CHARTIS® PULMONARY ASSESSMENT SYSTEM CONSOLE

USER MANUAL

(Date of Issue: To be added once approved)

Manufactured by:

Pulmonx Corporation
700 Chesapeake Drive
Redwood City, CA 94063
United States of America
Tel: +1 (650) 364-0400

Pulmonx GmbH
Fürstenrieder Straße 263
81377 München
Germany

UK REP MDSS-UK RP Ltd.
6 Wilmslow Road, Rusholme
Manchester M14 5TP
United Kingdom

CH REP **Pulmonx International Sàrl**
Rue de la Treille 4, 200
Neuchâtel, Switzerland
Tel: +41 32 475 2070

CE 2797 UKCA 0086

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Contents

1. Introduction

The Pulmonx Chartis Pulmonary Assessment System is designed to measure pressure and flow in order to detect the presence of collateral ventilation in isolated lung compartments.

The system consists of:

- **Chartis Catheter and Connector Set (see Chartis Catheter Instructions for Use)**
- **Chartis Console**

The Chartis Console is a 2-part device consisting of a touchscreen tablet computer and a Patient Interface Box (PIB). The touchscreen tablet computer provides the user interface while the PIB houses the sensing equipment and associated electronics.

The Chartis Console includes:

- **1 Patient Interface Box (PIB)**
- **1 Touchscreen tablet computer**
- **2 Power Supplies with regional AC power cable**
- **1 User Manual (this document)**

Note: In this manual the word "device" is used to indicate the 2-part Chartis Console only, and the word "System" is used to indicate the Chartis Console in combination with the Chartis Catheter.

2. Indications for Use

The Chartis System is indicated for use by bronchoscopists during a diagnostic bronchoscopy in adult patients with Chronic Obstructive Pulmonary Disease (COPD) and emphysema in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information.

3. Safety and Performance

The Chartis System safety and performance information is available as a downloadable pdf of the IFU on the Pulmonx website: www.pulmonx.com.

4. Contraindications

The Chartis System is contraindicated in the presence of active infection or major bleeding diathesis. There are no known interfering substances.

4. Warnings and Precautions

- **Read all instructions carefully and in their entirety. Failure to properly follow the instructions, warnings and precautions may lead to patient injury.**
- **The System is to be operated by trained personnel only.**
- **The System is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.**
- **Check equipment for physical damage prior to use.**
- **As with any medical equipment, carefully route electrical cabling (i.e., power supply cabling) and pneumatic tubing (i.e., Chartis Catheter) to reduce the possibility of patient or user entanglement.**
- **To ensure patient safety, do not place the device in any position that might cause it to fall on the patient, or any position where its fall might cause it to pull on the Chartis Catheter while deployed in a patient.**
- **Do not move the Patient Interface Box while in use.**
- **Do not subject the device to excessive shock or vibration.**
- **Do not subject the device to excessive magnetic fields. Damage to the touch screen tablet computer and incorrect device operation may occur.**
- **Only the power supplies listed in the Specifications section of this manual are approved for use with the device. No other power supply should be used under any circumstances.**
- **The Chartis Catheter is the only type of catheter that can be used to safely interface with the Chartis Console**
- **The Chartis Console needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.**
- **Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Chartis Console, including cables specified by Pulmonx. Otherwise, degradation of the performance of this equipment could result.**
- **The use of accessories, transducers and cables other than those specified by Pulmonx, may result in increased emissions or decreased immunity of the Chartis Console.**
- **The Chartis Console should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.**
- **No modification of this equipment is allowed.**
- **The power supply must be unplugged from the wall power outlet in order to fully isolate the system from electrical power.**

- **Any serious incidents or serious adverse events that occur due to the use of the Chartis Console should be reported to Pulmonx (the manufacturer) and any relevant regulatory bodies (e.g., the European Competent Authority in the relevant EU Member State).**

5. Hardware

Warranty

Refer to the Chartis® Pulmonary Assessment System Limited Warranty card included with your shipment.

Disposal

For proper disposal of the Chartis Console or any of its accessories, dispose it in accordance with local, state, and federal regulations. Alternatively, you can return it to Pulmonx.

Radio Frequency Wireless Technology

The radio frequency functionality within the Chartis Console is completely redundant providing an alternative connection between the Patient Interface Box (PIB) and the Touchscreen tablet computer which can be physically connected to each other via the docking station provided on the Patient Interface Box (PIB). The data transmitted wirelessly are not life-supporting or life-sustaining and do not contain any patient data. This device complies with part 15 of the FCC Rules. Operation is subject to the following conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Below are the technical features of the wireless technology used:

Wireless Specification	
Design Name	BTM431 Laird Technologies
Transmitter Module FCC ID	PI4411B (Full Modular Approval)
Bluetooth® Version	2.0+EDR
Transmit Class	Class 2
Bluetooth SIG website Declaration ID	B016510
Frequency	2.402 – 2.480 GHz
Channels	79 channels Frequency Hopping, Adaptive Frequency Hopping
Max Transmit Power	+4 dBm from integrated antenna
Bluetooth Stack	V2.0 compliant. Fully integrated
EU Directive	RTTE 1995/5/EC
EU Directive Conformity Assessment:	Annex IV

6. Security

Information Security

Patient information is private, confidential, and subject to various regulations. Access to the Chartis Console is designed be controlled and limited to authorized users, and any patient data contained or generated by this device should be protected accordingly.

When entering data using the Chartis Console, it is your responsibility to protect your security credentials (e.g. passwords) and keep it confidential. Please do not use any patient protected health information (PHI) or individually identifiable health information of patients (e.g. names) to identify the assessments.

Wireless Security

The Chartis Patient Interface Box (PIB) and the Chartis Touchscreen tablet computer are directly connected when the tablet computer is placed in the docking station of the Patient Interface Box. The Chartis Touchscreen tablet computer may also be operated 'undocked' allowing it to connect with the Patient interface box via Bluetooth® Version 2.0+EDR using frequencies within 2.402 – 2.480 GHz - Class 2. To hinder connections with untrusted Bluetooth device(s) in the vicinity and to prevent malicious parties from intercepting the Bluetooth signal, multiple layers of security have been incorporated:

- The Chartis Tablet is not a discoverable Bluetooth device.
- The Chartis Tablet searches for the PIB using a unique prefix.
- Once discovered the Chartis Tablet pairs with the PIB using a preset PIN number.

Confidentiality

Confidentiality of patient information is assured as follows:

- The data transmitted between the Chartis Tablet and the Chartis PIB does not contain any patient-identifying information.
- All patient assessments are stored within the Chartis Tablet and access is limited to specific user login credentials.
- In the case of multiple users, you cannot access assessments created under another user's login credentials.
- Exported reports are also password protected and require the same password that was used to login to the user account when the patient report was exported.

Wireless Data Integrity

The Chartis software incorporates data integrity checks for data transmitted/received via the Bluetooth to ensure the completion and validity of the data received. If any data is incomplete or invalid, an error is displayed.

7. Symbols

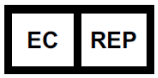
In this manual, displayed on device labels or the device itself, the following symbols are used:

Symbol	Meaning
CONT	Contents
REF	Catalog Number
SN	Serial Number
	Date of Manufacture
	Manufacturer
EC REP	Authorized European Representative
UK REP	United Kingdom Responsible Person
CH REP	Authorized Representative in Switzerland
	BF (Body Protected). The input connectors are suitable for connection to humans provided that there is no direct connection to the heart.
	See accompanying documentation. The supplied documentation must be consulted for operating, cautionary or safety information before using the device.
	Non-sterile
	WEEE (Waste from Electrical and Electronic Equipment). Device must be taken to a recycling center for proper disposal.
Rx only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

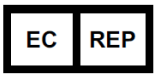
Symbol	Meaning
	Medical Device
	Fragile, handle with care
	Keep Dry
	Temperature Limit
	Humidity Limitation
	This way up
	Stacking Limitation: Do not stack more than two high when placing on a pallet.
	To indicate that the marked item or its material is part of a recovery or recycling process.
	MR Unsafe

7.1 Patient Interface Box (PIB)

Symbol	Meaning
	“ON”/”OFF” (push-push). Push to turn power ON or OFF
	Catalog Number
	Serial Number
	BF (Body Protected). The input connectors are suitable for connection to humans provided that there is no direct connection to the heart.

Symbol	Meaning
	Direct Current. The device uses direct currents.
	Date of Manufacture
	WEEE (Waste from Electrical and Electronic Equipment). Device must be taken to a recycling center for proper disposal.
	Non-sterile
	Manufacturer
	Authorized European Representative
	United Kingdom Responsible Person
	Authorized Representative in Switzerland
	Medical Device
	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
	Caution
	MR Unsafe
	See accompanying documentation. The supplied documentation must be consulted for operating, cautionary or safety information before using the device.
	Use By

7.2 Touchscreen Tablet Computer

Symbol	Meaning
	"ON"/"OFF" (push-push). Push to turn power ON or OFF
	Catalog Number
	Serial Number
	Direct Current. The device uses direct currents.
	Date of Manufacture
	WEEE (Waste from Electrical and Electronic Equipment). Device must be taken to a recycling center for proper disposal.
	Manufacturer
	Authorized European Representative
	United Kingdom Responsible Person
	Authorized Representative in Switzerland
	Medical Device
	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

	**Caution**
	**USB**
	**MR Unsafe**
	**See accompanying documentation. The supplied documentation must be consulted for operating, cautionary or safety information before using the device.**

8. Getting Started

8.1 Console Preparation

The Chartis Console may be placed on a tray, desktop or cart.

Warning	***The power supply when used must be connected to a grounded outlet.***

SETUP CONFIGURATION 1 – Tablet docked on PIB

1. **Connect the PIB to AC mains using the power supply provided.**
2. **Connect the touchscreen tablet computer to the Patient Interface Box by docking the tablet computer into the docking station on the Patient Interface Box.**
3. **Turn ON the system by pressing the power button on the front panel of the PIB. Both the PIB and touchscreen tablet will be powered on.**
4. **The tablet software will display a data connection symbol  to indicate that a data connection was established between the PIB and the touchscreen tablet.**

SETUP CONFIGURATION 2 – Undocked Bluetooth

1. **Connect the touchscreen tablet computer to power outlet using the power supply provided.** *Note: In case of a fully charged tablet computer, the power supply may not be required.*
2. **Connect the Patient Interface Box (PIB) to power outlet using the power supply provided.**
3. **Turn ON the Touchscreen tablet computer using the power button ⏻ to the side of the computer.**
4. **Turn ON the PIB by pressing the power button on the front panel.**

5. **The tablet software will display a data connection symbol to indicate that a data connection via Bluetooth was established between the PIB and the touchscreen tablet.**

SETUP CONFIGURATION 3 – Tablet docked using battery power

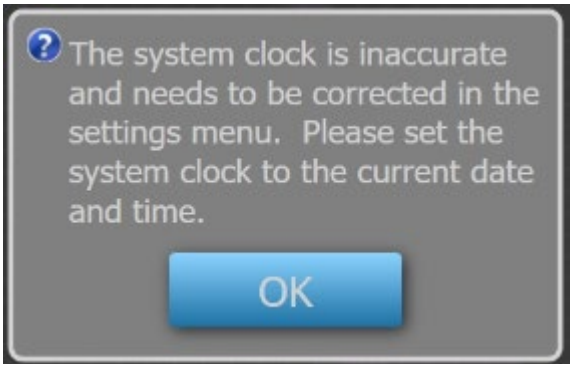
1. **Connect the touchscreen tablet computer to the Patient Interface Box by docking the tablet computer into the docking station on the Patient Interface Box. *Note: Setup Configuration 3 may only be used when the tablet battery is sufficiently charged.***
2. **Turn ON the Touchscreen tablet computer using the power button to the side of the tablet computer.**
3. **Turn ON the PIB by pressing the power button on the front panel.**
4. **The tablet software will display a data connection symbol to indicate that a data connection was established between the PIB and the touchscreen tablet.**

The Chartis Catheter will connect to the front quick-disconnect socket via the Connector Set. The socket on the back of the console is to remain unplugged during console operation.

Warning	***The Chartis Catheter should only be connected to the front quick-disconnect socket of the Patient Interface Box.****
Precaution	***All dust plugs must be unplugged before initiating a patient assessment.***

*** Refer to the Chartis Catheter Instructions For Use for preparation and proper attachment of the catheter to the console via the connector set.**

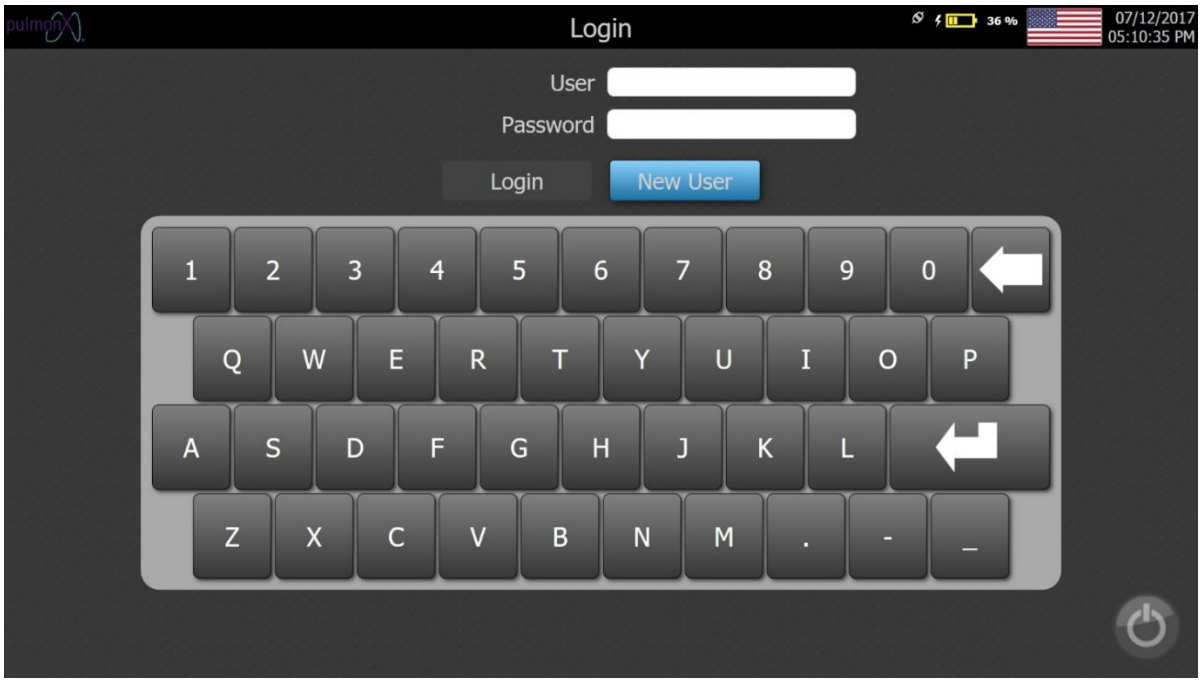
If the Chartis Console displays the following message at power-up, you must reset the date and time before performing a patient assessment to ensure that patient records reflect the correct date and time data.



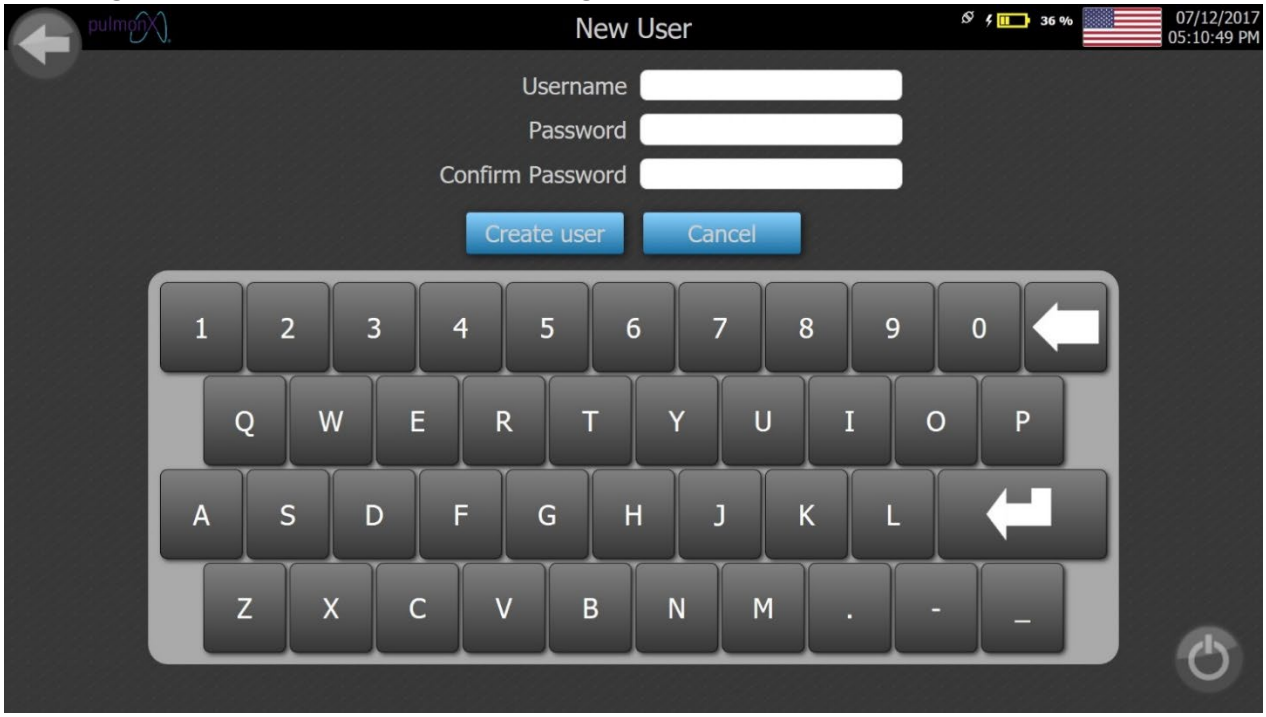
Dismiss this message by pressing OK, and then follow the instructions in Section 8.4.6 of the User Manual for setting the correct date and time.

