NiOxMINO®

NIOX MINO® Data Manager
User Manual

for version 1.0.0.11 and higher

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Intended Use

The NIOX MINO® Data Manager is a software program to be used for transferring patient data between a NIOX MINO and a PC. It also contains a visual incentive program for the inhalation / exhalation procedure.

This provides the user the possibility to save patient data in a stand alone database. Patient data can be trended over time and presented graphically. The software also provides the option to create patient reports that can be either printed or saved as pdf-files.

Measurement data can be further exported for statistical analysis.

Cautions

This is a summary of all Cautions found in this User Manual

- If the **Send** button is clicked (*in the Patient Card*) the user will be questioned in case the NIOX MINO Test Card belongs to another patient or if a generic card is in place. If you answer "**Yes**", the NIOX MINO Test Card will be configured with the information entered in the *Patient Card* tab. ***This will erase any previous configurations of the Test Card and all measurement data saved on the Test Card.***
- It is recommended to use the Standard blue Test Card in NIOX MINO. The NIOX® Value received from a NIOX MINO without a Test Card can be transferred several times to more than one Patient Card.
- Regular database backups are recommended. Each customer carries the sole responsibility to perform backups.

License Agreement

Technical Information

- A computer with Windows® OS is required. NIOX MINO® Data Manager is compatible with Windows 2000, XP and Vista; with NIOX MINO units containing software version 1470 and higher.
- The program installation requires up to 300 MB of hard disk space and will install the .NET Framework 2.0 (if not already installed on your PC)
- A PC with an IR port is required to transfer data to and from NIOX MINO. If your PC does not have a built-in IR port, an external IrDA USB Adapter is required. A desktop model has to be used for the Visual Incentive. In case you have a built-in IR port, it needs to be deactivated if you use an external IrDA USB Adapter.

Windows® is a registered trademark of Microsoft Corporation.

Install NIOX MINO Data Manager on a PC

Note!
- Only one installation of the NIOX MINO Data Manger application is possible on a PC.
- The NIOX MINO Data Manager requires .NET Framework to be installed. If not installed, the installer will ask you to install it. It is included on your installation CD.

You need to uninstall any previous version of NIOX MINO Data Manager before you install a new version.
We recommend that you make a backup of your database before you uninstall the previous version.
See instructions on page 12.

To remove the program:
1. Select the **Control Panel** from the **Start** menu.
2. Double-click on **Add/Remove Programs**.
3. Select **NIOX MINO Data Manager** and click **Remove**.

This procedure will not remove the Patient Database
The database can be found at **C:/Documents and Settings/All users/Application Data/Aerocrine**
You must have your Windows software set to show hidden files and folders to see the file. Please refer to Appendix 1 of this manual.

Installation
1. Insert the NIOX MINO Data Manager CD into the CD-ROM drive.
2. The program installation should launch automatically.
3. Follow the on–screen instructions.

If the program does not launch automatically:
1. Select **My Computer** from the **Start** menu.
2. Double-click on the CD icon "NIOX MINO Data Manager"
3. Follow the on–screen instructions to install the program.

The Patient database will be automatically retrieved if you have a previous version of NIOX MINO Data Manager.

You need to recover the Patient database if you previously have been using NIOX MINO FE$_{NO}$ Data Manager
(version 1.0.0.4 , see page 5 and the **About** tab (**C**) for identification)
This can be done by restoring your database, see page 12 or:
1. Browse to: **C:/Documents and Settings/All Users/Application Data/Aerocrine**
2. Move all data from the folder "**NIOX MINO FENO Data Manager/Data" to "NIOX MINO Data Manager/Data"**
You must have your Windows software set to show hidden files and folders to see the file, see Appendix 1.

