select **File|Open Design**. Highlight the desired design and click on "OK." The chosen design format will appear on the screen. All functions explained in the previous section, **New Design**, are exactly identical to those used to change an existing design. Therefore, make sure you are familiar with the process of creating a new design before attempting to change an existing design.



**Important:** The process of modifying a design requires some basic knowledge of Windows features, such as cutting, copying, pasting, moving, re-sizing etc. Please consult the Help system for details instructions for modifying a report.

**Caution:** Do not click on **File|Save design** unless you are very certain that you wish to replace the original design with the modified version on the screen. To be safe, always click on the **Save design as** option and give the modified design a new name. This way you will still be able to access the original design if desired.

**Note:** Right clicking on any object in a report design will bring up a small menu. Choose **Attributes** to change any setting for that object.

**Note:** Cutting and pasting is a quick way to copy common elements to different sections of a report. Right click on an object and choose **Copy**. Move the cursor to the new location, then Right click and choose **Paste**. The pasted object will appear at the new cursor location.



# CHAPTER 6 SYSTEM

View the System Menu by selecting `System` from the Main Menu or type Alt+S.

## 6.1 CONFIGURATION

### 6.1.1 KOKO PNEUMOTACH

#### *Data Connection*

In 2.4, the serial or USB port used to connect the pneumotach to the computer was recognized. If the serial or USB port changes or if the system does not recognize the connection, the serial or USB port should be designated again by `Pneumotach data connection`.

#### *DigiDoser*

Check the `digidoser` option in order to perform Challenge testing with the KoKo DigiDoser. If the option is unchecked, you will not be able to complete administrations with the Challenge testing portions of the software.

### 6.1.2 CUSTOM INTERPRETER

You may need to modify the way that the automatic interpreter works, either by changing the values used at any decision point, or by changing the phrases the interpreter uses.

Select the type of interpreter you want to use as the basis for your customized interpreter. The choices are the Standard interpreter, or the ITS interpreter. Using the Standard Interpreter logic or the ITS Interpreter logic as a guide, select the decision point values or the phrases you want to edit, click on Edit, and enter the new values.

### 6.1.3 CUSTOM EXPORT FORMAT

Select the specific fields you want to include in the export the next time `File|Import/Export|Export test series...` is chosen. Or, click the check box on the bottom of the dialog box and specify a file name and path for the KoKo-PFT to automatically export the specified fields each time the KoKo-PFT saves any new or changed data. **This feature is very powerful for interfacing to electronic medical records programs.**

### 6.1.4 ATS WAVEFORM VALIDATION

Selecting the `ATS waveform validation mode`, enables the software to use stored ATS waveforms instead of real-time data from the pneumotach. You do not need to have a pneumotach connected to perform this check. If you enable this mode, you should first linearize and calibrate, then run an FVC test. When finished validating, de-select the Mode to resume normal real-time testing.

## 6.2 PREFERENCES

### 6.2.1 PREDICTED NORMALS

You can select a default predicted equation set which will always be used unless the set is changed for an individual test series. To designate the default set, select `Predicteds` and then the desired set.

### 6.2.2 BASIC DIALOGS

There are two patient dialogs available for your use. The Basic patient dialog automatically appears upon installation. This dialog should be sufficient for most of your needs. However, if you need to complete functions such as delete a patient or test series, or view a specific test series, the Advanced patient dialog will simplify those tasks. To activate the Advanced dialog, click on `Basic dialogs` to uncheck it. You can return to using Basic dialogs by clicking on it again to check it.

### 6.2.3 F-KEY MENU ACCELERATORS

To activate F-Keys, click on `F-key Menu Accelerator`. See the "Useful Keys" section in Chapter 2.

### 6.2.4 PATIENT CONFIRMATION

If this option is checked a patient confirmation screen will appear every time you enter the testing screen. If unchecked, the last test series opened or modified will appear when the test screen is reopened.

### 6.2.5 AUTO INTERPRET RESULTS

If one of the "interpret" functions in this option is checked, interpretations will automatically be added to all reports. As new efforts are completed, the interpretation will change to reflect the modified results. You may override the automatic re-interpretation by selecting `File|Interpret` in the "Read/Interpret/Print Results" screen and then checking "Mark as final."

### 6.2.6 BASIC REPORTS

### 6.2.7 FACILITY NAME/LOCATION

Select this option to enter a facility name and location or to change the entry made at install.