8.2 Login Screen

Once the system software finishes booting up, the Login screen will appear.

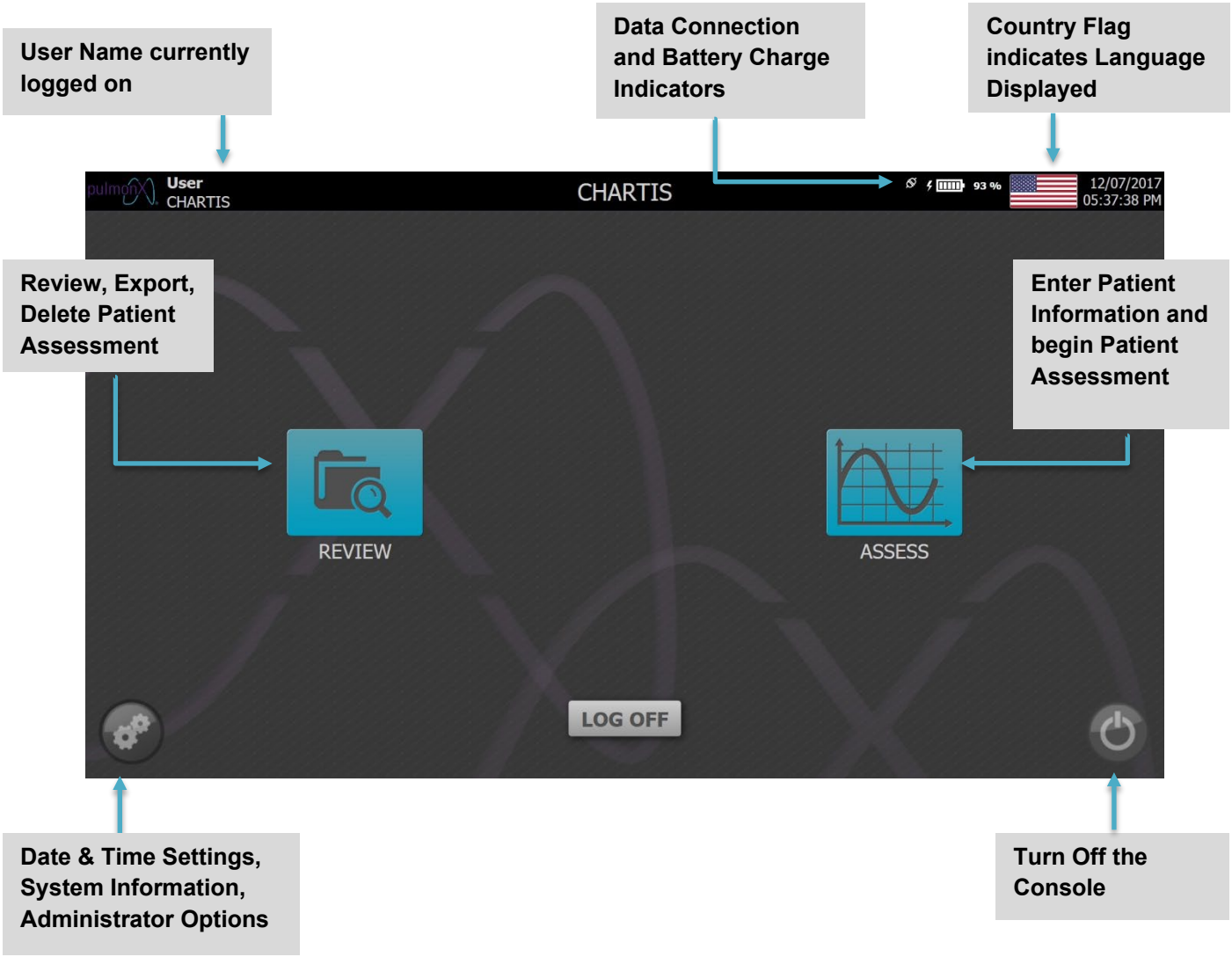


On the Login screen, an existing user may login by entering an existing user name and password and then pressing the login button. Additionally, a new user may be created by pressing the new user button and creating a new user name and password.



8.3 Home Screen

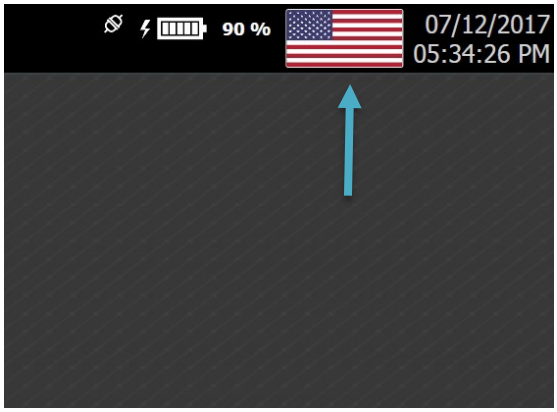
Once a User is logged in, the HOME screen will appear.



8.3.1 Language Selection

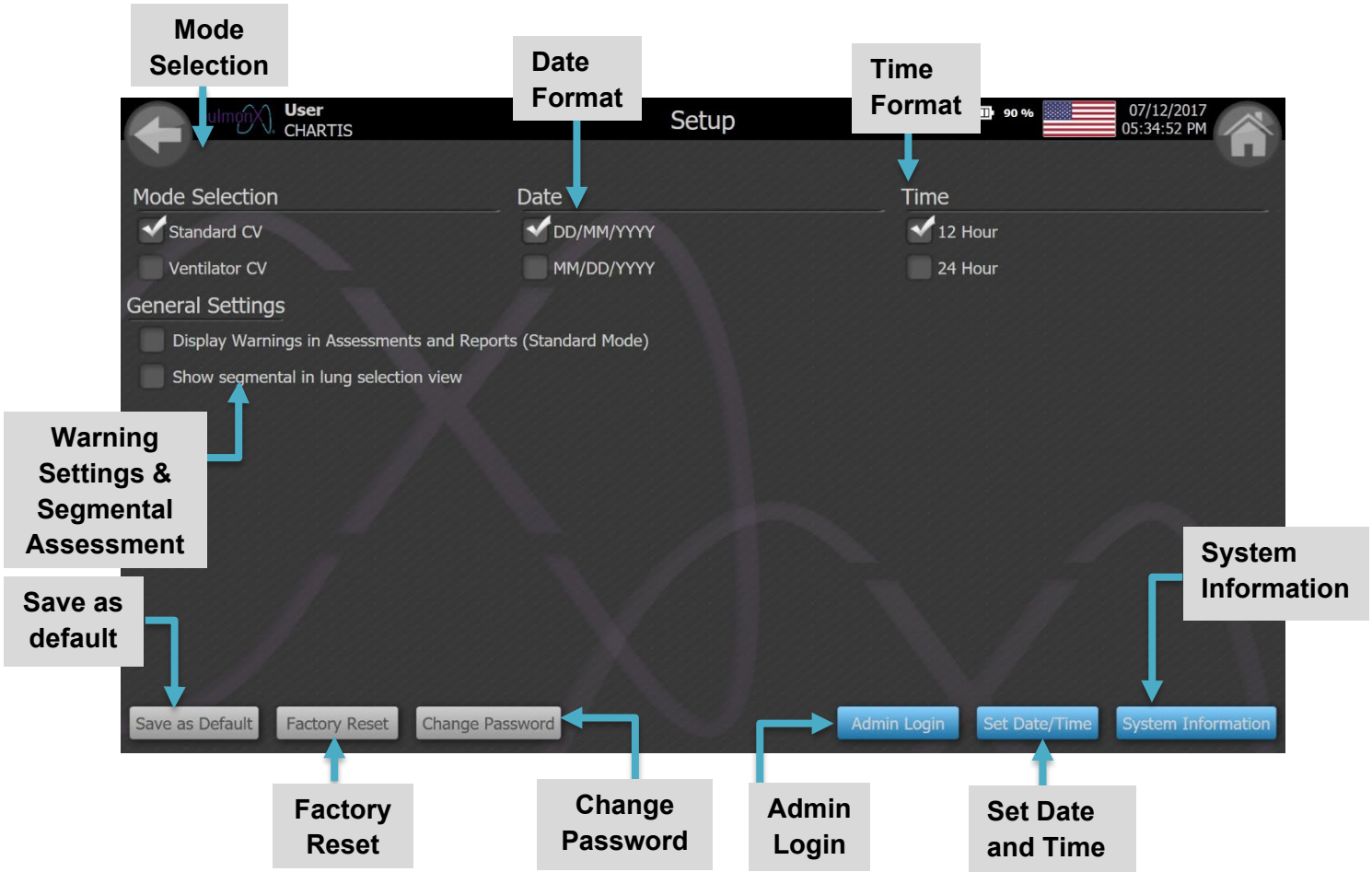
The default language for the Chartis Console is English. To change the displayed language on the Console, follow the directions below.

From any screen, touch the picture of the country flag. A language selection screen will pop up. Select the country flag for the desired language. This change will take place instantly and will remain in effect even when the console is power cycled.
Note: The German screens for data entry will use the English keyboard.



8.4 Setup Screen

From the HOME screen, press the icon on the bottom left corner of the page to display the SETUP screen. The Administrator screen (not shown) is only accessible via correct password entry and available to Chartis Console manufacturing representatives for calibration, testing, and troubleshooting.



8.4.1 Mode Selection

The MODE SELECTION checkboxes allow you to choose between Standard Mode [default] and Ventilator Mode for assessing a patient.

8.4.2 Date and Time Format

The DATE check box allows you to choose the date format that is displayed throughout the interfaces on the console. You can currently choose between DD/MM/YYYY (default) and MM/DD/YYYY. The TIME check box allows you to choose the time format that is displayed throughout the interfaces on the console. The selection options are in the 12 hour or 24 hour formats.

8.4.3 Warning Display

The 'Display Warnings' checkbox allows you to enable/disable warnings during a Standard Mode assessment, as well as on Review screens and in assessment reports. You can turn off the warnings by unchecking the box. To view a list of warnings, see Section 9.4.3.

8.4.4 Segmental Assessments

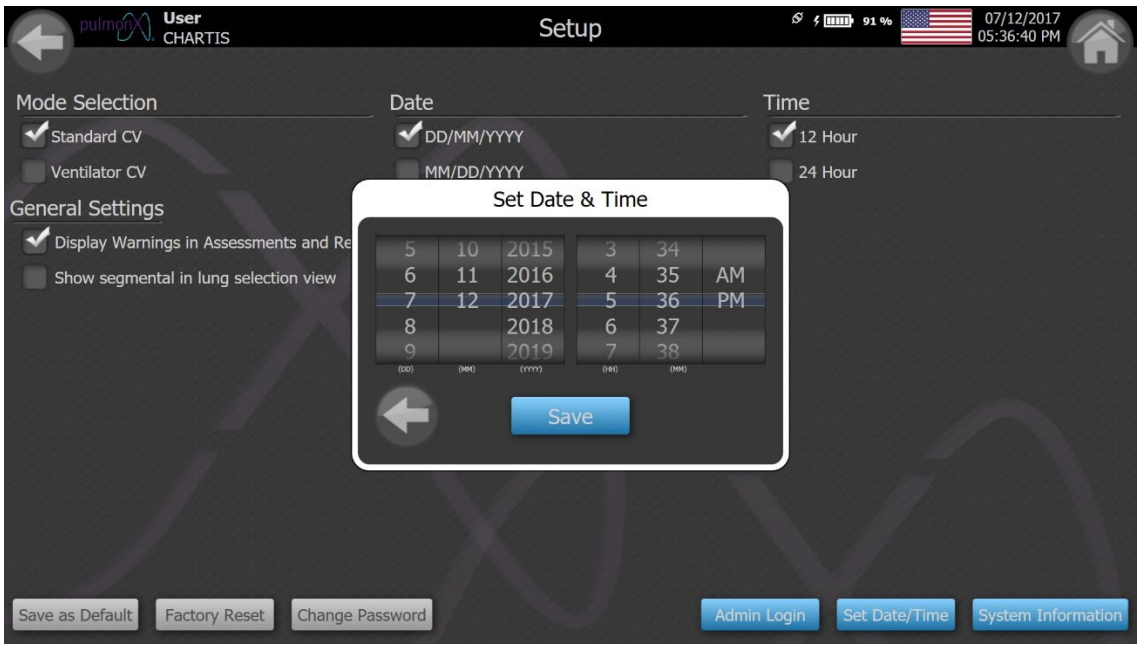
The "Show Segmental" checkbox allows you to enable/disable the segmental lung map on the assessment lung map.

8.4.5 Default and Factory Settings

The SAVE AS DEFAULT button allows you to save your settings so that they are the same when you restart the console. Choose your settings, and then press the SAVE AS DEFAULT button to save them. If you would like to revert back to the factory settings, press the FACTORY RESET button.

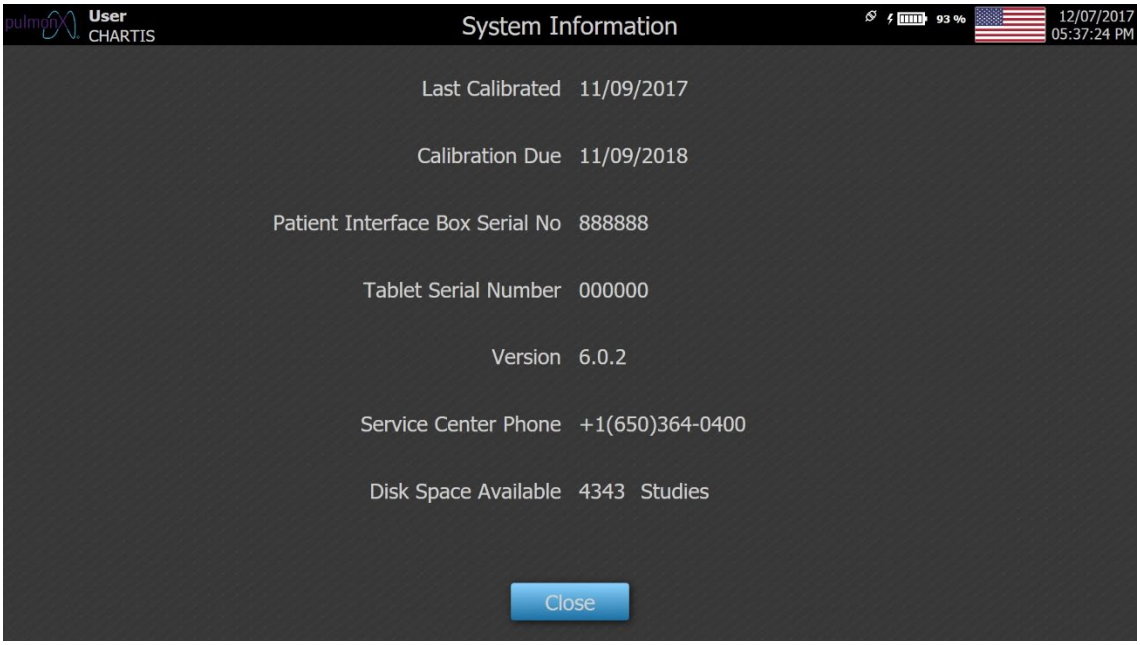
8.4.6 Setting Date and Time

Press 'Set Date/ Time' to open the Set Date and Time screen. Scroll up and down on each value to set the calendar date and local time. When the correct date and time are set, press the save button.