Start up NIOX MINO Data Manager

1. Double-click on the NIOX MINO Data Manager icon on the Windows desktop.
2. The *Main* tab is shown.

Main tab Overview
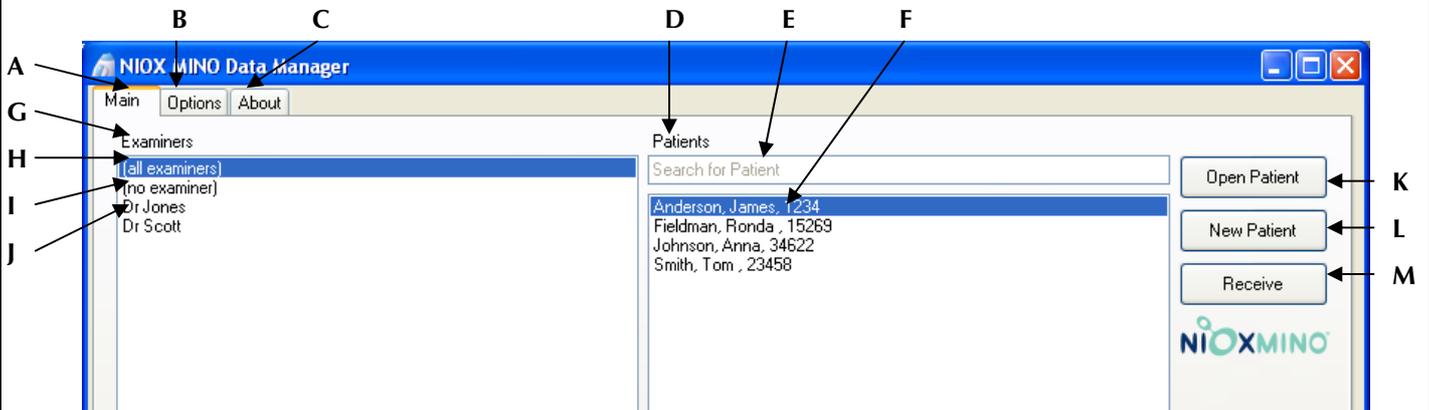
A. *Main*: Open/add Patients and Receive data from NIOX MINO®.

B. *Options*: Back up/restore database. Language and report settings (overview, page 12)

C. *About*: View software version and copyright information.

D. *Patients*: List of Patients in the database.

E. *Search for Patient*: Enter the first letters of the Patient's last name to search in the Patients list.

F. Existing Patient names in the database, [Last name, First name, Patient ID].

G. *Examiners*: List of all Examiners in the database.

H. *(all examiners)*: Click to view all Patients.

I. *(no examiner)*: Click to view all Patients not connected to a specific Examiner.

J. Click to view all Patients that belong to the specific Examiner.

K. *Open Patient*: Open a Patient selected in the patient list.

L. *New Patient*: Add a new Patient to the database.

M. *Receive*: Transfer data via the IR port from NIOX MINO (with or without NIOX MINO Test Card) to your PC.

NIOX MINO Overview

NIOX MINO Test Card (**blue**)

IR Port
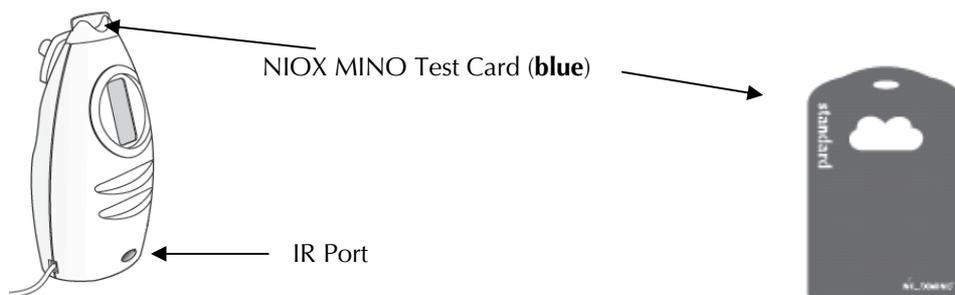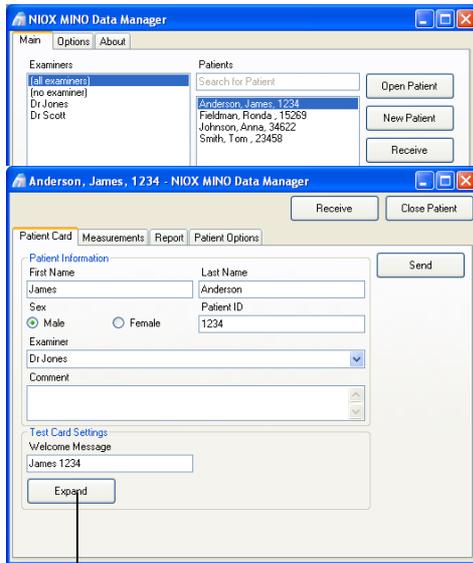
Add a New Patient