### 6.2.8 AUTO-SELECT REPORT DESIGN

Select this option to activate the default settings for report designs. You may not select this option until default settings have been established. See 5.3.1 Auto-Select Report Design for instructions.

## 6.3 CALIBRATE

To ensure accurate test results, the system must be calibrated on a regular basis. Calibrate the pneumotach once a day prior to performing any tests, or:

- when a different pneumotach is used
- after the pneumotach is sterilized








- when test results are questionable
- before performing a disability study

PDS Instrumentation recommends the use of a positive stop 3-liter calibrated syringe for pneumotach calibration. The accuracy cannot be guaranteed with a smaller syringe.

**Note: Always calibrate the KoKo Spirometer with a new KoKo filter in place. Accuracy will be affected if the filter is not in place during calibration, while it is used for testing.**

To perform a calibration, click on `Calibrate`.

1. Select the pneumotach to be calibrated by highlighting the appropriate description and ID #. If the system is new, follow the instructions in 2.4. 
2. Verify, and change if necessary, the environmental conditions.  
3. Enter the name or initials of the person performing the calibration. 
4. If you are using a PDS MultiFlow syringe, click on the `Setup|MultiFlow Syringe` (unless it is already has a check mark). This option provides a prompt between syringe pushes to set the syringe flow rate to a new setting. It is important to still inject at the suggested flow rates shown below. The settings on the MultiFlow syringe will assist you in attaining those desired flow rates.
5. To begin the calibration, select `Test|Start calibration`. (Note that the calibration can be canceled by clicking on `Cancel calibration`.) The procedure will begin by nulling the pneumotach. During nulling, you must assure that there is no air flow through the pneumotach. You will be prompted to perform at least three trials. You should vary the flow rates for each effort. PDS recommends that you use: 
  - ♦ Low Flow (approximately 0.5 L/sec (or inject 3 liters in 6 seconds)
  - ♦ Medium Flow (approximately 1 L/sec (or inject 3 liters in 3 seconds)
  - ♦ High Flow (approximately 3 L/sec (or inject 3 liters in 1 second)

When calibration has been successfully completed, a message will come on the screen informing that "the pneumotach's calibration has been adjusted and is now within tolerance." Click on `OK`.

6. You may print a report of the calibration graphic results prior to exiting the calibration screen. Click the "print" icon.

**NOTE: If calibration cannot be completed successfully, verify that the I.D. # selected is entered correctly and matches the pneumotach being calibrated.**

## 6.4 CALIBRATION LOG

To view the log of calibration activity for all pneumotachs entered into the software, select `Calibration Log`. You may edit information within the log if desired. To print the log, click on `File|Print`. To print a calibration report, see 5.1.2.

## **6.5 LINEARIZE**

Linearization is a procedure to be used when a pneumotach is definitely known to be non-linear, or a pneumotach ID cannot be determined from original factory documentation.

The pneumotach linearization function is typically used only as a service function. If your system will not calibrate and/or is known to be non-linear, contact the PDSI Service department.

# APPENDIX A CLEAN & DISINFECT THE KOKO

Pulmonary Data Service Instrumentation (PDS) recommends the use of KoKo Filters to reduce the need for disassembly and cleaning the KoKo spirometer.

## DUST REMOVAL

To remove dust from the surface of the pneumotach core, PDS recommends using a moisture free dust remover spray. Moisture free compressed air can also be used.

## NEBULIZER CLEANING

At least once a day, disassemble and wash the entire nebulizer and tubing with a decontaminant/sterilant solution according to the directions accompanying the solution. Rinse with hot tap water and allow to air dry prior to reassembly.

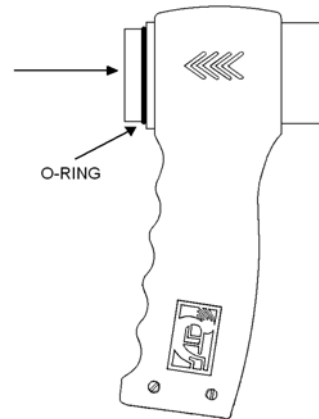
## CLEANING THE CORE ASSEMBLY.

If it becomes necessary to disinfect and/or submerge the pneumotach in a cleaning solution, the core assembly must be removed from the spirometer handle (follow directions in the figures shown). **This is the only part of the KoKo Spirometer that can be submerged in liquid.** The core of the pneumotach is made from a brass alloy. Care should be taken that the disinfectant solution used does not damage the core. PDS recommends Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride, or any equivalent non-corrosive solution.