8.4.7 System Information

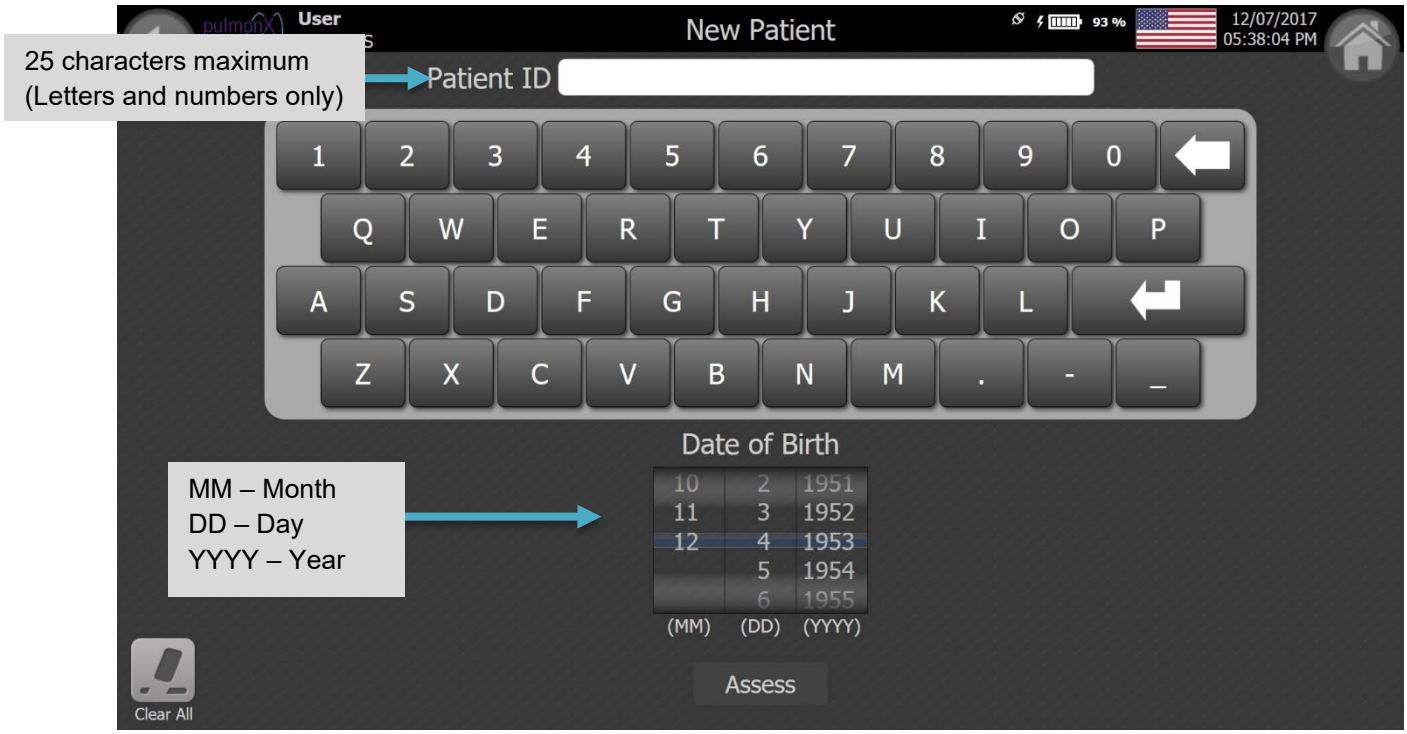
From the SETUP screen, press SYSTEM INFORMATION to display the system information (sample screen shown below). Press CLOSE to return to the SETUP screen, and then press HOME to return the HOME screen.



9. Standard Mode Patient Assessment

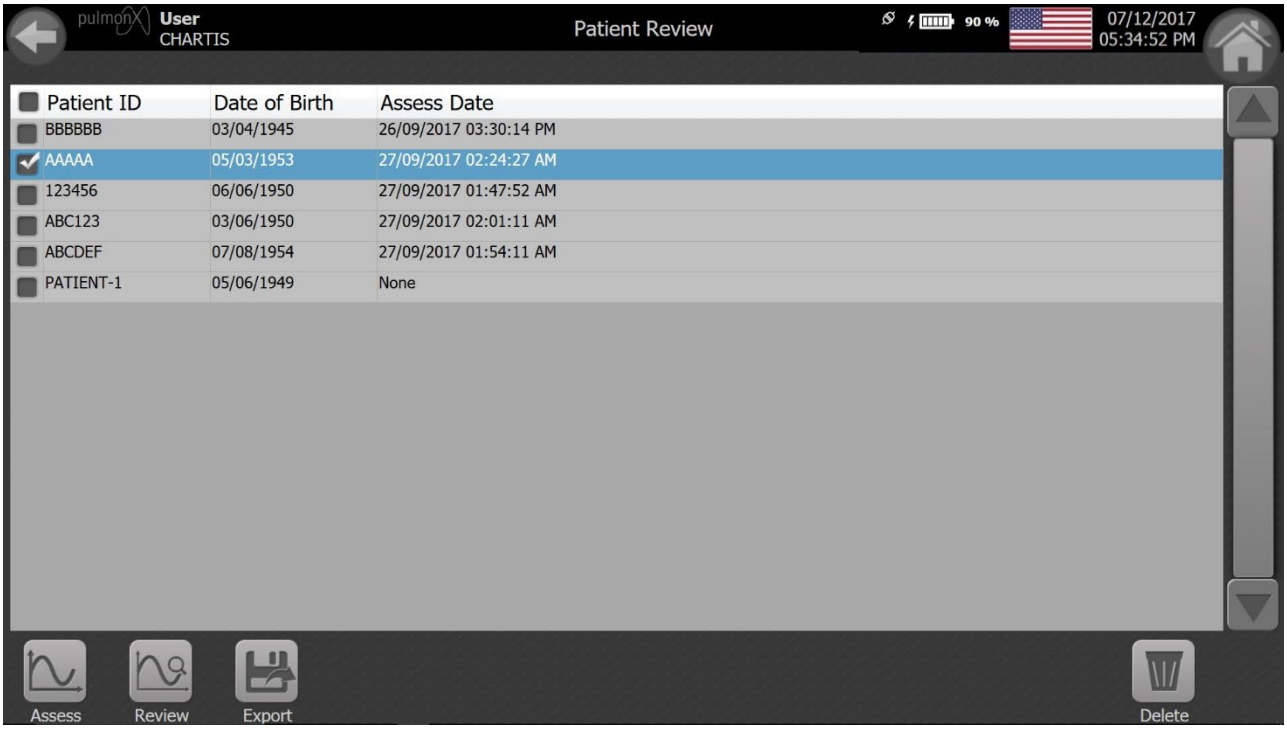
9.1 Patient Information

From the HOME screen press ASSESS to display the NEW PATIENT screen below. Press the field below Patient ID to enter the Patient ID using the keyboard below. Scroll up and down on the MM, DD, and YYYY values to set the Date of Birth.



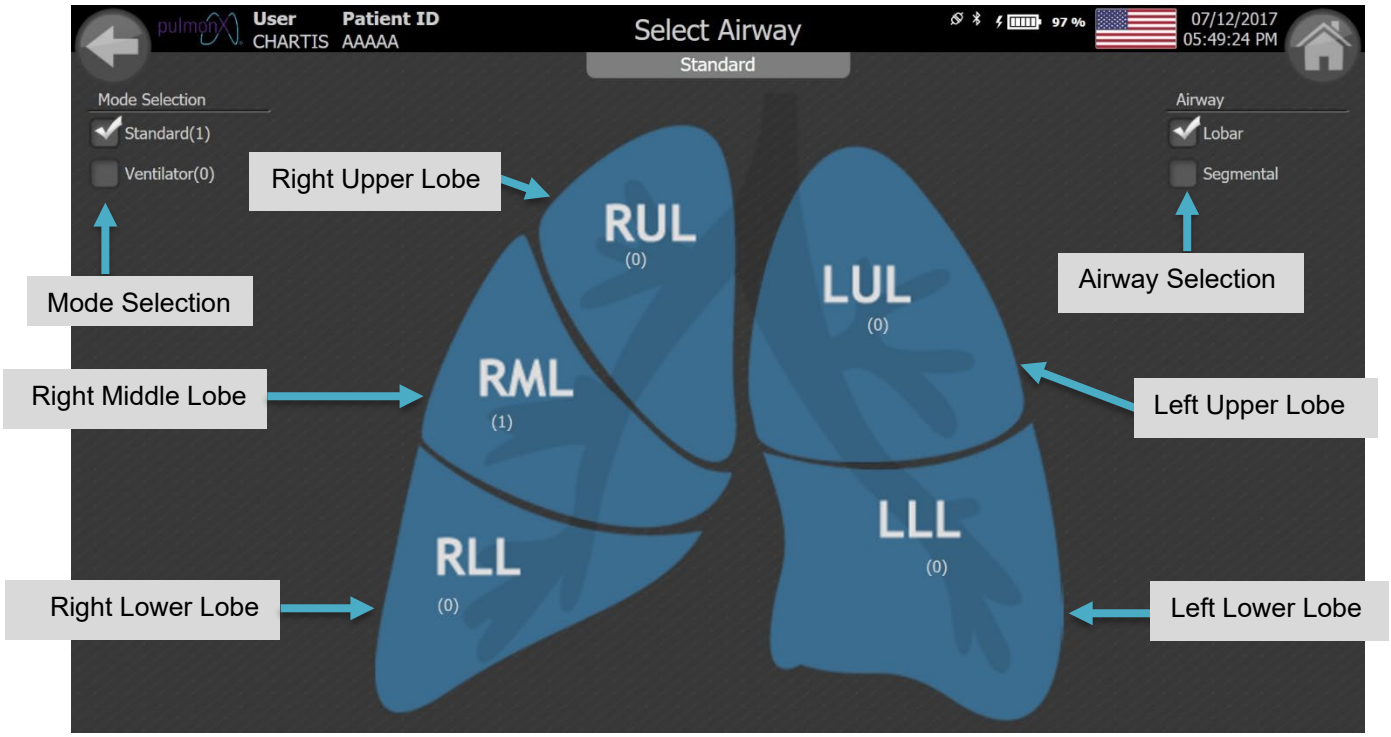
Once the Patient ID and Date of Birth have been entered, press the ASSESS button on the bottom of the screen to create the patient record and continue to the SELECT AIRWAY screen.

Note: Patients previously assessed that already have patient records can be reassessed through the PATIENT REVIEW screen. From the HOME screen, press REVIEW. Press a row to highlight the patient you would like to do another assessment for, and press ASSESS (see below).



9.2 Select Airway Screen

The SELECT AIRWAY screen for lobar and segmental assessments appears after pressing ASSESS on the NEW PATIENT screen. ***Note: the Segmental Airway Selection will only be available if this setting is checked on the Settings Screen.***

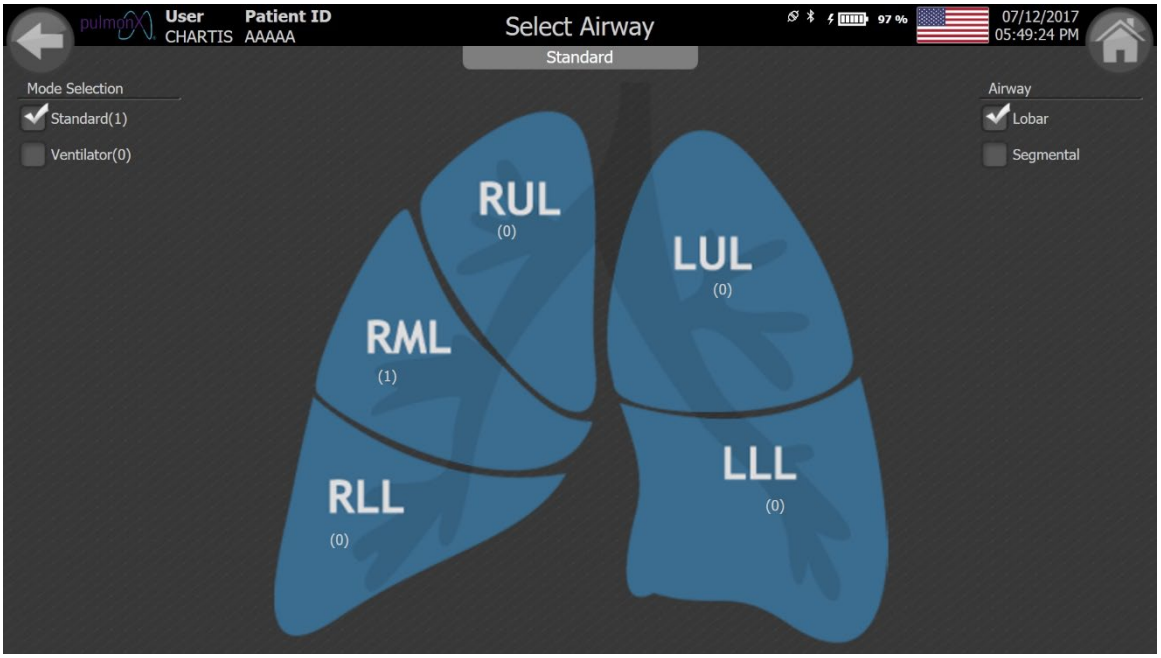


The MODE selection check boxes toggle between Standard and Ventilator modes. The AIRWAY selection check boxes toggle between the LOBAR and SEGMENTAL lung maps. Selecting LOBAR will record assessments at the lobe level and SEGMENTAL will allow assessments of individual airways within the lobe. The number of assessments in each mode performed for each lobe and segmental region is shown below the lobe name with the following format:

([# LOBAR ASSESSMENTS]**, S:** [# SEGMENTAL ASSESSMENTS] **)**

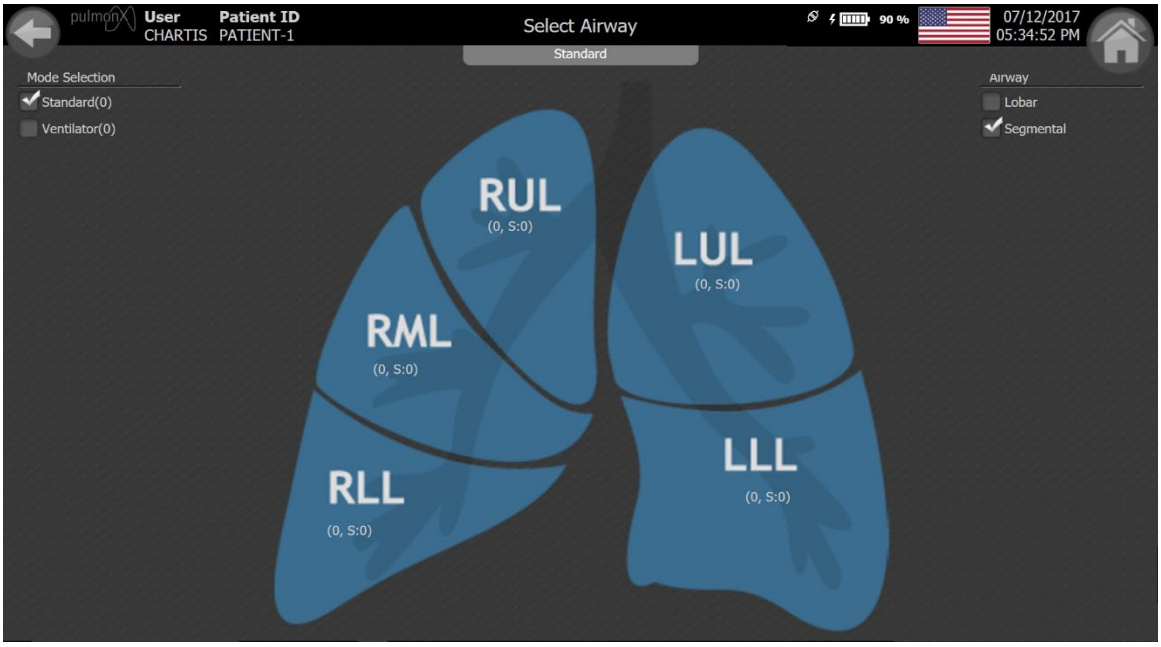
9.2.1 Lobar Assessment

Press LOBAR using the Airway selection check boxes [default selection]. Select the mode to perform the assessment in. Select a lobe to assess by pressing the desired lobe in the diagram. The ASSESS screen will appear.

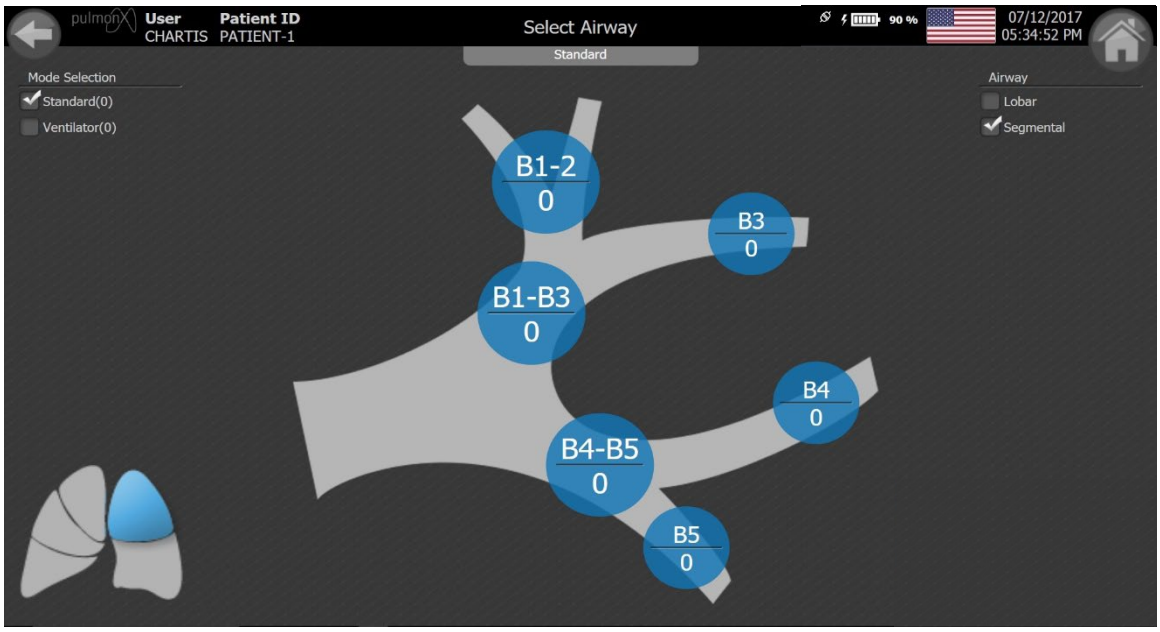


9.2.2 Segmental Assessment

Press SEGMENTAL using the AIRWAY selection check boxes (as shown below).