1. Click **New Patient** in the *Main* screen.

2. Enter *First Name*, *Last Name* and *Patient ID*. (It is **mandatory** to enter a Patient ID [letters and/or numbers] to fully prevent mix-up of patients with the same first and last name)
3. Enter a new *Examiner* or choose an existing examiner from the drop down list.

Optional
4. Enter *Sex, Comment* and/or *Welcome Message (*a text displayed on the NIOX MINO® screen when the Test Card is inserted and configured as a patient specific card).
5. Click **Expand** to:
   • Set low and high NIOX® Value limits presented in the measurements graph, (see page 10; **E**).
   • Select if The NIOX Value should be visible on the NIOX MINO display. The default setting is that The NIOX Value is displayed. Uncheck the box if it should not be displayed. (See page 9, *Configure a NIOX MINO Test Card*).
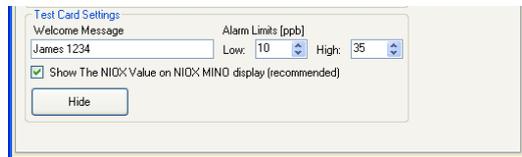
Receive Data from NIOX MINO
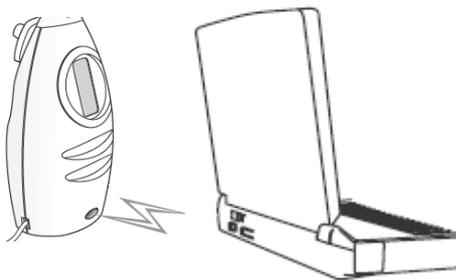
1. Place the NIOX MINO IR port close to the PC IR port.

2. The IR icon on the Windows tool bar indicates that a NIOX MINO is within range.

Note!
If your PC does not have a built-in IR port, connect and install an IrDA USB Adapter. Refer to the accompanying product documentation. An external USB Adapter should be used if you intend to use the Visual Incentive (page 13).

Transfer The NIOX® Value from a NIOX MINO® <u>with a generic</u> Test Card

A generic NIOX MINO Test Card is not given a Name and Patient ID.

A. Main screen

1. Click **Receive**. (The IR icon on the Windows tool bar indicates that a connection to NIOX MINO has been established.)

2. *For a patient already in the database:*
   a. Click **Select Patient** to select a patient from the list of patients in the database.
   b. Highlight a patient in the *Select Patient* screen and click **Select**.

   For a new patient:
   Click **New Patient** to create a new Patient. (See Add a New Patient, page 6).

B. Patient Card screen

1. Click **Receive**. (The IR icon on the Windows system tool bar indicates that a connection to NIOX MINO has been established.)
2. Click **Yes** in the *Receive Preview* screen to add The NIOX Value to the Patient Card.

Note!
Only the latest NIOX Value can be transferred from a NIOX MINO with a generic Test Card. The NIOX Value from a generic Test Card can only be transferred to one Patient Card. To transfer more than the latest NIOX Value from a Test Card, it must be *configured to that patient* **prior** to performing the NIOX MINO measurements. (See page 9, on how to configure a Test Card).