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

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

1. Remove the O-ring from the side of the pneumotach to which the arrows point.
2. Push the core assembly out of its holder in the direction shown
3. Once you have removed the core assembly from the pneumotach handle, submerge the core assembly in the chosen disinfectant solution, rinse thoroughly in distilled water, air dry and then reassemble the system.
4. Slide the core assembly back into the handle, making sure that the tab matches with the slot provided for it in the handle.
5. Replace the O-ring.



# APPENDIX B TROUBLESHOOTING

## ERRONEOUS RESULTS

If receiving erroneous results, check the following:

- ◆ Is the filter attached correctly?
- ◆ Has the pneumotach been calibrated lately?
- ◆ Is the pneumotach screen free of debris?
- ◆ Are there any restrictions being place on the air flow through the pneumotach?

## DIFFICULTY CALIBRATING

If the system is not calibrating:

- ◆ Make sure the syringe connection is leak free.
- ◆ Check that the ID # entered into the software matches the ID # that accompanied the pneumotach.
- ◆ Check the syringe for internal leaking.

## LOST SYNC

If you frequently receive a message that the software has lost sync with the pneumotach, check the following:

- ◆ Other programs are closed while running KoKo PFT. If not, shut down unnecessary applications, disconnect the pneumotach for a few seconds and restart Windows.
- ◆ The computer meets the recommended minimums.

## NULLING THE PNEUMOTACH

The KoKo PFT software detects flow that occurs while nulling the pneumotach, due to starting breathing at the wrong time, or moving the pneumotach.

To avoid errors while nulling the pneumotach, you should place the KoKo Spirometer on some surface, away from airflows such as open windows or ventilation ducts.

If you experience nulling problems, try placing a hand over the pneumotach during nulling. If problems persist, contact PDS to determine if you have a "noisy" pneumotach.

## **PTACH NOT CONNECTED**

If an error message states that the pneumotach is not connected:

- ◆ Make sure the pneumotach power supply is connected to the KoKo DigiDoser correctly.
- ◆ Make sure the KoKo is attached to the correct COM or USB port.

## **TEST COULD NOT BE COMPLETED**

If you receive a message that the test could not be completed, there may be another process executing on your computer that uses an excessive amount of processor time, disrupting data communications with the pneumotach.

One cause has been found to be when a defective battery is plugged into certain notebook computers, and the computer is trying to determine the charge of the battery. To correct this condition:

- ◆ Select Start | Settings | Control Panel,
- ◆ Select System,
- ◆ Click on the Device Manager tab.
- ◆ Double-click on System Devices to open that branch.
- ◆ Double-click on Advanced Power Management to open its properties.
- ◆ Click on the Settings tab.
- ◆ In the Troubleshooting group, click on Disable Power Status Polling.
- ◆ Click on OK, OK,
- ◆ Close Control Panel.

KoKo should now operate properly.

## **"FIND ALL MATCHES" RETURNS INCORRECT RESULTS**

In the unlikely event that the database has become corrupted due to an abnormal termination of your workstation, or an abnormal termination of the server/network (multi-user version) due to power failure, etc., the database may be left in an inconsistent state in which the "Find all matches" does not return any (or incorrect) test series.

To correct this, you should rebuild the database keys. First, check the Help|About dialog box to determine if you have the single- or multi-user version.

- Multi-user version:

From the database administrator's system, select File|Database|Administrator|Rebuild database keys.

- Single-user version:

The database keys can be automatically rebuilt at next startup by making an addition to the KoKoPFT.INI file.

- 1) Exit the KoKo PFT System.
- 2) Find the KoKoPFT.INI file (usually in the C:\Program Files\KoKo PFT System\Bin folder) using Windows Explorer
- 3) Double-click the KoKoPFT.INI file to start the Notepad editor.
- 4) Find the section titled [Database]
- 5) Add a new line under that section:  
  
AutoRebuild=True
- 6) Close Notepad.
- 7) Restart the KoKo PFT System.

## **FAILURE TO COMPLETE PRINTING**

Under certain circumstances, 'Print Multiple Test Series' will fail to complete with an "Unable to complete printing" message. The reasons for this include:

- Patient(s) for the unprinted test series are locked by another task (multi-user version)

If the patient for a specific test series being printed becomes "locked" (opened by another user, or another task on your system) during printing (i.e.: after multiple test series have been selected and printing starts), the test series can't be printed. The reason is that the report function needs access to the test series in order to update the "printed" status, but can't because the patient is locked.