Select a lobe to view the segmental lung map for that lobe by pressing on the desired lobe in the diagram. The system will navigate to the segmental lung map (as shown below).



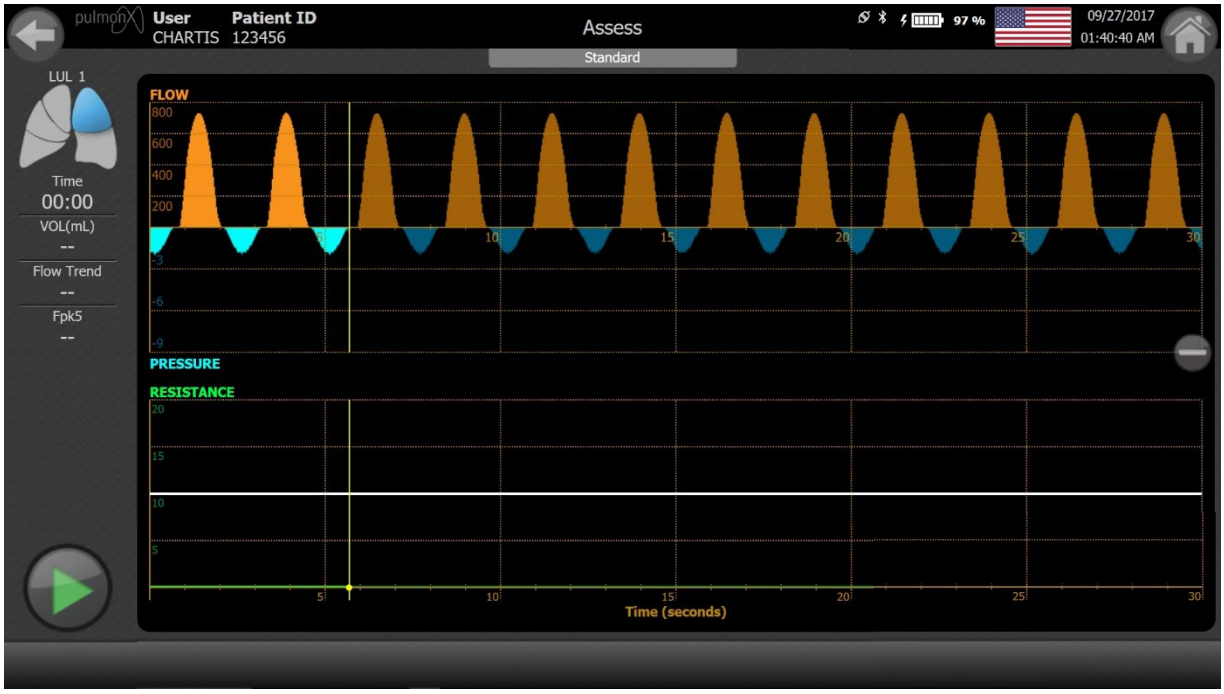
Select the mode to perform the assessment in. Select a segment to assess by pressing on the desired segment in the diagram.
You will be directed to the ASSESS screen.

9.3 Assessment Screen

The selected lobe and corresponding total number of assessments performed for that lobe will be displayed at the top left of the assessment screen in the format <LOBE>-<ASSESSMENT #>. The ASSESSMENT screen has two charts:

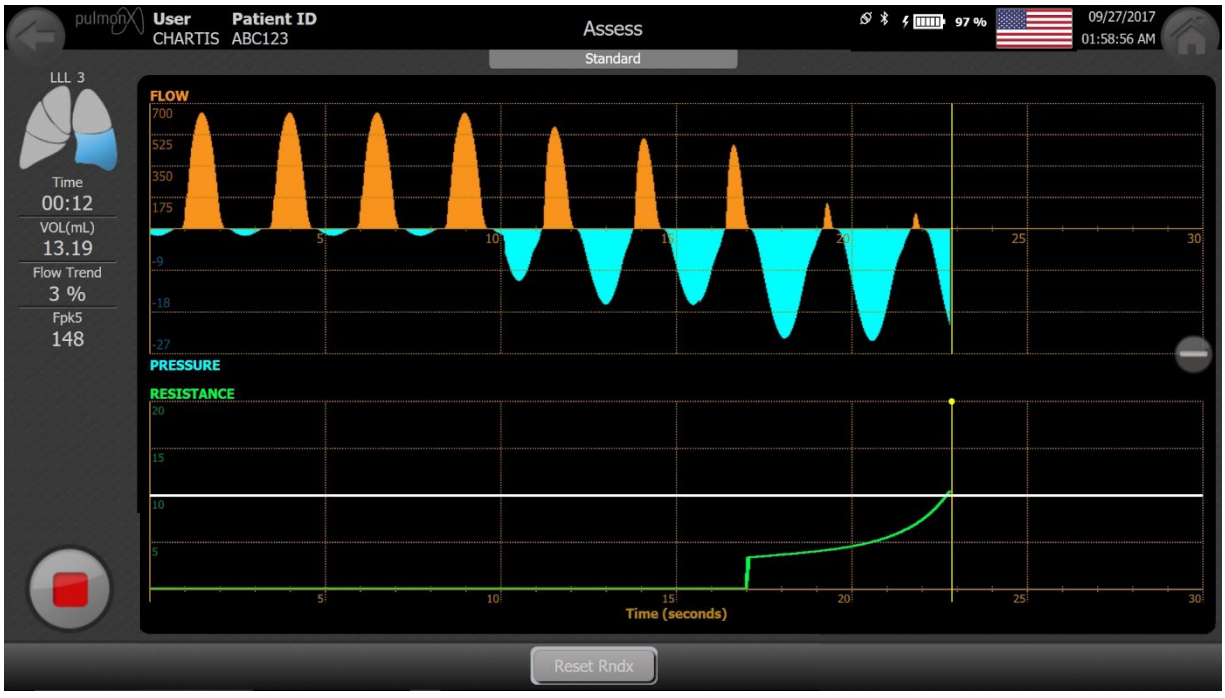
CHART	PARAMETER / COLOR	DESCRIPTION
UPPER	F (mL/min) / *ORANGE*	EXPIRATORY FLOW (F) VS. TIME
	P (cmH_2O) / *LIGHT BLUE*	INSPIRATORY PRESSURE (P) VS. TIME
LOWER	Rndx / *GREEN*	AIRWAY RESISTANCE INDEX (Rndx) VS. TIME (UNITS OF cmH_2O×sec/mL)
	Rrt / *WHITE BALL CURSOR*	REAL-TIME AIRWAY RESISTANCE (UNITS OF cmH_2O×sec/mL)

The baseline state of the combined flow and pressure trace is displayed below. When the dataset reaches the far right of the screen, it continues from the left, overwriting the previous data sweep. Note that the previous data sweep is dimmed to highlight the location of the newest data (yellow vertical cursor).



9.4 Performing an assessment

Press the START button on the lower right hand corner to initialize the assessment. This collects 10 seconds of baseline flow and pressure data from the isolated airway.



After the 10-second initialization is complete, the console will close a valve to prevent flow back into the isolated lobe during inspiration. This will result in the inspiratory pressure increasing in magnitude. The top chart autoscales the positive region of the vertical axis based on the maximum value of flow in the 10-second initialization, after which this region is fixed. The top chart continuously autoscales the negative region of the vertical axis based on maximum value of inspiratory pressure throughout the assessment. The bottom chart has a vertical scale fixed at a maximum Rndx of 20 $cmH_2O \times sec/mL$.

9.4.1 Parameters

At the left side of the ASSESS screen, the following parameters are displayed:

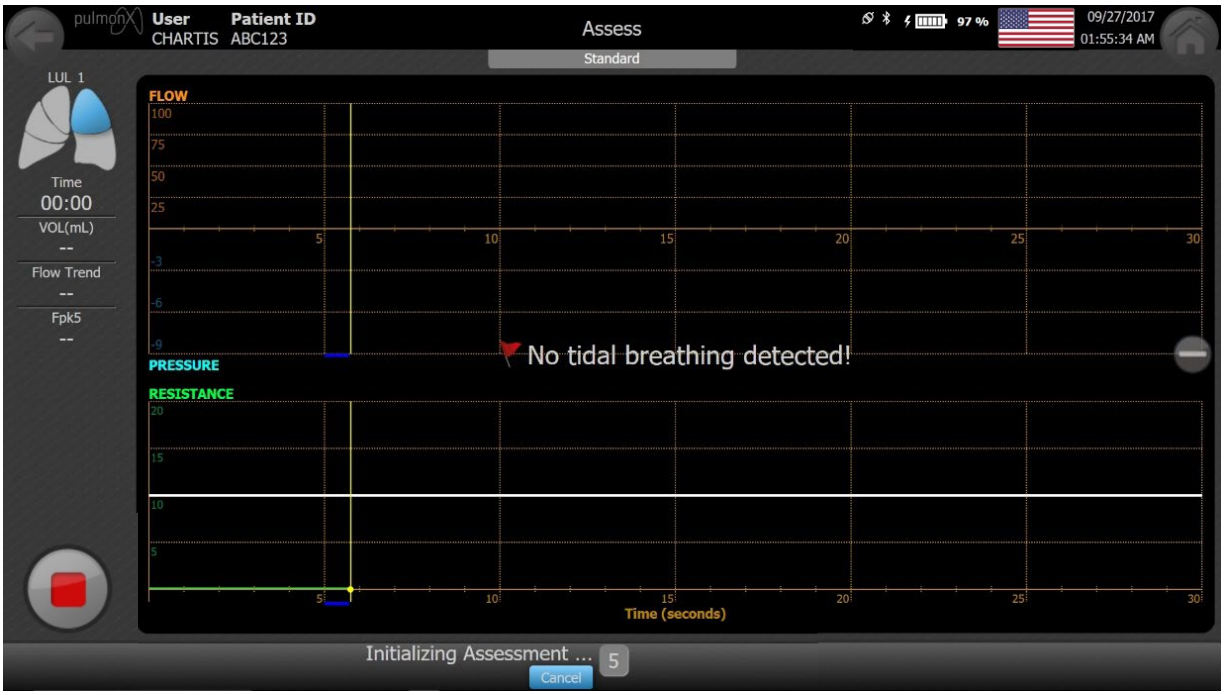
PARAMETER	DESCRIPTION	UNITS
Time	ASSESSMENT DURATION	minutes:seconds
Volume	TOTAL EXPIRED AIR VOLUME	mL
Flow Trend	EXPIRATORY FLOW VOLUME AS A PERCENTAGE OF THE AVERAGE EXPIRED VOLUME PER BREATH CALCULATED DURING THE 10-SECOND INITIALIZATION PERIOD	%
F_{PK5}	PEAK EXPIRATORY FLOW UPDATED EVERY 5 SECONDS OVER THE MOST RECENT 5-SECOND WINDOW	mL/min

9.4.2 Window Buttons

BUTTON	DESCRIPTION
	The ZOOM button, located between the pressure and Rndx graphs, allows the user to zoom in (+) or zoom out (-). On Review screens in Standard Mode, there is a ZOOM button for the combined flow and pressure graph, and another for the combined Rndx and Rrt graph.
	Press the START button to start an assessment.
	Press the STOP button to stop at the end of a satisfactory assessment period. The ASSESSMENT REVIEW screen will appear.
	Press the Reset Rndx button to reset the resistance index calculation. A caret (^) shall be displayed in the pressure and Rndx graphs, indicating when the user reset the calculation.

9.4.3 Warnings

During an assessment you may see the following warnings flash on the display next to the red flag between the two charts (see below).



The following table describes warnings that may be encountered during a Standard Mode assessment.

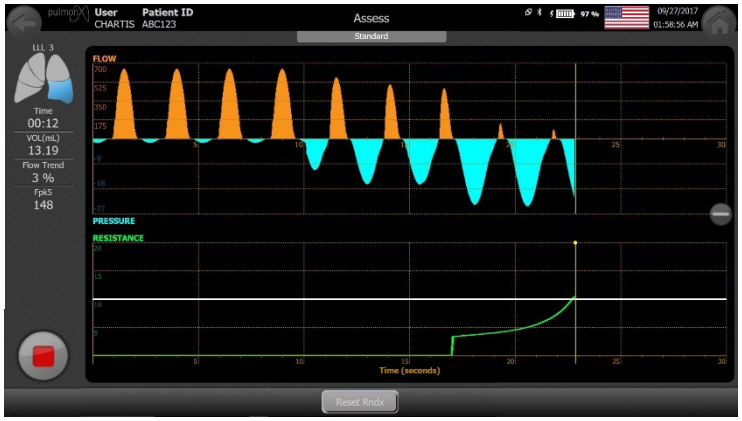
WARNING	DESCRIPTION
Clog Detected	The system displays a text warning and yellow warning indicator bars to indicate detection of clogs during a Standard Mode assessment.
No Tidal Breathing Detected	The system displays a text warning and dark blue warning indicator bars to indicate failure to detect tidal breathing during the 10-second pre-assessment and post-assessment periods of a Standard Mode assessment.

If enabled on the SETUP screen, the warning bars will be displayed on the Review screens and assessment reports.

9.4.4 Rndx Trend

The 3-image sequence below shows the rise in calculated airway resistance index (R_{ndx}) that may occur during a Standard Mode assessment.

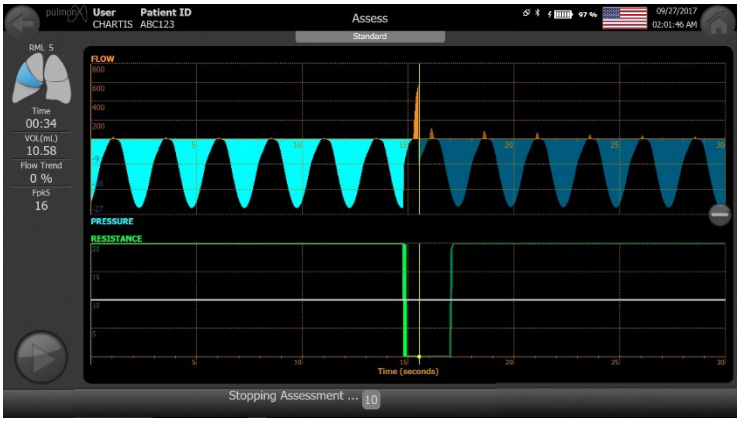
Increasing Rndx graph



Rndx graph at its peak

The STOP button is pressed to end an assessment, and the valve then opens during inspiration, as illustrated by the drop in magnitude of the inspiratory pressure. Ten seconds of post-assessment flow and pressure data are recorded.

Drop in Rndx after the valve opens



9.5 Post-Assessment Review

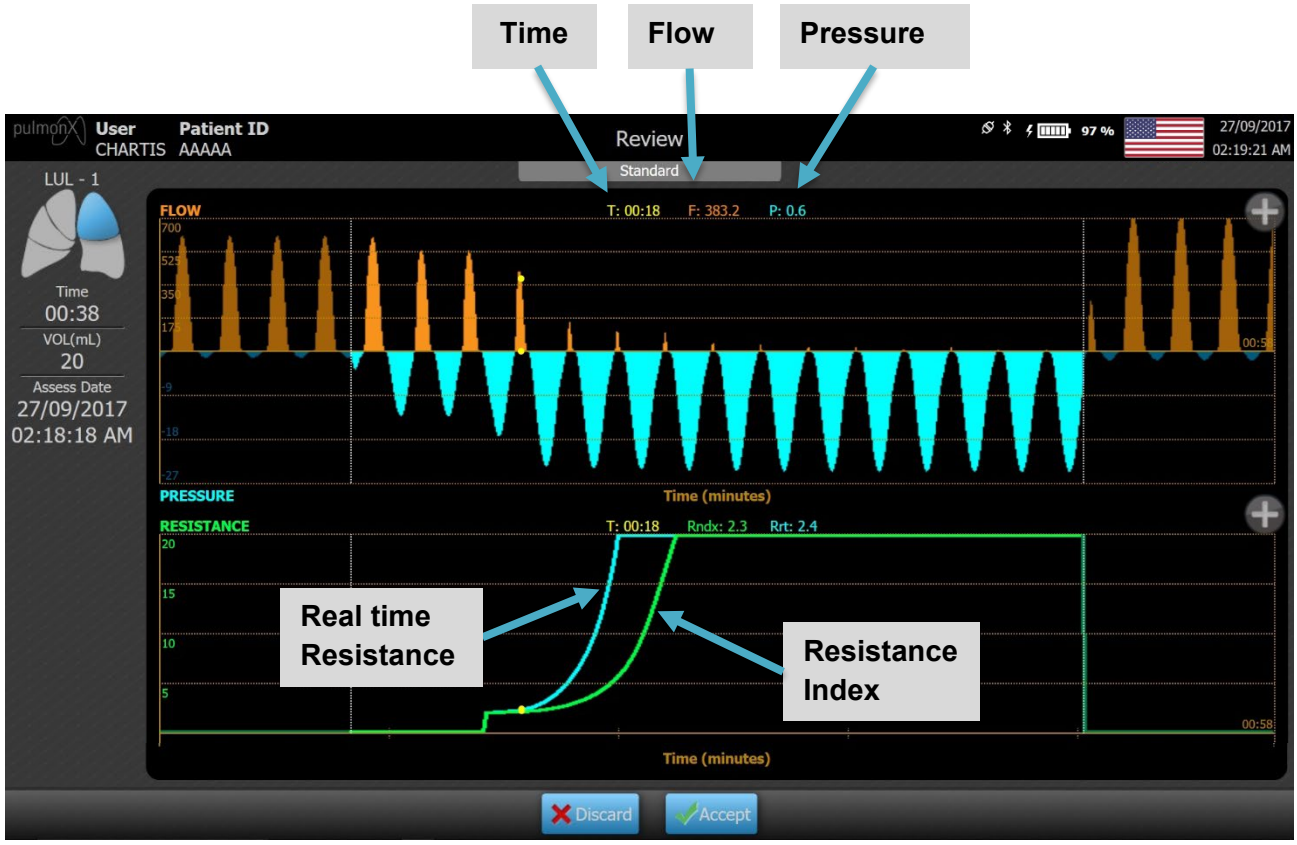
The ASSESSMENT REVIEW screen appears showing the pre-assessment initialization, assessment period, and post-assessment period, all separated by two vertical white dotted lines. Both the pre-assessment initialization and post-assessment periods are dimmed to further highlight the assessment period.

