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Welch Allyn® Diagnostic Cardiology Suite:

September 2020

Introduction

The **Welch Allyn Diagnostic Cardiology Suite** is more than a PC-based ECG it is a **multi-modality diagnostic testing platform**.

The Diagnostic Cardiology Suite is a software platform capable of acquiring, storing, reviewing, editing, signing tests, with many customization and connectivity options.



Welch Allyn Diagnostic Cardiology Suite

The Welch Allyn Diagnostic Cardiology Suite makes diagnostic testing simple by providing two reimbursable tests within a single platform. The product connects to the market leading EMRs, and unlike anyone else, can be connected to hospital ECG management for standardization of ECG connectivity. It uses the same core workflows with a focus on simplicity to make training and use as easy with repeatable, good quality results that physicians can use confidently in their diagnoses.

Welch Allyn Diagnostic Cardiology Suite

Key Improvements

- Improved Out-of-box-experience - all components professionally packaged; quick reference guides included (modality quick guide & installation instructions)
- New spirometry dongle and spirometer that is weighted
- DCS ECG and DCS with Spirometry are now sold separately, no combo units offered
- Streamlined installation process

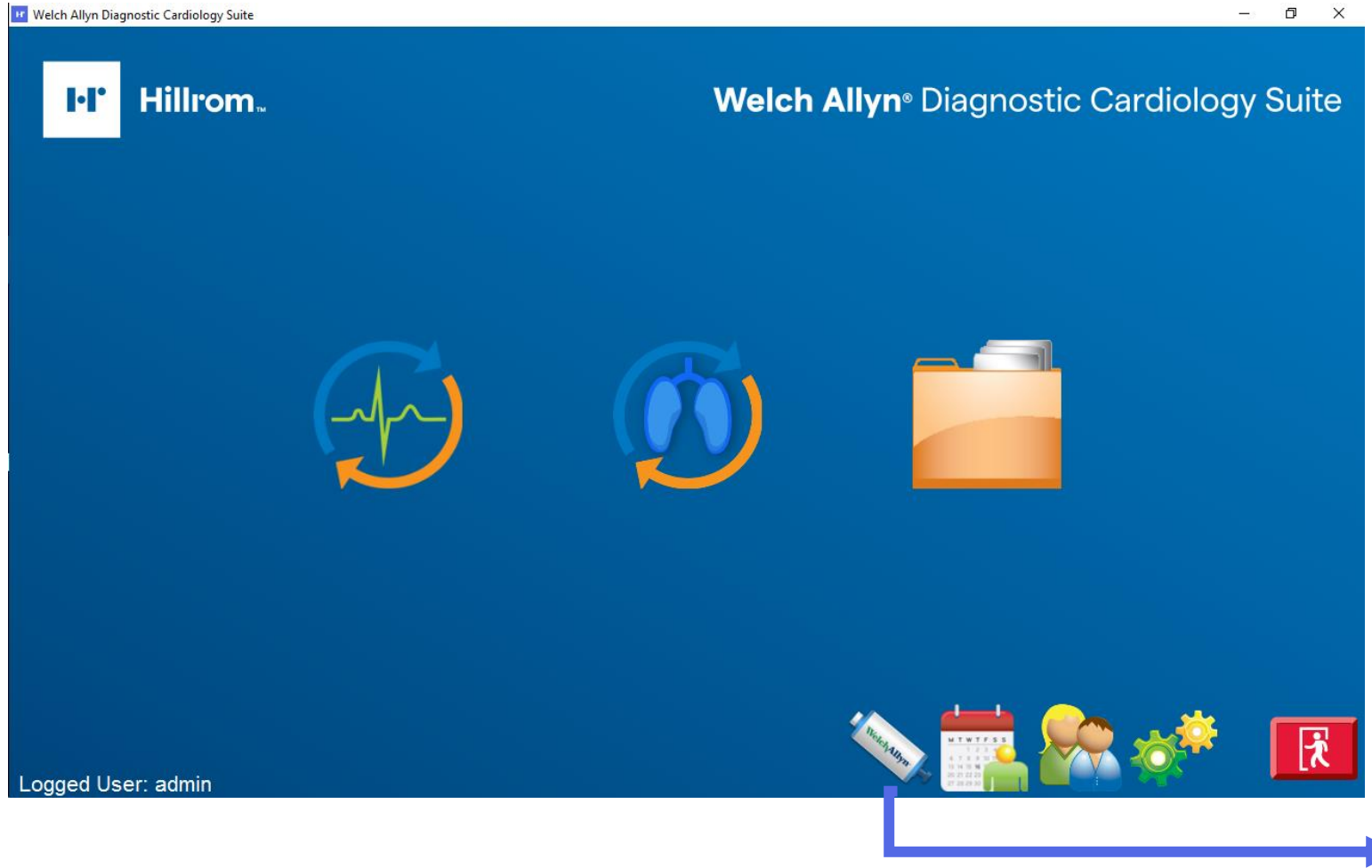




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**Welch Allyn®
Diagnostic Cardiology Suite
Modality Manager**

Software Overview... the “Manager”



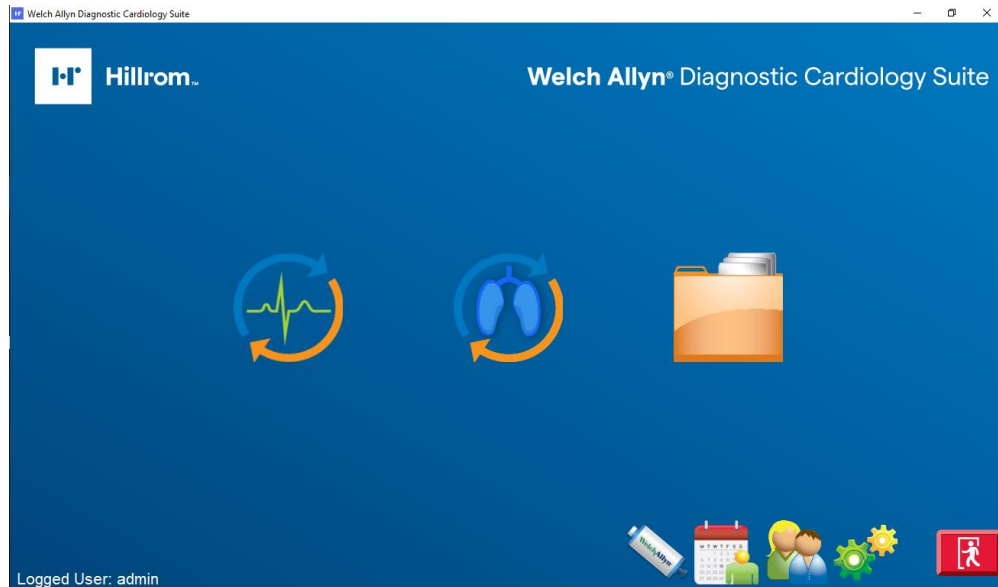
The “Manager” refers to the part of the Diagnostic Cardiology Suite that manages the data collected by the modalities. This is the first screen that’s seen after logging into the product from the desktop

For EMR-integrated installations, the Manager is installed, but not seen when launching from the EMR to acquire tests. To modify configuration settings in the EMR-integrated setup, launch the desktop application to access system configurations.

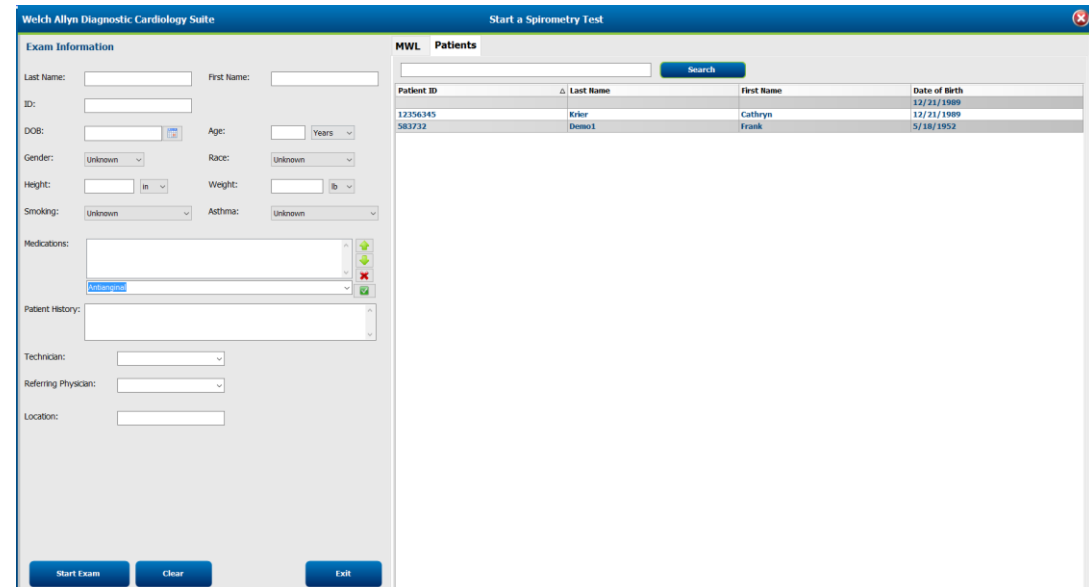
A Start Calibration icon was added to perform spirometer calibration without the need to enter the spirometry application