The solution is to allow the other task(s) to complete. If you then simply select 'Print Multiple Test Series' again, the unprinted (and/or unupdated) test series will still be highlighted and ready for you to re-attempt printing.

- Test series in use in another window (single-user version)

If the specific test series being printed is opened in another window during printing (i.e.: after multiple test series have been selected and printing starts), the test series can't be printed. The reason is that the report

function needs access to the test series in order to update the "printed" status, but can't because changes are pending to that test series in another window.

The solution is to close the window for that test series. If you then simply select 'Print Multiple Test Series' again, the unprinted test series will still be highlighted and ready for you to re-attempt printing.

- Printer error(s):

The printer may have caused an error during printing, such as printer off-line, paper out, power off, disconnected from system, etc. Correct the problem, making sure the printer is now "on-line". If you then simply select 'Print Multiple Test Series' again, the unprinted test series will still be highlighted and ready for you to re-attempt printing.

- Database keys corrupted:

In the unlikely event that the database has become corrupted due to an abnormal termination of your workstation, or an abnormal termination of the server/network (multi-user version) due to power failure, etc., the database may be left in an inconsistent state in which the "printed" status cannot be updated. To correct this, you should rebuild the database as described in the next section.

## DATABASE ERROR

If you encounter an error message at startup indicating that there is a problem with the database, you should contact PDS for assistance *before proceeding*.

*If assistance is unavailable*, the following sections explain the causes and cures of possible error messages:

Caution: Before proceeding with the suggestions provided below, exit the KoKo PFT System and copy the *entire* contents of the database directory (see below) to a safe location, so that you will be able to return to the current state of your database in any event.

Before describing the possible errors, a short explanation of the database used by the KoKo PFT System will be helpful:

All of the database files are contained in one directory:

- ◆ For single-user systems, in C:\Program Files\KoKo PFT System\PtData, or
- ◆ For multi-user systems, at the server path shown in the [Database]section of the file KoKoPFT.INI under the NetworkDbPath= key.

The database is transaction-oriented, meaning that changes you make to the database (i.e.: adding a new patient, performing tests, interpreting results, etc.) are stored in the database *and* in a log of all transactions (changes). Also, there must always be a current on-line backup for the database. The benefit is that you should always be able to return to the most recent state of the database in case any of the database files become corrupted (this can happen if the power to your system is turned off in the middle of accessing the database, if a network connection fails, or if a related subsystem, such as a printer driver, fails during printing).

There are several possibilities for the cause of a database error at startup:

- 1) The database files are corrupted ("Unable to open database").
- 2) The transaction log files are corrupted ("Unable to open transaction log" or "The transaction log ... could not be opened. Do you want to proceed...?").

- 3) The database directory could not be created ("Could not create \\<servername>\<path>").
- 4) The database file set is incomplete ("Could not create database" or "The database is not present...").
- 5) The transaction log file set is incomplete ("Could not create transaction log").

## DATABASE FILE(S) CORRUPTED

(Review the "Database error" section first for important precautionary instructions).

- ◆ Error message at startup says: "Unable to open the database"

This message means that the database has been corrupted, and the backup should be restored. This error has an automated recovery option if both the transaction log file set and the database backup file set are present.

Click on "Ok".

- ◆ If you see this message:

"The database is damaged and unusable. Since a local backup from <date/time> and the transaction log exist, it may be possible to completely restore the database from this backup. Do you want to restore the database from the local backup now?"

then, to use the automated option, answer "Yes", and the backup files will replace the database files. After an automatic recovery is performed, the program should proceed normally (be sure to continue to make frequent local backups). *Skip the rest of this section.*

- ◆ If you see this message:

"Both the database and the transaction log are damaged and unusable (but a local backup from <date/time> is present). You must restore from the most recent backup, local or off-line. No data since the most recent backup can be recovered. Do you want to restore the database now from the local backup? (Answer 'No' if you are not sure, or have a more recent off-line backup) "

a much more serious problem exists, and you must determine where the most-recent backup is located. Make a note of the local backup date in the message, answer "No", and compare the date of the local backup to the date of your most-recent off-line backup (assuming you have one):

- ◆ If the off-line backup is more recent, restore that backup, and restart KoKo.
- ◆ If you have no off-line backup, or the local backup is more recent than the off-line backup, restart KoKo, and answer "Yes" to the restore question above. You will not be able to recover any data from the backup date to present.