Transfer NIOX® Values from a NIOX MINO® _with a configured_ Test Card

A configured NIOX MINO Test Card is given a Name and Patient ID. See page 9 on how to configure a Test Card.
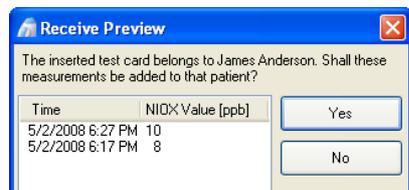
From the _Main_ screen or the _Patient Card_ screen

1. Click **Receive**. (The IR icon on the Windows system tool bar indicates that a connection to NIOX MINO has been established.)
2. Click **Yes** in the _Receive Preview_ screen to add the NIOX Values to the Patient.

Note!
NIOX Values from a configured Test Card can only be transferred to the set Patient Card. All new NIOX Values since last time data was transferred can be received at the same time.

Transfer NIOX Values from a NIOX MINO without a Test Card

A. _Main_ screen
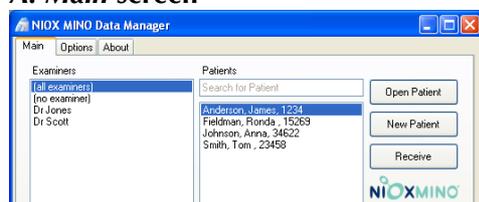
1. Click **Receive**. (The IR icon on the Windows system tool bar indicates that a connection to NIOX MINO has been established.)

2. **_For a patient already in the database:_**
   a. Click **Select Patient** to select a patient from the list of patients in the database.
   b. Highlight a patient in the _Select Patient_ screen and click **Select**.
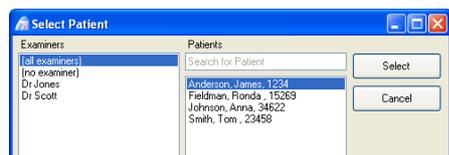
   For a new patient:
   Click **New Patient** to create a new Patient. (See Add a New Patient, page 6).

B. _Patient Card_ screen

1. Click **Receive**. (The IR icon on the Windows system tool bar indicates that a connection to NIOX MINO has been established.)
2. Click **OK** in the _Receive Preview_ screen to add the NIOX Value to the Patient Card.

Note!
Only the latest NIOX Value can be transferred from a NIOX MINO.

Caution!
It is recommended to use a Test Card in NIOX MINO. NIOX Values received from a NIOX MINO without a Test Card can be transferred several times to more than one Patient Card.

Configure a NIOX MINO® Test Card

A NIOX MINO Test Card (blue) can be configured with a Name and Patient ID. Please contact Aerocrine, Inc. if you would like to order additional NIOX MINO Test Cards (contact details on page 16).

1. Add a New Patient to the database, see page 6.
2. Optional: Enter a text (*Welcome Message*) to be displayed on the NIOX MINO screen when the Test Card is inserted.
3. Insert a NIOX MINO Test Card into the top of the device.
4. Place the NIOX MINO IR port close to the PC IR port.
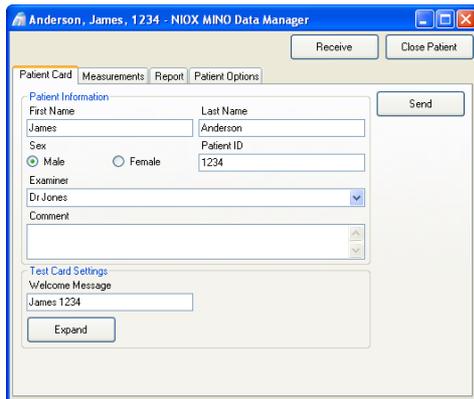
5. Make sure that the IR icon on the Windows system tool bar is visible to indicate that a NIOX MINO is within range.

Caution!
If the **Send** button is clicked (*in the Patient Card*) the user will be questioned in case the NIOX MINO Test Card belongs to another patient or if a generic card is in place. If you answer "**Yes**", the NIOX MINO Test Card will be configured with the information entered in the *Patient Card* tab. ***This will erase any previous configurations of the Test Card and all measurement data saved on the Test Card.***

6. In the Patient tab click **Send**. (The IR icon changes to , which indicates that a connection to NIOX MINO has been established.)