Pressure and Flow data (upper chart): Touch and drag the yellow cursors to determine the value of flow (orange) or pressure (light blue) anywhere in the patient assessment dataset.

Resistance Index (lower chart): Shows the time history of the airway resistance index (green) and real-time resistance (light blue). Touch and drag the yellow cursors to determine the value of airway resistance index and real-time airway resistance anywhere in the patient assessment dataset.

Assess Time: Reports the duration of the assessment.

Vol (mL): Reports the total volume exhaled during the assessment.



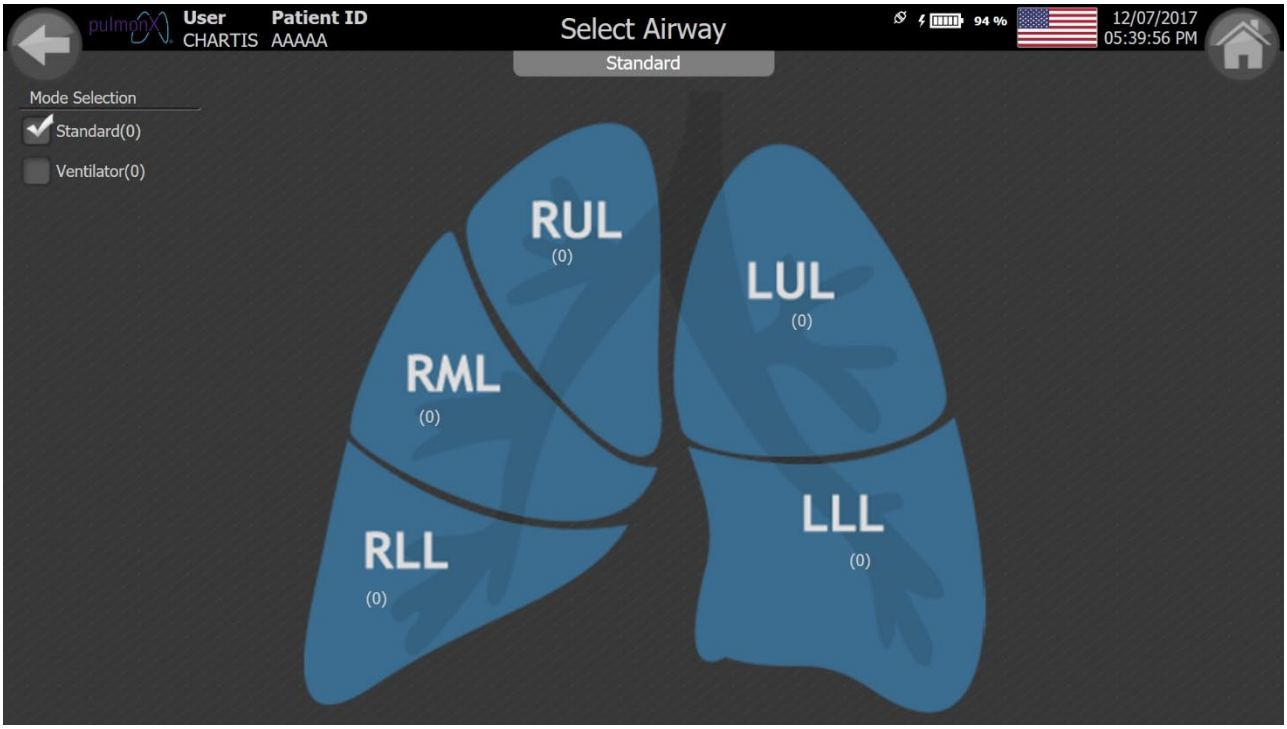
If there are reasons to discard the assessment, press DISCARD and then press CONFIRM.

Otherwise, press ACCEPT to accept the assessment.

The system will redirect to the most recently visited airway selection screen (lobar or segmental map). The user can select a new airway for assessment, or the user can press the HOME button to return to the HOME screen (return to 8.3).

9.6 Performing additional assessments

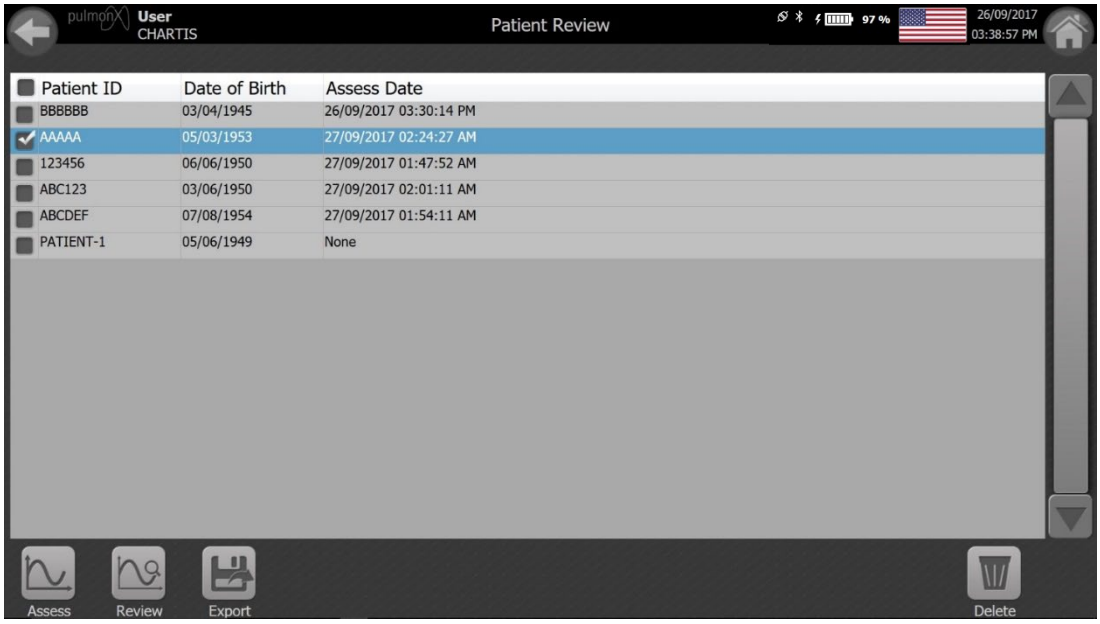
If necessary, deflate the balloon, reposition the catheter, and re-inflate per the Chartis Catheter Instructions for Use. Upon returning to the SELECT AIRWAY screen, the number of assessments will update accordingly.



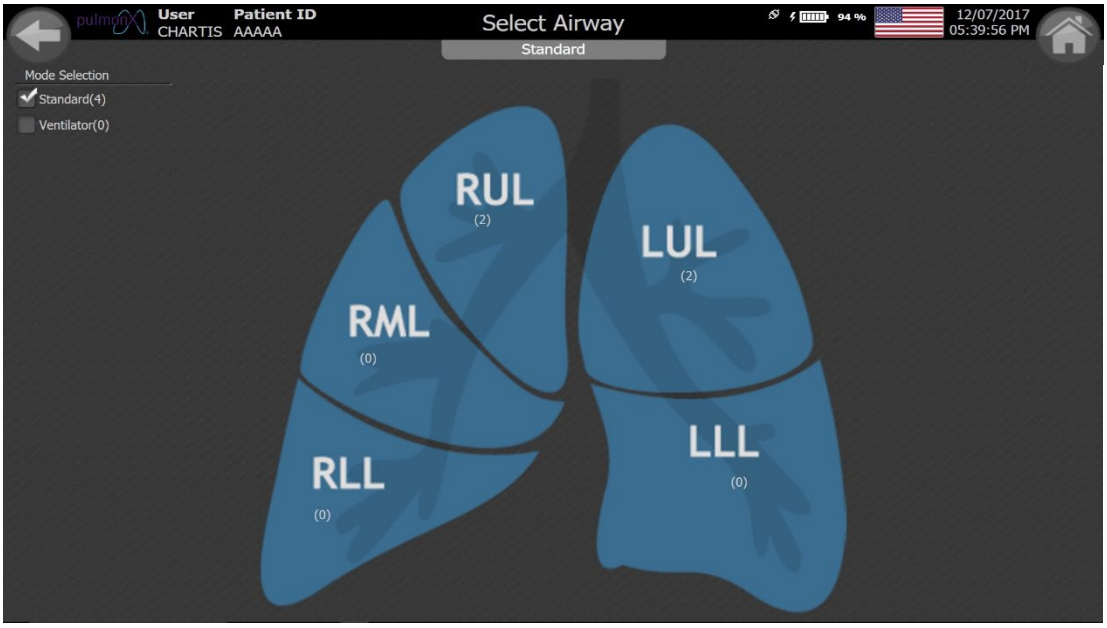
Perform additional assessment(s) per Section 9.3, ASSESSMENT SCREEN.

9.7 Patient Review Screen

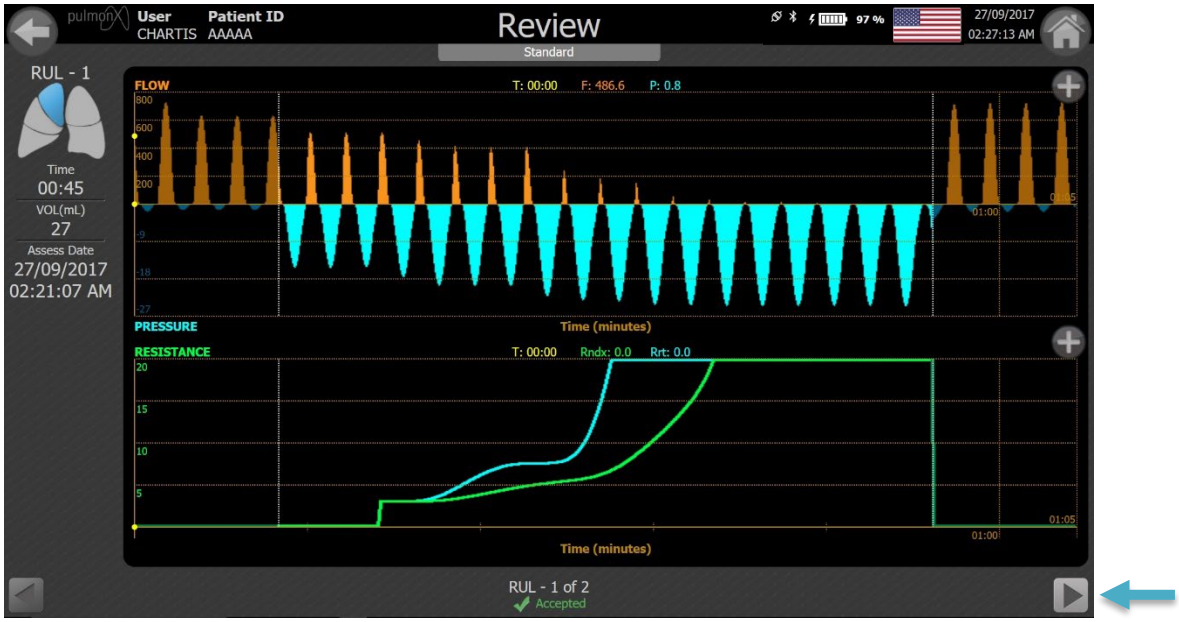
From the HOME screen, press REVIEW to display the PATIENT REVIEW screen. Touch a row to highlight the patient for review, and press REVIEW.



The SELECT AIRWAY screen appears. Select an airway to review by pressing on the desired area in the diagram. The AIRWAY check boxes can be used to review segmental assessments by pressing SEGMENTAL, pressing a lobe, and then pressing a segment to review (refer to 9.2.2).



The ASSESSMENT REVIEW screen appears, and the arrow buttons at the bottom of the screen can be used to toggle through multiple assessments for the same lobe. Touch and drag the yellow cursors to determine the value of flow, pressure, airway resistance index, and real-time airway resistance anywhere in the patient assessment dataset.



In the sample image above, it is indicated that the assessment was ACCEPTED. In the sample image below, the assessment was DISCARDED.

To zoom in at the cursor location, press the magnifying glass (+) in the upper right corner of the chart. Press the magnifying glass (-) to zoom out. Note: The upper and lower charts zoom controls are independent of each other.

10. Ventilator Mode Patient Assessment

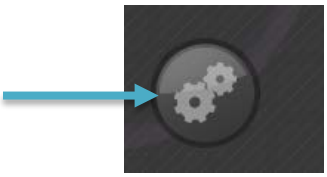
Ventilator Mode is a simplified assessment screen to display only flow data when assessing patients under a ventilator. Presence of continuous flow determines presence of CV. As a result, inspiratory pressure is no longer required on display. The valve actuation algorithm does not change between Ventilator and Standard modes.

10.1 Enabling Ventilator Mode

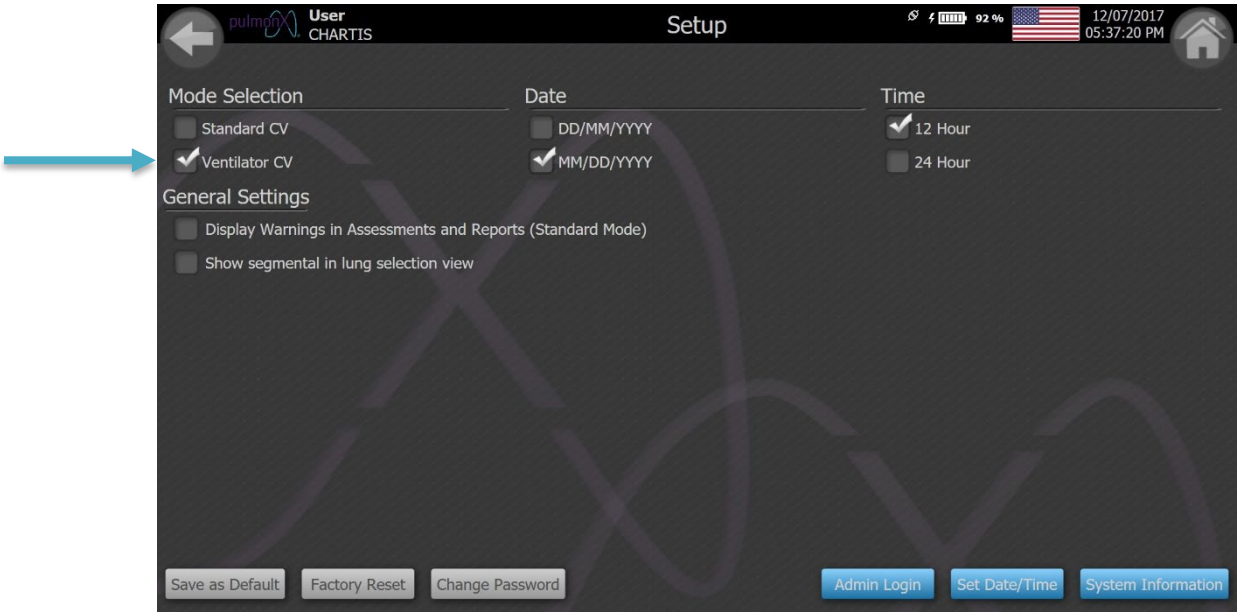
Ventilator mode can be enabled in 2 ways:

10.1.1 From the Settings Panel

On the HOME screen, press the settings icon at the bottom left of the screen (shown below).