The program should proceed normally (be sure to continue to make frequent local backups). *Skip the rest of this section.*

**Note: If all 10 of the backup files in the backup file set do not exist, you will *not* see the "restore" messages described above. In this case, you must manually restore the KoKoPFT.\* database file set (not the backup file set!) from the most recent off-line backup.**

During the automated recovery process, the database backup files (named `KoKoPFT.b*`) will be copied over the database files (named `KoKoPFT.*`), then the transaction log files (named `TxnLog.*`, containing all changes to the database since the last local backup, will be applied to the database to return it to its most recent state.

## TRANSACTION LOG FILE(S) CORRUPTED

(Review the "Database error" section first for important precautionary instructions).

- ◆ Error message at startup says: "The transaction log (used for restoring the database from the local backup) is damaged and unusable. It may be possible to proceed by bypassing the transaction log. Do you want to proceed?"

This message means that the transaction log file set has been corrupted, or the transaction log file set is incomplete, and can't be used in its present state.

Answer "Yes" to have the system attempt an automated recovery. (The transaction log files will be renamed, the database opened, and a backup performed immediately to assure that the database backup file set and the transaction log file set are current and consistent with each other).

*Note:* Answer "No" if you prefer to investigate the problem further and want to correct the problem manually. (You can restart the system later to use the automatic recovery if you change your mind about the manual recovery). Proceed with the following instructions (which also apply when an automated recovery is not possible):

- ◆ Error message at startup says: "Unable to open the transaction log"

(If you received this error message after attempting the automated transaction log error recovery described above, the system could not rename the transaction log files, probably because transaction log backup files already exist from a previous recovery attempt).

You will need to disable the transaction log function temporarily by moving the transaction log files from the database directory, then determining if further errors exist (make sure the KoKo PFT System is *not* running before continuing with manual recovery):

The transaction log file set consists of the 5 files:

`TxnLog.vot`

`TxnLog.vs1`

`TxnLog.vs2`

`TxnLog.txn`

`TxnLog.tsq`

1) Move these 5 files from the database directory (usually located at `C:\Program Files\KoKo PFT System`) to a separate directory for safekeeping.

2) Restart the KoKo PFT System, and if startup is successful, be sure to perform a local backup immediately so that you ensure continuous protection from database file corruption. Following a successful backup, you may delete the old transaction log files you moved to the safe location. *Skip the remainder of this section.*

3) If restarting is unsuccessful and you see the message "Unable to open virtual object manager", the database files are also corrupted. The recovery for this problem depends on where the most-recent backup of the database is obtainable:

a) If there is *no* off-line backup (or the off-line backup is *older* than the local backup file set), you must use the latest local backup:

**Note: Since the transaction log was found to be corrupted, changes made to the database since the last local backup will not be present after this form of recovery. Plan accordingly, you may need to repeat some previously-performed tasks.**

i) Move the database file set to a separate directory for safekeeping:

KoKoPFT.vot

KoKoPFT.vs1

KoKoPFT.vs2

KoKoPFT.txn

KoKoPFT.tsq

ii) Restart the KoKo PFT System, and at the prompt that offers to restore the backup database, answer "Yes". You should now be able to proceed normally.

b) If the off-line backup file set is *newer* than the local database backup file set, you must use the off-line backup file set:

i) Restore the database file set from the off-line backup to the database directory.

ii) Restart the KoKo PFT System. You should now be able to proceed normally.

iii) Be sure to perform a local backup immediately so that you ensure continuous protection from database file corruption.

## DATABASE DIRECTORY NOT CREATED

- ◆ Error message at startup says: "Could not create \\<servername>\<path>"

The system is attempting to create the database (one-time time only), but does not have directory read/write/create access rights to the database directory.

Check that the path to the database directory (if explicitly specified) is correct, and that you have the read/write/create privileges to the directory (if multi-user and database is in a shared directory).

## DATABASE FILES INCOMPLETE

(Review the "Database error" section first for important precautionary instructions).

- ◆ Error message at startup says: "Could not create database" or "The database is not present..."

There are two possible cases:

1) A local backup exists (message: "The database is not present (or some components are missing), but a backup is present. Do you want to restore the database from the backup and transactions?")

If you answer "Yes", the system will perform an automated database restoration. Answer "No" if you prefer to investigate the problem further and want to restore the missing database file(s) manually. See "Database file(s) corrupted" for more information.

2) A local backup does not exist (message: "The database is not present (or some components are missing), and no backup is present. Warning: If you have a separate backup of the database, you should attempt to restore it instead of creating a new database. Do you want to create a new database?").