The NIOX MINO Test Card can be a Personal Test Card for a certain patient or a general configured Test Card to collect NIOX MINO measurements from several patients.

Tip!
To configure a NIOX MINO Test Card to be a general card (a non-personal card) and store NIOX® Values from several patients; Add a New Patient, see page 6, and name this Patient Card for example *First Name*: "Card" *Last Name*: "Test" *Patient ID*: "1" and follow steps 2-6 above. This must be done prior to performing NIOX MINO measurements.

Measurements tab Overview

Open a Patient from the Main tab to reach the Measurements tab.
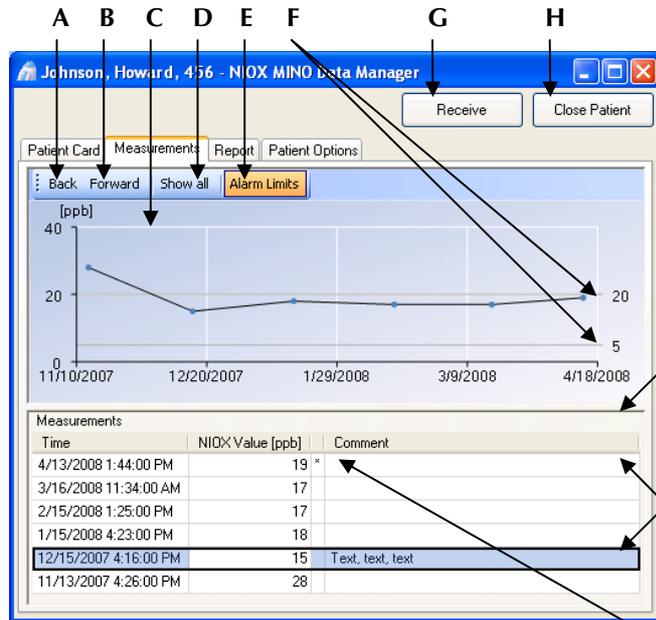
A. *Back*: Move backward in the graph.
B. *Forward*: Move forward in the graph.
C. To zoom in the graph: Press the left mouse key and drag to the left or right to form a box. Click the *Show All* button to restore default scale.
D. *Show All*: Show all NIOX® Values in the graph.
E. *Alarm Limits*: Show The NIOX Value alarm limits in the graph. (Values are set in the *Patient Card*).
F. Alarm Limits.
G. *Receive:* Transfer Data from NIOX MINO®, with or without Test Card, refer to page 7-8.
H. *Close Patient:* Return to the *Main* tab.
I. Click the line between the graph and the Measurements list to adjust the size of the graph/list.
J. Enter a *Comment* for a NIOX MINO measurement by double-clicking
K. A star (*) in the column next to The NIOX Value indicates that the measurement was performed without having done the daily QC, refer to the *NIOX MINO Quality Control Procedure User Manual*.
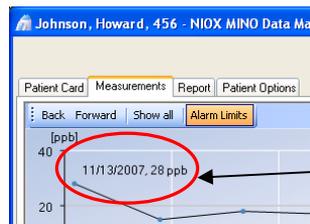
Tip! Place the pointer over a measurement dot in the graph to view the date and The NIOX Value.

Advanced View

1. Right-click in the Measurements list, (below the graph).
2. Select *Advanced* from the drop-down list.

A. *Mode:* Standard (10 seconds measurement).
B. *Test Card ID:* A unique identifier for all NIOX MINO Test Cards.
C. *Sensor ID:* Serial Number of the NIOX MINO Sensor.
D. *NIOX MINO ID:* Serial Number of NIOX MINO.

Copy and export NIOX MINO Measurement Data

1. Open a *Patient* from the *Main* tab and select the *Measurements* tab.

To copy all measurements	To copy individual measurements
1. Right-click in the Measurements list. 2. Click *Select all* in the pop-up menu. 3. Select *Copy* from the pop-up menu.	1. Choose one of the alternatives below. • Press the *Ctrl* key to select measurements one by one with the mouse • Press the *Shift* key to select a section of measurements with the mouse. 2. Select *Copy* from the pop-up menu.