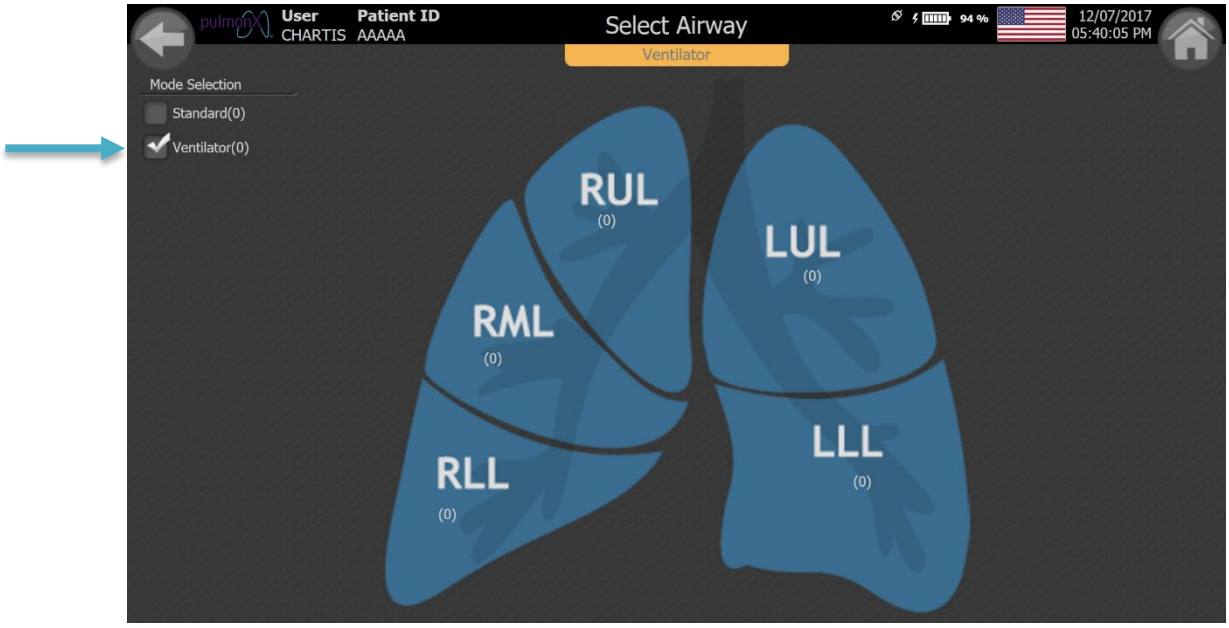


On the SETUP screen, press the VENTILATOR check box under MODE SELECTION to enable Ventilator Mode. Press the HOME button in the upper right hand corner to return to the HOME screen (return to 8.3).



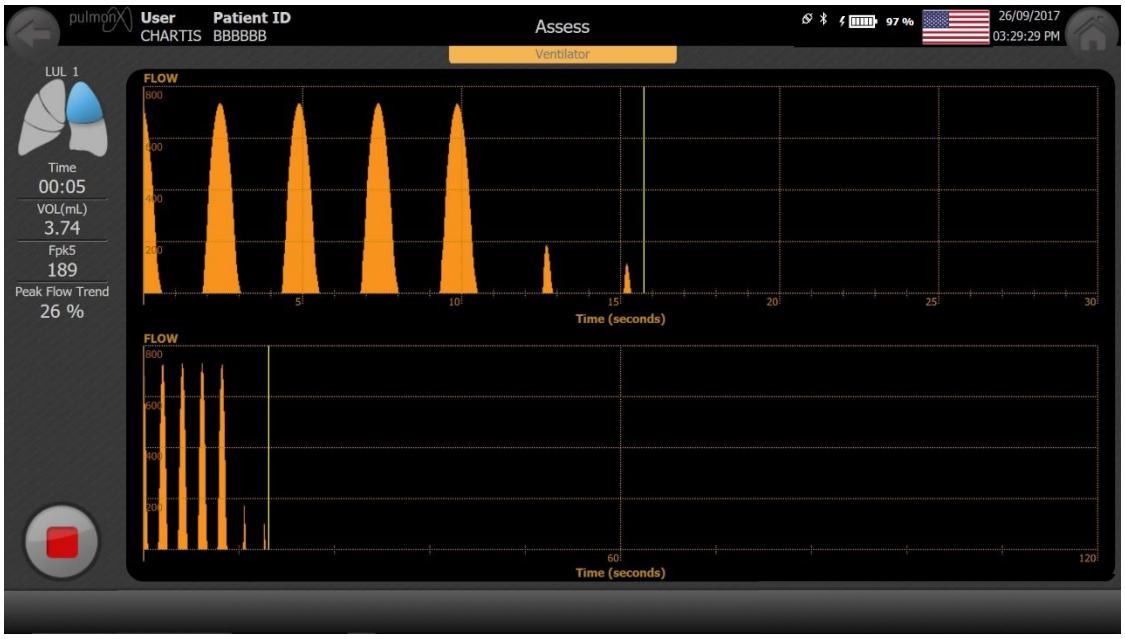
10.1.2 On the Select Airway Screen

Before performing an assessment, the SELECT AIRWAY screen provides the user the ability to select the mode of assessment.



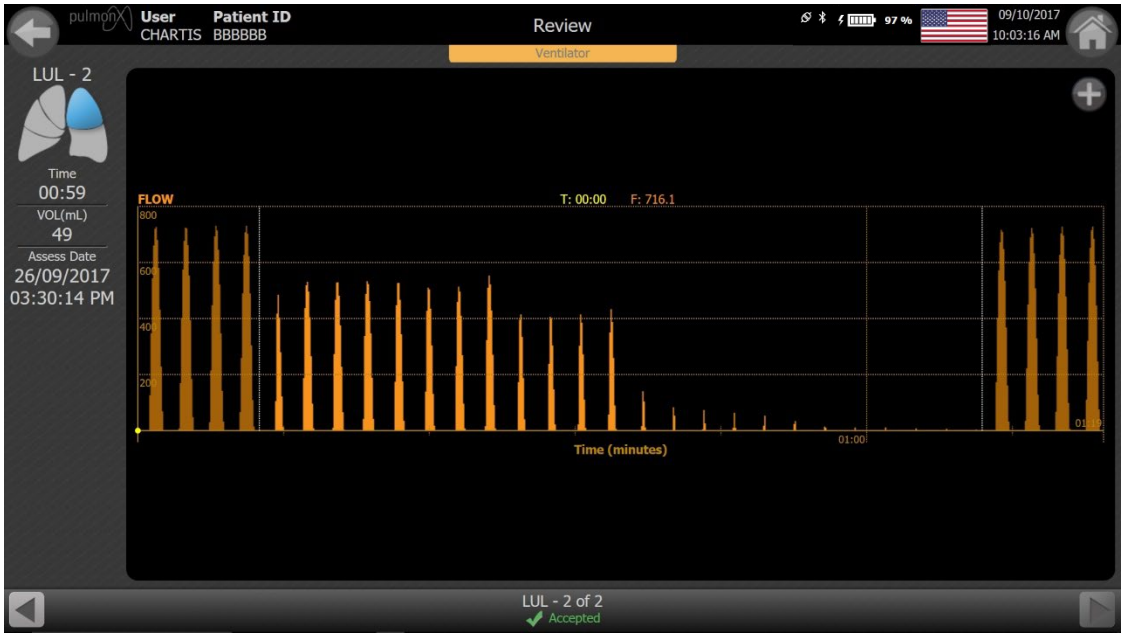
10.2 Performing an Assessment

The steps leading up to an assessment such as creating a patient (refer to Section 9.1 for Patient Information) and selecting a lobe (see Section 9.2 for Select Lobe Screen) are the same as Standard Mode. The assessment screen for ventilator mode is similar to the Standard Mode except it does not show the combined Flow and Pressure trace (see 9.3). The upper chart shows only 30 seconds of positive expiratory flow while the lower chart shows 2 min of flow data. The Peak Flow Trend that is displayed in the Ventilator mode is the Expiratory Peak Flow during assessment expressed as a percentage of the average peak flow calculated in the 10-second pre-assessment period. Navigating the POST-ASSESSMENT REVIEW screen is the same as for Standard Mode assessments (refer to Section 9.5).



10.3 Reviewing an Assessment

Follow the same steps for Standard Mode to review a Ventilator Mode assessment (refer to Section 9.7). The REVIEW screen for Ventilator Mode will only display the summary Flow chart and Volume measurement.



11. Exporting Patient Assessment Data

Insert a USB flash memory device into the USB-A port on the side of the touchscreen tablet computer.

Warning ***No other type of device is approved for connection to the touchscreen tablet computer USB ports including, but not limited to, keyboards, mice or other pointing devices, powered memory devices (which require external power to operate), still cameras, video cameras, music players, and other multimedia devices.***

From the PATIENT REVIEW screen, press the checkbox next to the patient (or double- press the row) to select it, and then press EXPORT.

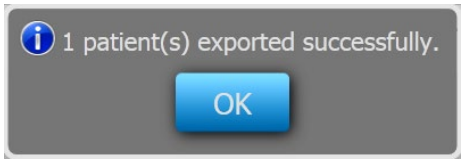
The patient data files, including a report in PDF format for each saved assessment (see below), will be copied to the USB flash memory device.

PDF Report Filename Format:
[Patient ID]_[Lobe]-[Assessment #] [Assessment Mode]_Report.pdf

PDF Report Drive Location:
[Drive]:\Pulmonx\ChartisConsole\patient_data\[Patient ID]_[Assessment Mode]

[Assessment Mode] will be either STD (Standard Mode) or VEN (Ventilator Mode).

When exporting patient data from the Chartis Console, you must complete the data export process by pressing OK to this message before removing the USB flash memory device.



NOTE: Removing the USB device before the data export process is complete will corrupt the data on the USB flash memory device.

Warning ***Wait 10 seconds before removing the USB device.***

The reports can be opened on any Windows PC system with a PDF viewer. The report is password protected and requires the same password that was used to login to the user account when the patient was exported.

Sample PDF reports for Standard Mode and Ventilator Mode are shown below:

SAMPLE STANDARD MODE ASSESSMENT REPORT

Standard Assessment Report

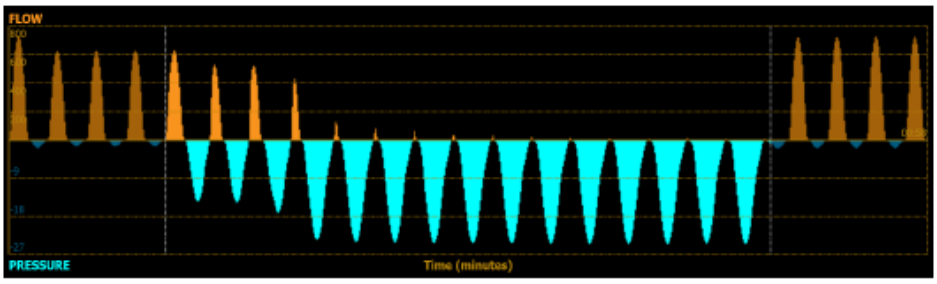
S/N 000000; B-S/N 0; SW VER 5.2.3

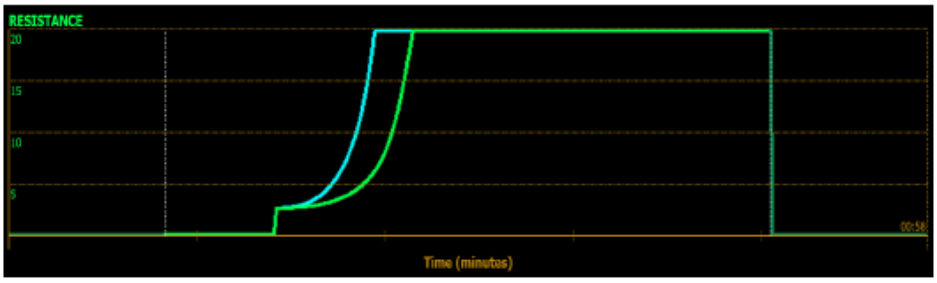
Patient Information

Patient ID:	**AAAAA**
Date of Assessment:	**09/27/2017(MM/DD/YYYY)**
Date of Birth:	**03/05/1953(MM/DD/YYYY)**

Assessment

Assessed Airway:	**LUL (Assessment # 1)**
Assessment Start Time:	**02:18:18**
Assessment Duration:	**00:38**
Total Exhaled Volume:	**20 mL**
Assessment Result:	**Accepted**





SAMPLE VENTILATOR MODE ASSESSMENT REPORT

Ventilator Assessment Report

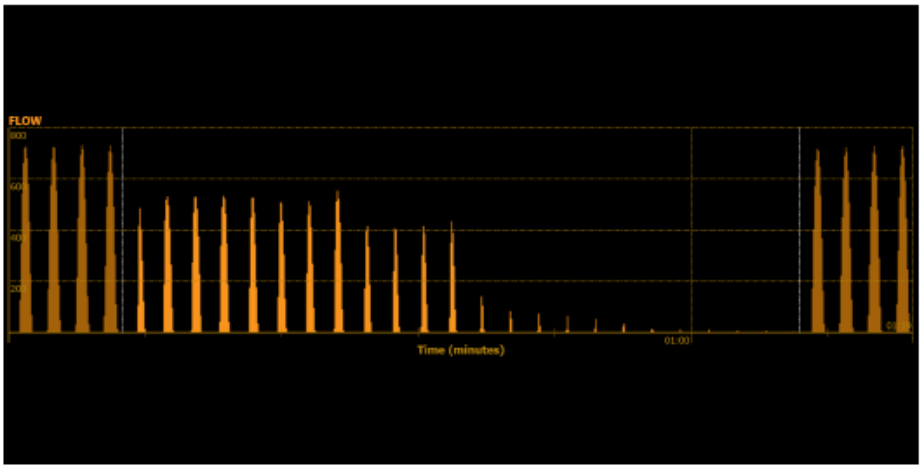
S/N 000000; B-S/N 0; SW VER 5.2.3

Patient Information

Patient ID:	**BBBBBB**
Date of Assessment:	**09/26/2017(MM/DD/YYYY)**
Date of Birth:	**04/03/1945(MM/DD/YYYY)**

Assessment

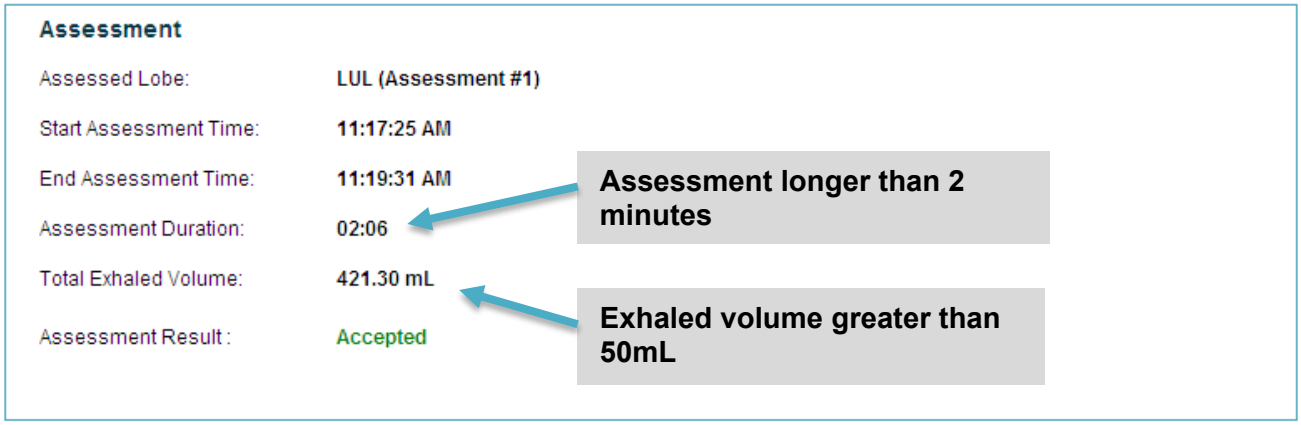
Assessed Airway:	**LUL (Assessment # 2)**
Assessment Start Time:	**15:30:14**
Assessment Duration:	**00:59**
Total Exhaled Volume:	**49 mL**
Assessment Result:	**Accepted**

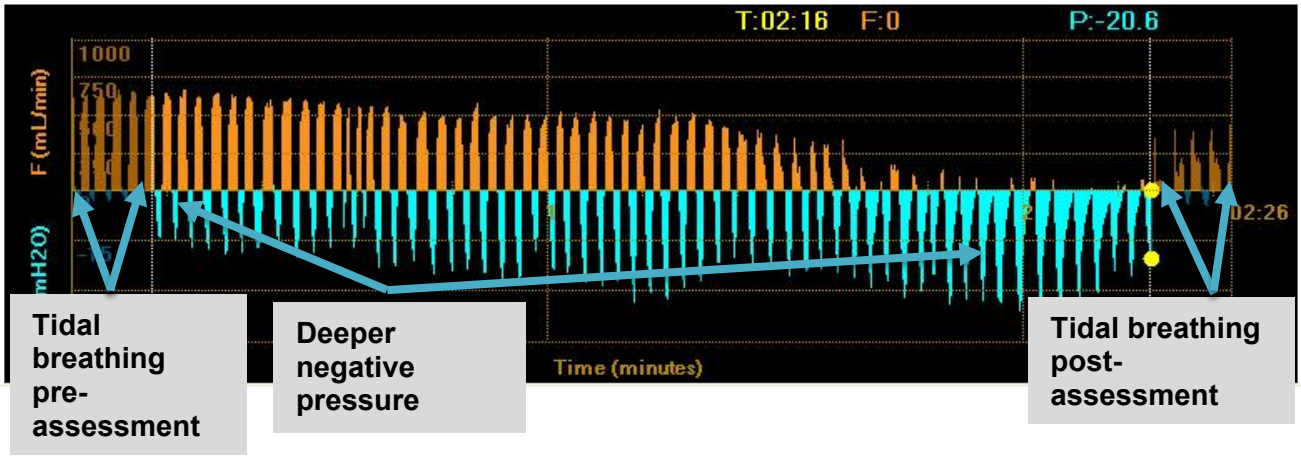


12. Interpreting Assessment Reports

An example output for an acceptable Chartis System assessment is shown below. While reviewing collateral ventilation status of an assessment report, there are several important items to note, including:

1) The report should demonstrate consistent tidal breathing prior to start of assessment. This indicates that the patient was adequately sedated. Ensuring adequate sedation will aid in achieving complete sealing of the assessed airway with the Chartis system.
2) Duration of the assessment should be 2 minutes or longer.
3) Throughout the assessment, consistent deeper negative pressure should be observed. This indicates that proper catheter balloon positioning and sealing was achieved.
4) At the end of the assessment, the total volume of air exhaled by the patient during the assessment should have been greater than 50 ml.
5) During the post-assessment period, ensure that tidal breathing pattern returned.
6) If the report indicates that the patient coughed, the catheter tip clogged, or the balloon seal was lost in such a manner that affect the assessment, then the assessment should be repeated.
7) During the assessment, if there was an instantaneous loss or drop in flow within the first 30 seconds and flow did not resume, the assessment should be repeated.