Caution: Only answer "Yes" to create a new database if you are *sure* that you want to discard *all data you have ever saved previously*.

Otherwise, if you know you have saved data previously, answer "No" to creating a new database. In this case, you must manually restore the KOKOPFT.\* database file set (*not* the backup file set) from the most recent off-line backup.

## TRANSACTION LOG FILES INCOMPLETE

(Review the "Database error" section first for important precautionary instructions).

At least one of the files in the transaction log file set is missing. You should attempt to locate the missing file(s) and replace them in the database directory.

Be careful: you *must* find exactly the same file that is missing (check the file date/time stamp).

Otherwise, if you can't locate the missing files, proceed as if the transaction log file(s) are corrupted.

## TRANSACTION LOG FILES CAN'T BE CREATED

- ◆ Error message at startup says: "Could not create transaction log"

The most likely cause of this error is that the your system does not have file read/write/create access to the database directory, where the transaction log files will be stored.

Check that the path to the database directory (if explicitly specified) is correct, and that you have the read/write/create privileges to the directory (if multi-user and database is in a shared directory).

## DATABASE FILES NOT FOUND

(Review the "Database error" section first for important precautionary instructions).

If the database files can't be found in the standard database directory at startup, a single-user system will attempt to find the database (a message states: "Searching for database...").

- ◆ If no database files can be found, you will see a message asking if you want to create a new database (see the "Database files incomplete" section).
- ◆ If database files are found on any non-removable and writeable disk, a list of directories ("folders") that contain these files will appear.
- ◆ If one of the folders contains the appropriate database files, select it and click **OK**.
- ◆ If none of the folders contain the appropriate database files, click on **Cancel** and continue with the "Database files incomplete" section.



## APPENDIX C 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/ECCX recommended 5% of the total FVC (or 100 ml, whichever is greater), thereby introducing some inaccuracy into the measurement of all timed FEV's.
BTPS	Body Temperature and Pressure, fully Saturated with water.
Challenge	Test of airways hyperreactivity – methacholine, or other known inducers of hyperreactivity (ie. Histamine) is introduced in a stepwise fashion. The decrease in FEV-1 at each level is measured to define the presence and degree of hyperreactivity.
Patient Demographics	Information about a patient which includes height, age, sex, race, etc. Used to calculate the predicted values.
FEF <sub>max</sub>	See PEFR
FEF-25%	Forced Expiratory Flow at a point in time at which 25% of the FVC has been expired, expressed in liters per second.
FEF-50%	Forced Expiratory Flow at a point in time at which 50% of the FVC has been expired, expressed in liters per second.
FEF-75%	Forced Expiratory Flow at a point in time at which 75% of the FVC has been expired, expressed in liters per second.
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.
FEF 75-85%	The averaged FEF between the expiration of 75% and 85% of the FVC, expressed in liters per second.
FEF .2-1.2	The averaged Forced Expiratory Flow at a point in time at which between .2 and 1.2 liters of the FVC has been expired, expressed as liters per second.
FIF 50%	Forced Inspiratory Flow at a point in time at which 50% of the FIVC has been expired, expressed as liters per second.

FIVC	Forced Inspiratory Vital Capacity – important in determining upper airway obstruction.
FIVC/FVC %	The ratio of FIVC to FVC, expressed as a percentage. Useful in determining air trapping and upper airway obstruction.
FIF50/FEF 50 %	The ratio, expressed as a percentage of FIF 50% to FEF 50%, useful in determining air trapping.
FEV-0.5	Forced Expiratory Capacity at ½ second into the expiratory maneuver.
FEV-1.0	Forced Expiratory Capacity at 1 second into the expiratory maneuver.
FEV-3.0	Forced Expiratory Capacity at 3 seconds into the expiratory maneuver.
FEV-1/FVC %	The ratio of FEV-1 to FVC, expressed as a percentage.
FVC	Forced Vital Capacity – the maximal volume obtained in one forced expiratory maneuver.
MVV	Maximum Voluntary Ventilation – expressed in liters per minute. The volume of air expired over a 12 to 15 second period, extrapolated to one minute.
PEFR	Peak Expiratory Flow Rate – the highest flow registered during the forced expiratory maneuver.
RV	Residual Volume – The amount of air remaining in the lungs after a maximal slow exhalation.
SVC	Slow Vital Capacity – The maximal amount of air exhaled in one slow expiratory maneuver.
TLC	Total Lung Capacity – the amount of air in the lungs after a maximal inhalation.