Tip!
Measurement data is copied from NIOX MINO Data Manager as tab delimited text and can be pasted into (for example) Microsoft® Excel.

Create a Report/Print-out

1. Select the *Report* tab.
   - Select *Print* to print a report.
   - Select *PDF* to convert a report to PDF format

Tip!
See *Report Settings*, below, on how to set a text or an image header on the report.

Archive or Delete Patient
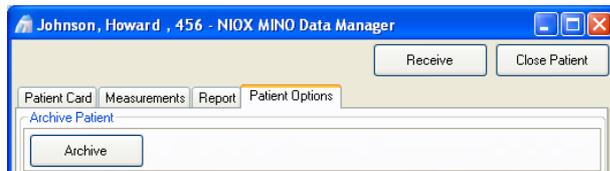
To remove a Patient from the database.
1. Open the Patient to be archived from the Main screen.
2. Select the *Patient Options* tab.
3. Click **Archive**.
4. Select a destination for the Patient file.
5. Click **Save**.

The complete Patient File is then deleted from the database. To retrieve an archived Patient to the database, see Restore Archived Patient, page 12.

Options tab Overview
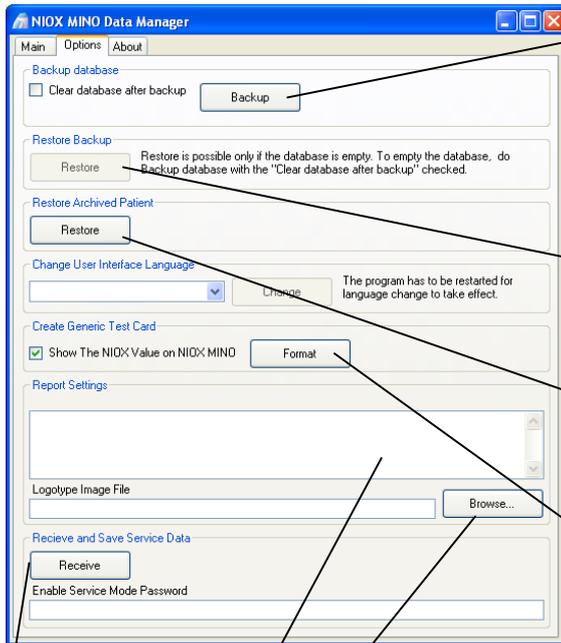
Backup Database

1. Decide if the database should be cleared following backup.
2. Click **Backup**.
3. Select a destination for the backup.
4. Click **Save**.

Restore Database

- Click **Restore** and select the Database to restore.

Restore Archived Patient

- Click **Restore** and select the Patient to restore.

Create Generic Test Card

1. Place the NIOX MINO® IR port close to the PC IR port.

2. Make sure that the IR icon on the Windows system tool bar is visible to indicate that a NIOX MINO is within range.

3. Click **Format**. This will _**erase all configurations and measurement data**_ on a NIOX MINO Test Card. (The IR icon on the Windows system tool bar indicates that a connection to NIOX MINO has been established.)

Report Settings

Configure the Report (print-out) header: Enter text (for example the hospital name and address) and/or browse for an image (for example the hospital's logo) to use as a report header. The NIOX® Value logo is set as default and can be changed by selecting another _Logotype Image File_.

Receive and Save Service Data

Only to be used following contact with Aerocrine, Inc Support.

1. Place the NIOX MINO IR port close to the PC IR port.

2. Make sure that the IR icon on the Windows system tool bar is visible to indicate that a NIOX MINO is within range.

3. Click **Receive**. (The IR icon on the Windows system tool bar indicates that a connection to NIOX MINO has been established.)
4. Select a destination for the received Service Data.
5. Click **Save**. (It can take up to 30 minutes to transfer all service data)

**Service Mode can only be enabled with a password, but you can receive and save Service Data without a password.**

Caution!
Regular database backups are recommended. Each customer carries the sole responsibility to perform backups.