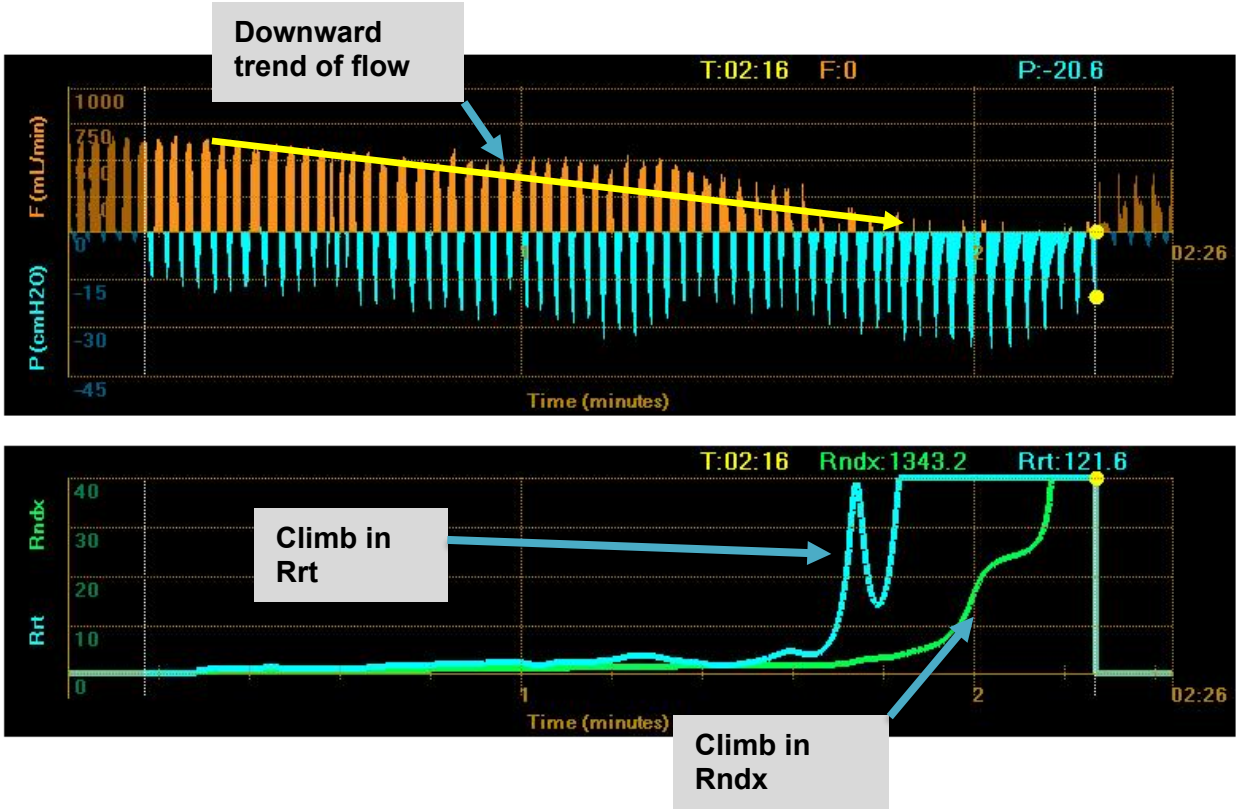
Assessment report of an airway that has Little or No Collateral Ventilation

1. When high resistance to collateral ventilation or high collateral resistance is noted, the Chartis assessment indicates that the assessed airway has little or no collateral ventilation (is CV negative or CV-).

2. An example of a report for a CV- assessment is shown below.

3. The key features of a CV- assessment include:

    a. The peaks of the flow indicator waveforms (orange) show a steady downward trend.
    b. The Airway Resistance index (Rndx) and / or Real-time Airway Resistance (Rrt) profile lines climb in a stepwise and steady fashion.
    c. Potential artifacts to avoid include:
        i. Instantaneous climbing of the Rndx and Rrt lines should not be considered a CV- assessment. This observation could be an artifact of an underlying issue such as clogging of the catheter tip.
        ii. An instantaneous drop in flow seen within the first 30 seconds of the assessment should not be considered a CV- assessment. This observation could be an artifact of distal airway collapse.



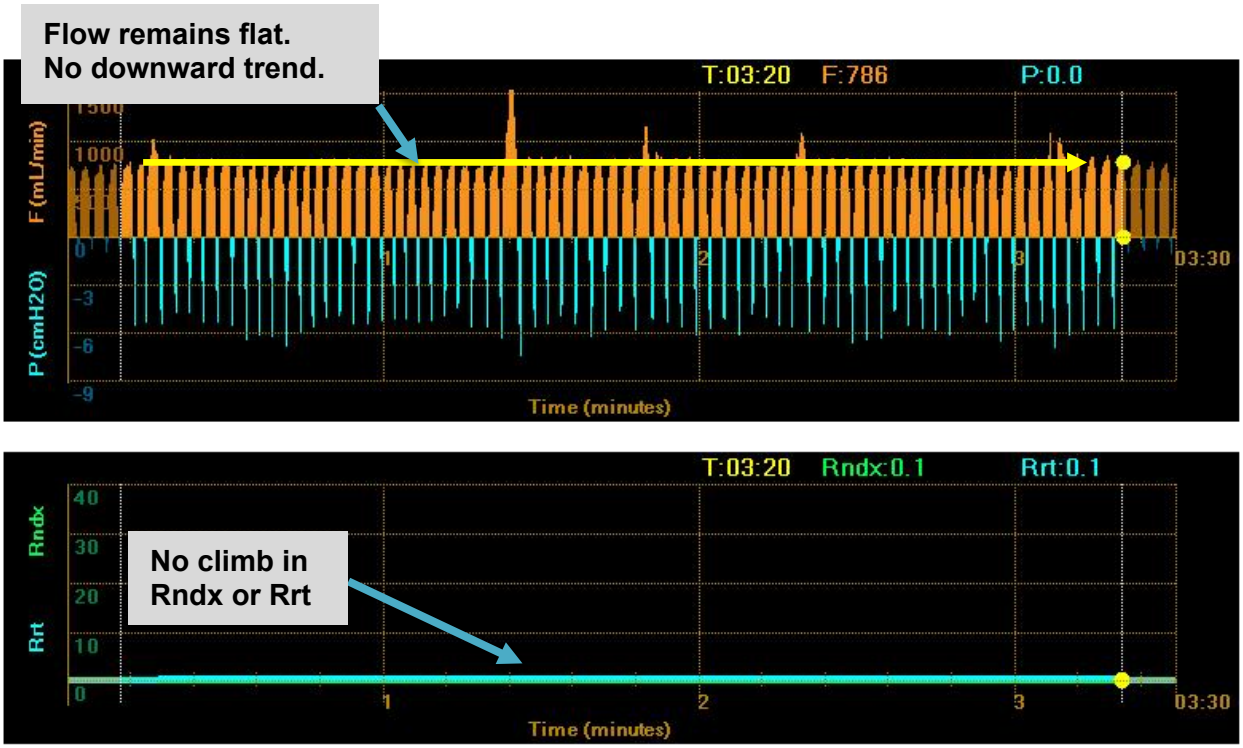
Assessment report of an airway that demonstrates presence of Collateral Ventilation

1. When low resistance to collateral ventilation or low collateral resistance is noted, the Chartis assessment indicates that the assessed airway has high collateral ventilation (CV positive or CV+).

2. An example of a report for a CV+ assessment is shown below.

3. The key features of a CV+ assessment include:

    a. The peaks of the flow indicator waveforms (orange) remain flat and do not show a downward trend.
    b. The Airway Resistance index (Rndx) and / or Real-time Airway Resistance (Rrt) profile lines have little or no change and do not steadily increase.



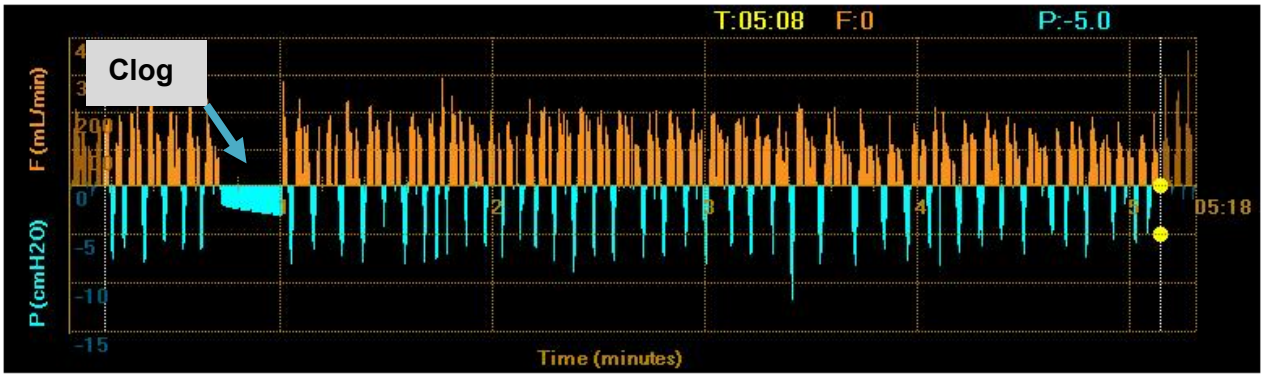
Other measurement anomalies which might affect the outcome of the collateral ventilation assessment include clogged catheter tip, instantaneous drop in flow, loss of balloon seal, and patient coughing. It should be noted that these anomalies can occur together or independently during the course of an assessment.

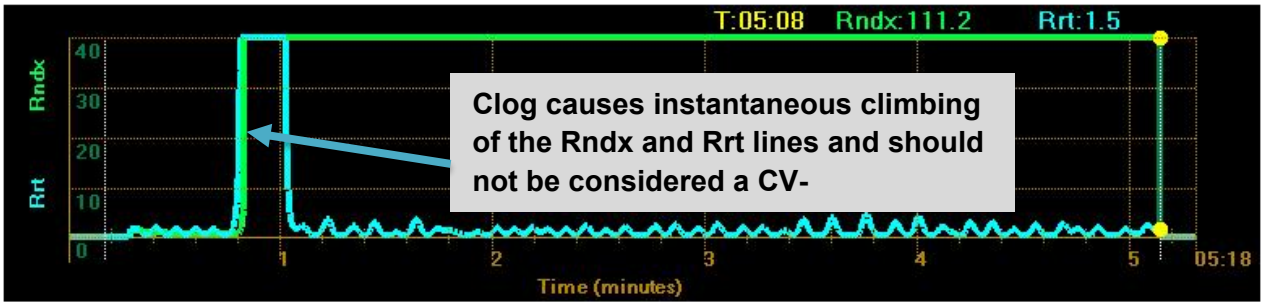
Assessment report of an airway assessment that has mucous clogging.

An example of a report with clogging at the catheter tip is shown below.

Assessment

Assessed Lobe:	RLL (Assessment #3)
Start Assessment Time:	9:56:26 AM
End Assessment Time:	10:01:24 AM
Assessment Duration:	04:58
Total Exhaled Volume:	438.70 mL
Assessment Result :	Accepted



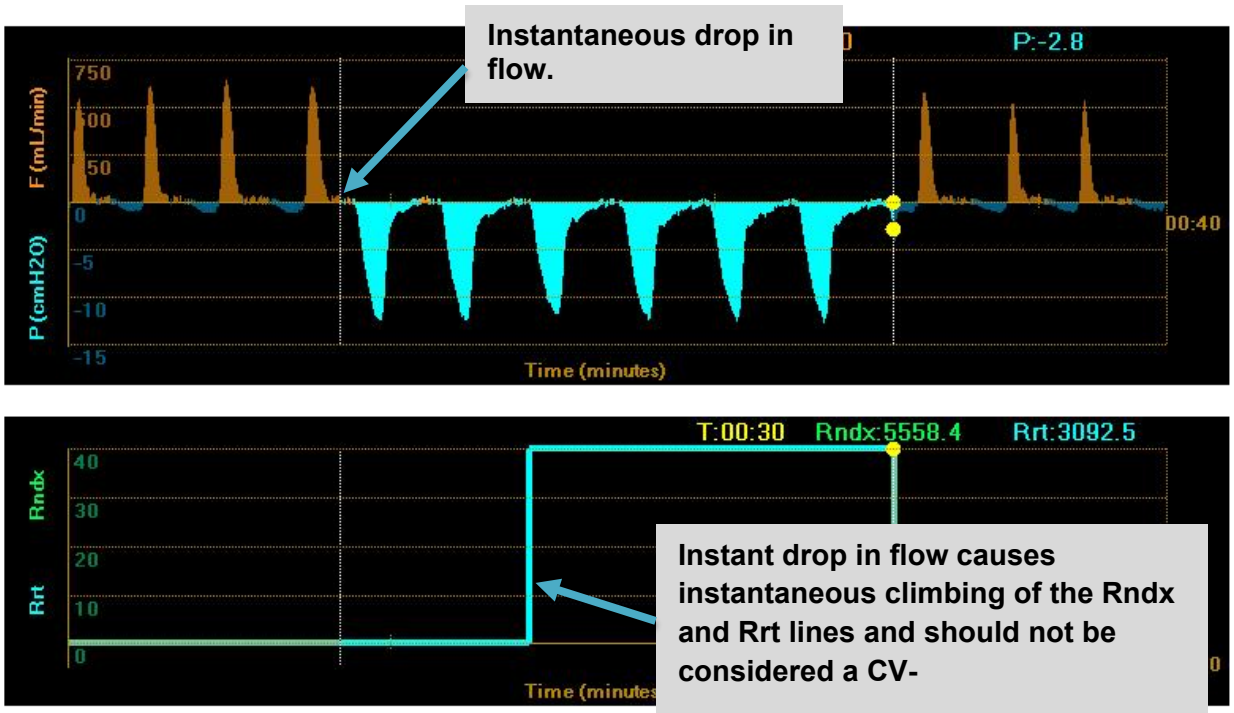


Assessment report of an airway assessment with instantaneous drop in flow.

An example of a report with an instantaneous drop in flow is shown below.