How to use the Visual Incentive

The Visual Incentive program will allow the patient to follow the exhalation procedure on a PC screen provided there is a stable IR link between the device and PC. There are a number of different desk-top IR adapters available.

Main Screen
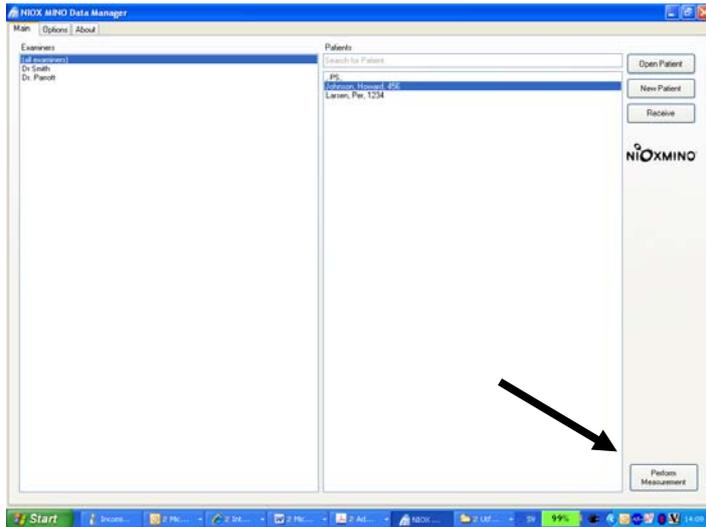
1. Click **Perform Measurement**
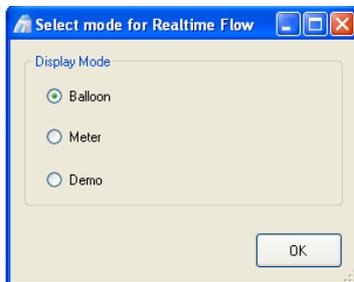
2. Select the display mode:

The **Demo** mode gives a possibility to demonstrate the measurement procedure when using the **Balloon** mode.

Balloon mode
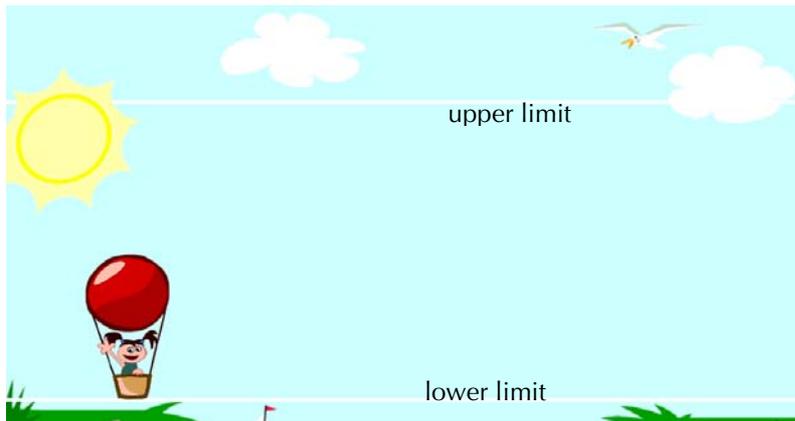
upper limit

lower limit

Too low pressure   Correct pressure   Too high pressure

Make sure that you have a quality connection between the device and PC.

The IR icon ▇ on the Windows system tool bar indicates that a connection to NIOX MINO has been established.
This is only visible just prior to the start of an inhalation maneuver.

Click **Balloon .**

1. **Insure NIOX MINO is activated**
2. Start to inhale from the device and a rising sun will be visible. Inhale to TLC (Total Lung Capacity).
3. Start to exhale and keep the balloon within the pressure limits. The balloon will not land, just disappear when the procedure has been completed.
4. Wait for the result to be presented on the NIOX MINO display
5. The IR connection will be disabled during the analysis of the sample

A pop-up will be shown in case you loose the IR communication.

- You can either continue the maneuver with the device without using the Visual Incentive

or

- Stop the maneuver and answer **Yes** and secure that you have a quality IR connection. Redo the maneuver from the beginning.

Meter mode
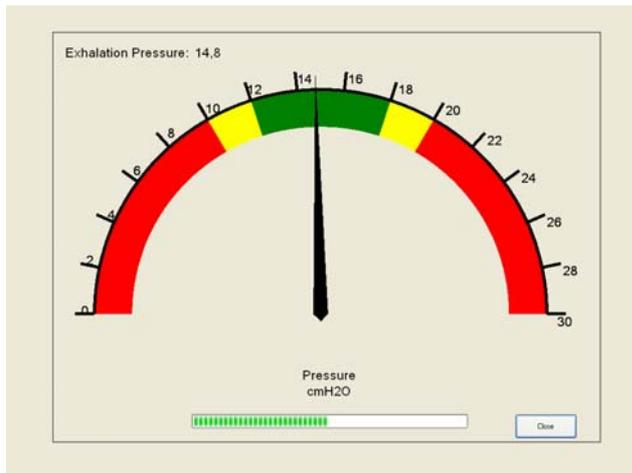
Exhalation Pressure: 14,8

Pressure
cmH2O

Close

Make sure that you have a quality connection between the device and PC.

The IR icon on the Windows system tool bar indicates that a connection to NIOX MINO has been established.
This is only visible just prior to the start of an inhalation maneuver
Click **Meter** .

1. **Insure NIOX MINO is activated.**
2. Start to inhale from the device. Inhale to TLC (Total Lung Capacity).
3. Start to exhale and keep the indicator in the green zone. The meter will just disappear when the procedure has been completed.
4. Wait for the result to be presented on the NIOX MINO display.
5. The IR connection will be disabled during the analysis of the sample

Device lost

Loss of IR communication, do you wish to restart measurement?

Yes   No

A pop-up will be shown in case you loose the IR communication.

- You can either continue the maneuver with the device without using the Visual Incentive

or

- Stop the maneuver and answer **Yes** and secure that you have a quality IR connection. Redo the maneuver from the beginning.

Measurement results can be transferred to a NIOX MINO Data Manager Patient Card as described on page 7-8 in this manual.

Troubleshooting

Error Messages (shown on the PC screen)	Action
Unable to find any device to communicate with	• Check that your PC has a built in IR Port. Otherwise you will need to have an external IrDA USB Adapter. A built in IR port cannot normally be used with the Visual Incentive. • Make sure NIOX MINO® is plugged in. • Check that the IR icon is visible in the Windows system tool bar and Check that the NIOX MINO IR port is facing the PC's IR port (see page 6) • Your NIOX MINO must have SW 1470 or higher and a NIOX MINO Data Manager software version 1.0.0.11 or higher in order to use the Visual Incentive.
No Test Card is inserted, unable to send data to it	Insert a NIOX MINO Test Card in NIOX MINO and retry.
An unknown error occurred (…)	Restart NIOX MINO Data Manager
Could not write to file	Contact Support
Could not write database backup file	Contact Support
Could not delete database after backing up	Contact Support
Data in the database is not consistent	Contact Support
An error occurred during transfer	Contact Support

For further assistance, please contact Aerocrine, Inc. support.

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New Providence, NJ 07974
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Phone: (866) 275-6469
Fax: (877) 329-6469
E-mail: service.US@aerocrine.com

Additional Programs included on the CD

Right-click on the CD icon (**Start** menu/ **My Computer**) and select **Open** to open the CD.

Windows 2000

Adobe Acrobat Reader installer
Double-click on the *AdbeRdr60_enu_full-Windows2000* icon to install.

Windows XP and Vista

Adobe Acrobat Reader installer
Double-click on the *AdbeRdr812_en_US* icon to install.

Appendix 1 - To display hidden files and folders

1. Open Folder Options in Control Panel.
   - Click **Start**, and then click **Control Panel**.
   - Click **Appearance and Themes***, and then click **Folder Options**.
2. On the **View** tab, under **Hidden files and folders**, click **Show hidden files and folders**.

*You might see the Folder Options directly