Assessment

Assessed Lobe:	**LLL (Assessment #1)**
Start Assessment Time:	**11:03:19 AM**
End Assessment Time:	**11:03:40 AM**
Assessment Duration:	**00:20**
Total Exhaled Volume:	**28.62 mL**
Assessment Result :	**Accepted**

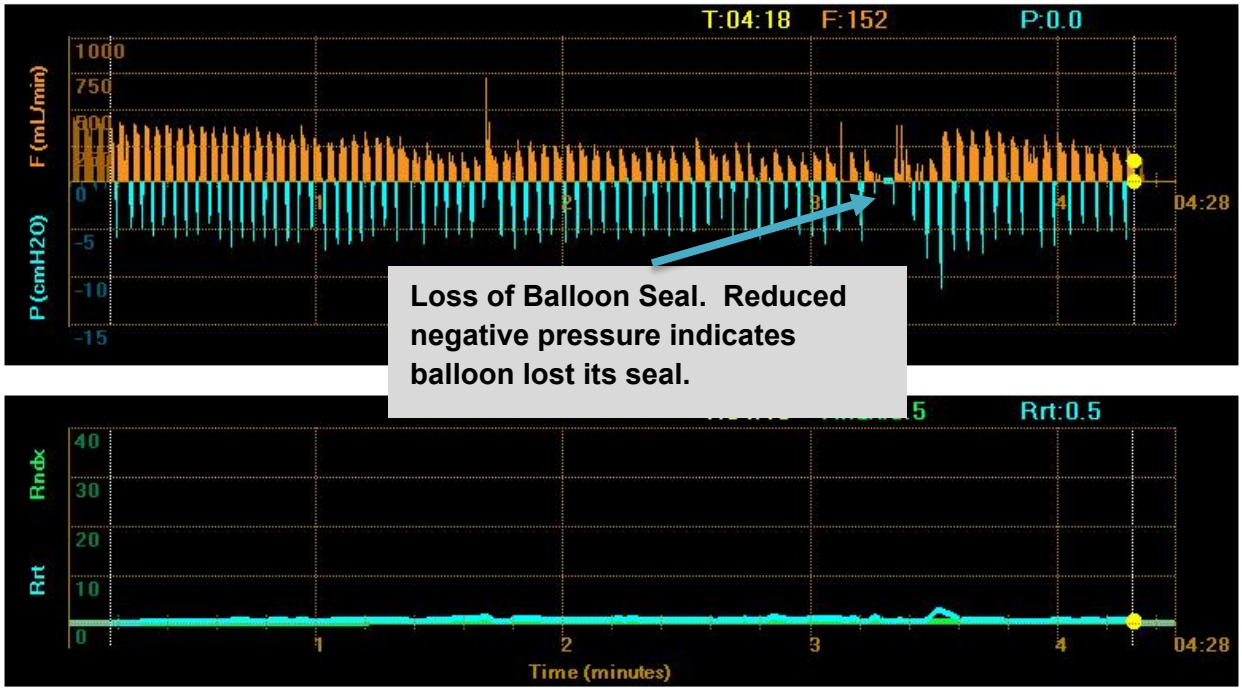


Assessment report of an airway assessment with loss of Chartis Catheter balloon seal.

An example of a report in which the balloon seal was compromised is shown below.

Assessment

Assessed Lobe:	RUL (Assessment #2)
Start Assessment Time:	1:50:00 PM
End Assessment Time:	1:54:08 PM
Assessment Duration:	04:08
Total Exhaled Volume:	600.83 mL
Assessment Result :	Accepted

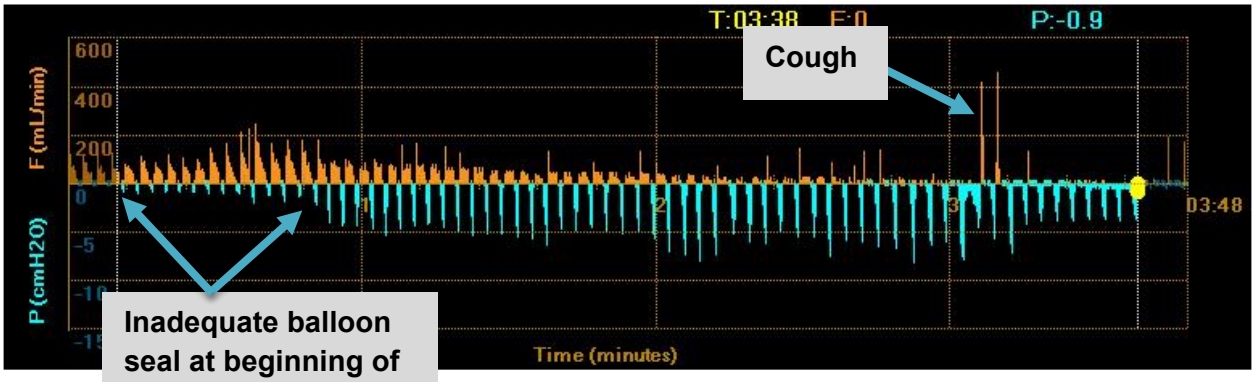


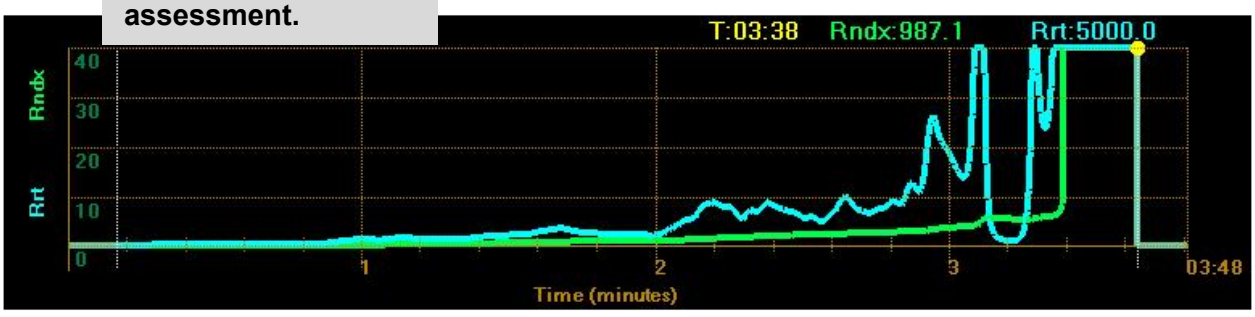
Assessment report of an airway assessment with inadequate Chartis Catheter balloon seal and coughing.

An example of a report with inadequate balloon seal at the beginning of the assessment and a cough at the end of the assessment is shown below.

Assessment

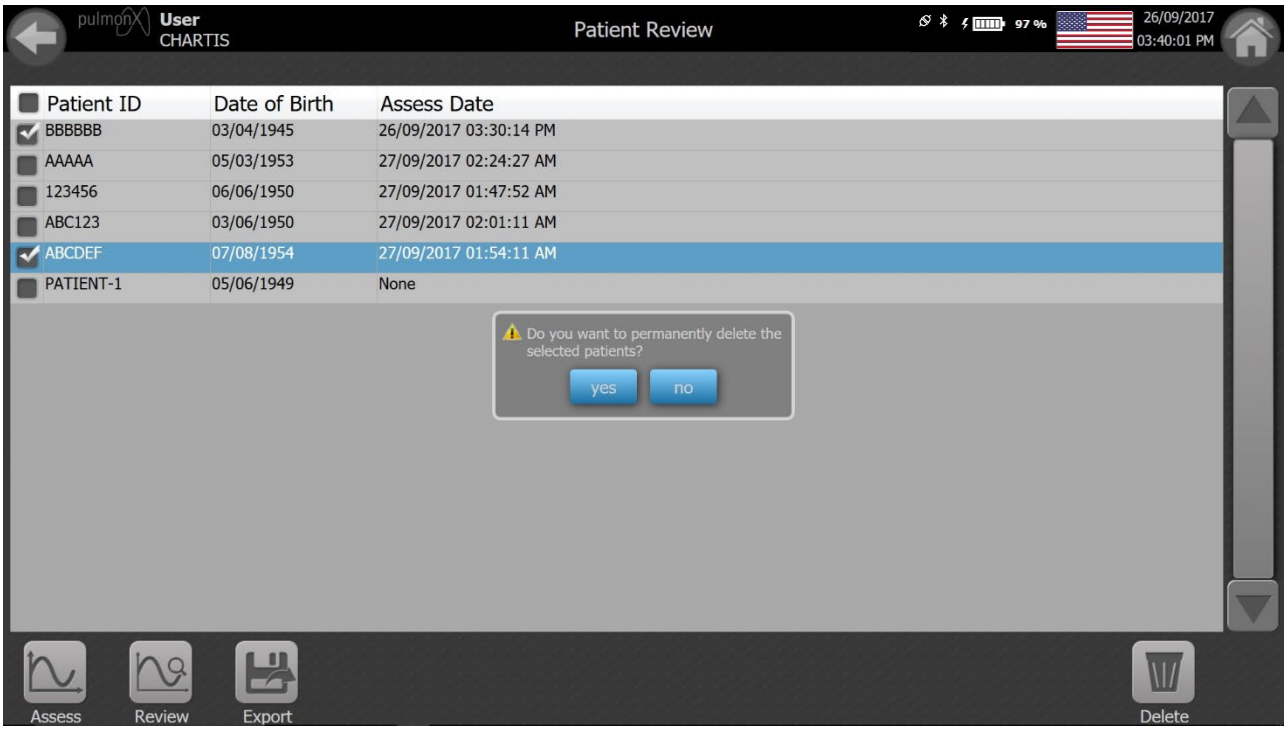
Assessed Lobe:	RUL (Assessment #7)
Start Assessment Time:	9:43:42 PM
End Assessment Time:	9:47:10 PM
Assessment Duration:	03:28
Total Exhaled Volume:	108.45 mL
Assessment Result :	Accepted





13. Deleting Patient Assessment Data

From the PATIENT REVIEW screen, press the checkbox next to the patient (or double- press the row) to select it, and then press DELETE. Confirm that is the desired action to complete the deletion process.



14. Console Shutdown

To power down the console from the HOME screen, touch SHUTDOWN, and confirm that is the desired action. Then press YES if ready to shutdown. Disconnect the Chartis Catheter from the front quick-disconnect socket. Insert the 2 dust plugs into their respective quick-disconnect sockets.

Precaution	***When the device is not in use, the two (2) dust plugs should be inserted into their respective quick-disconnect sockets.***

Wait until the screen turns black, then push the switch on the Patient Interface Box to complete the shutdown process. Turn the Power Switch off within 30 seconds, whether or not the black screen appears.

15. Maintaining the Console

This section describes maintenance, storage and service for the Chartis Console.

15.1 Preventive Maintenance

The Chartis Console may be surface-cleaned after each patient use.

Precaution ***Clean the Chartis Console according to the instructions in this document.***

Precaution ***Insert dust plugs into the quick-disconnect sockets before cleaning.***

15.2 Cleaning Instructions

Verify that the console is powered off. Use a lint-free cloth to clean the touch screen tablet computer and the Patient Interface Box. Spray a glass cleaning solution that is both alcohol-free and ammonia-free onto the lint-free cloth, and then wipe down both parts of the device. The tablet computer and patient interface box may be wiped with a cloth and a 70% isopropyl alcohol (IPA) solution. Never spray cleaning solutions directly onto the device surfaces.

Precaution ***Paper towels or other cloths that are not lint-free may leave a residue and/or scratch the touchscreen.***

Precaution ***Glass cleaners that contain ammonia or alcohol can degrade the touchscreen. Tap water or mineral water could leave white marks on the touchscreen due to the dissolved salts.***

Precaution ***Do not oversoak the lint-free cloth and do not spray the cleaner directly onto the patient interface box or touchscreen tablet computer to help minimize any cleaner from leaking into the console.***

15.3 Storage

When not in use, store the Chartis Console in a cool, dry environment. See Section 16 for temperature and humidity storage specifications.

15.4 Caring For The Tablet Battery

To maximize the performance of the battery, condition the battery once a month. To condition the battery, run the tablet on battery power until the battery's charge level is below 20%. Then use AC power until the battery is fully charged.

15.5 Servicing

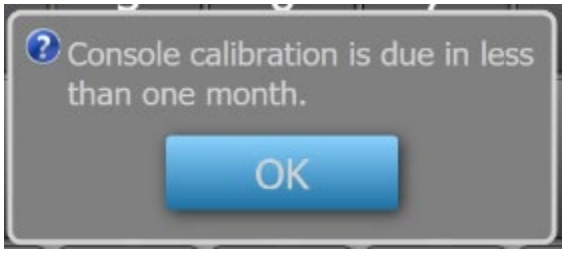
Contact your authorized distributor. Please provide the serial number of the console which is located (1) on the product labels and (2) on the SYSTEM INFORMATION screen while the unit is in operation.

Warning	***Do not open the device as it contains no User serviceable parts. Opening the device will void any warranty, and may cause damage to the device and may shock and injure you.***

Prior to returning the console for servicing, please EXPORT all patient assessment data per section 9 of the User Manual. Please do not delete any data sets, as they may be used to troubleshoot the console. All patient records will be deleted from the console prior to service completion.

15.6 Internal Sensor Calibration

The Chartis Console needs to be calibrated once every 72 months to ensure accurate sensor function. Starting one month prior to the calibration due date, the console will display this reminder message every time the device is powered up. Press OK to dismiss this message.



The system will display the calibration due date (MM/DD/YYYY) on the System Information Page. Calibration is performed by the manufacturer. Contact your authorized distributor to schedule a calibration service.

IMPORTANT: After the calibration due date, the Chartis Console will no longer perform assessments. You must have the console calibration performed before you will be able to assess a patient.

NOTE: Users will still be able to review stored patient data after the calibration due date.

16. Specifications

This section describes the product			
Specification	**Description**		
Display	1920 x 1080 Resolution 12.5 inch diagonal color touchscreen		
Approximate Dimensions (Touchscreen tablet docked and open)	Height	10.0 inches/ 25.4 cm	
	Width	13.6 inches/ 34.6 cm	
	Depth	10.5 inches/ 26.7 cm	
Approximate Weight (Touchscreen tablet computer)	2.95 lb / 1.34 kg		
Approximate Weight (Patient Interface Box only)	8.68 lb / 3.94 kg		
Input specifications	Input air flow	Range	±1500 ml/min
		Resolution	2ml/min
		Accuracy	±5% or ±5ml/min whichever is greater
	Input air pressure	Range	±50 cmH_2O
		Resolution	0.1 cmH_2O
		Accuracy	±5% or ±0.05 cmH_2O whichever is greater
	Expired air flow volume during assessment	Range	0-2 L
		Resolution	2 ml
		Accuracy	±5% or ±5 ml whichever is greater
	Voltage	19 VDC ± 5%	
	Current	3.43 A ± 5%	
Operational environment	Temperature	+15ºC TO +35°C (+59 TO +95 °F)	
	Humidity	15 TO 65% humidity, non-condensing	
	Maximum Altitude	2000 meter	
Storage and Transportation Environment	Temperature	-18ºC TO +55°C (0 TO +131 °F)	
	Humidity	15 TO 65% humidity, non-condensing	

Device Classification	Description
Applied part type	Type BF
Medical device	Class II Equipment (IIa EU)
Electrical protection	Class I Equipment
Ingress protection	IPX0
Mode of operation	Continuous

Power supply specifications	Description
Input voltage	100-240 VAC, 50-60 Hz, 2.0-1.0A
Output voltage	19 VDC
Output current	3.43A

17. Electromagnetic Emission Compliance (EMC) Information

This section describes the magnetic emission and immunity compliance information and recommended environments. The Chartis Pulmonary Assessment System is intended for use in the electromagnetic environment specified below. The customer or user should ensure that it is used in such an environment.

Emission standard	Compliance	Guidance
RF Emissions CISPR 11	Group 1	The Chartis Pulmonary Assessment System uses RF (radio frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Chartis Pulmonary Assessment System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics EN 61000-3-2	Class A	
Flicker EN 61000-3-3	Complies	

Immunity Test	IEC 60601-1-2 Test level/ Compliance Level	Guidance
IEC 61000-4-2: Electrostatic Discharge (ESD)	±8 kV Contact ±15 kV Air	Floors should wood, concrete, or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
IEC 61000-4-4: Electrical Fast Transient/burst (EFT)	±2 kV Mains ±1 kV I/Os	Mains power quality should be that of a typical hospital environment.
IEC 61000-4-5: Surge	±1 kV Differential ±2 kV Common	Mains power quality should be that of a typical hospital environment.
IEC 61000-4-8: Power Frequency (50/60 Hz) Magnetic Field	30 A/m	Power frequency magnetic fields should be that of a typical hospital environment.
IEC 61000-4-11: Voltage Dips/Dropout	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	Mains power quality should be that of a typical hospital environment. If the user of the Chartis Pulmonary Assessment System requires continued operation during power mains interruptions, it is recommended that the Chartis Pulmonary Assessment System be powered from an uninterruptible power supply or battery.
IEC 61000-4-6: Conducted RF	3 V 0.15 MHz – 80 MHz 6 V in ISM between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Professional healthcare facility environment
IEC 61000-4-3: Radiated RF	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	Professional healthcare facility environment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700 – 1900	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN, 820.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

18. Troubleshooting

This section describes troubleshooting symptoms and possible solutions.

Issue	Solution
Power switch (on the Patient Interface Box) is pressed to the ON position (depressed inward) but the device doesn't power up.	**(a) Verify that the power cable is properly plugged into the wall AC outlet on one end and the power supply on the other end. The blue indicator light on the power supply should be lit.**  **(b) Verify that the barrel plug of the power cable is plugged properly into the connector at the back of the Patient Interface Box.** **(c) Confirm that the power switch on the Patient Interface Box is set to the right position (depressed inside).** **(d) Try steps (a) through (c) with an alternate wall AC outlet.** **(e) Verify that the power supply is the unit that shipped with the device or is an approved model.** **(f) Contact your authorized distributor.**
Sensor initialization failed	**1. Verify that both dust plugs are unplugged** **2. Verify that there is no source of disturbance near the quick disconnect socket on the back panel of the Patient Interface Box**
Calibration due	**Contact your authorized distributor**

Issue	Solution
Unable to connect the Chartis Catheter or reattach the dust plug	Push the latch towards the orifice and try again.  
Unable to detect a USB storage device	1. Verify that the USB device is plugged in correctly. 2. Verify that the USB device is a storage device
No waveforms are visible on the assessment screen	Ensure that the Patient Interface Box is powered ON.

19. Unit Conversion

This section contains the pressure conversion factor from SI pressure units, pascals (Pa), to cmH_2O (4 °C).

PASCALS	cmH_2O (4°C)
1.00	0.010197443
98.0638	1.000