Workflow Similarities between Modalities

- 1 Launch the application from the same home screen. For integrated EMRs, launch steps are also often identical



- 2 Patient demographic entry process is the same, differences being that some fields are specific to one modality or the other

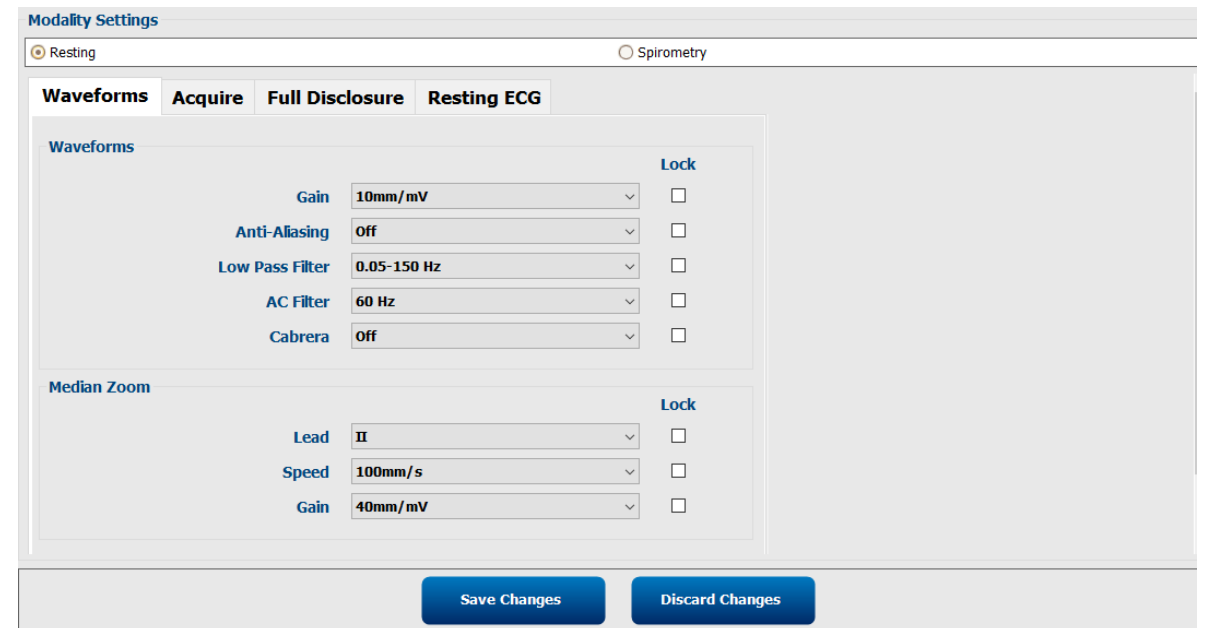


Workflow Similarities between Modalities

3 The same icons and process is used to view patient information, save, review, sign, print, or exit an opened test.



4 For administrators, there is one location for the settings, and customizations occur in the same location, just different tabs



New features of the Manager from Connex Cardio

Welch Allyn Diagnostic Cardiology Suite **System Configuration**

Manager	v2.1.0.64108	GTIN: 00732094315479v2.1.0	SN: ENTER SERIAL NUMBER HERE
Spirometry	v2.1.0.44	GTIN: 00732094315486v2.1.0	SN: ENTER SERIAL NUMBER HERE
ECG	v2.1.0.58	GTIN: 00732094315493v2.1.0	SN: ENTER SERIAL NUMBER HERE

An “About” section was added that indicates the software version and serial number of each installed module

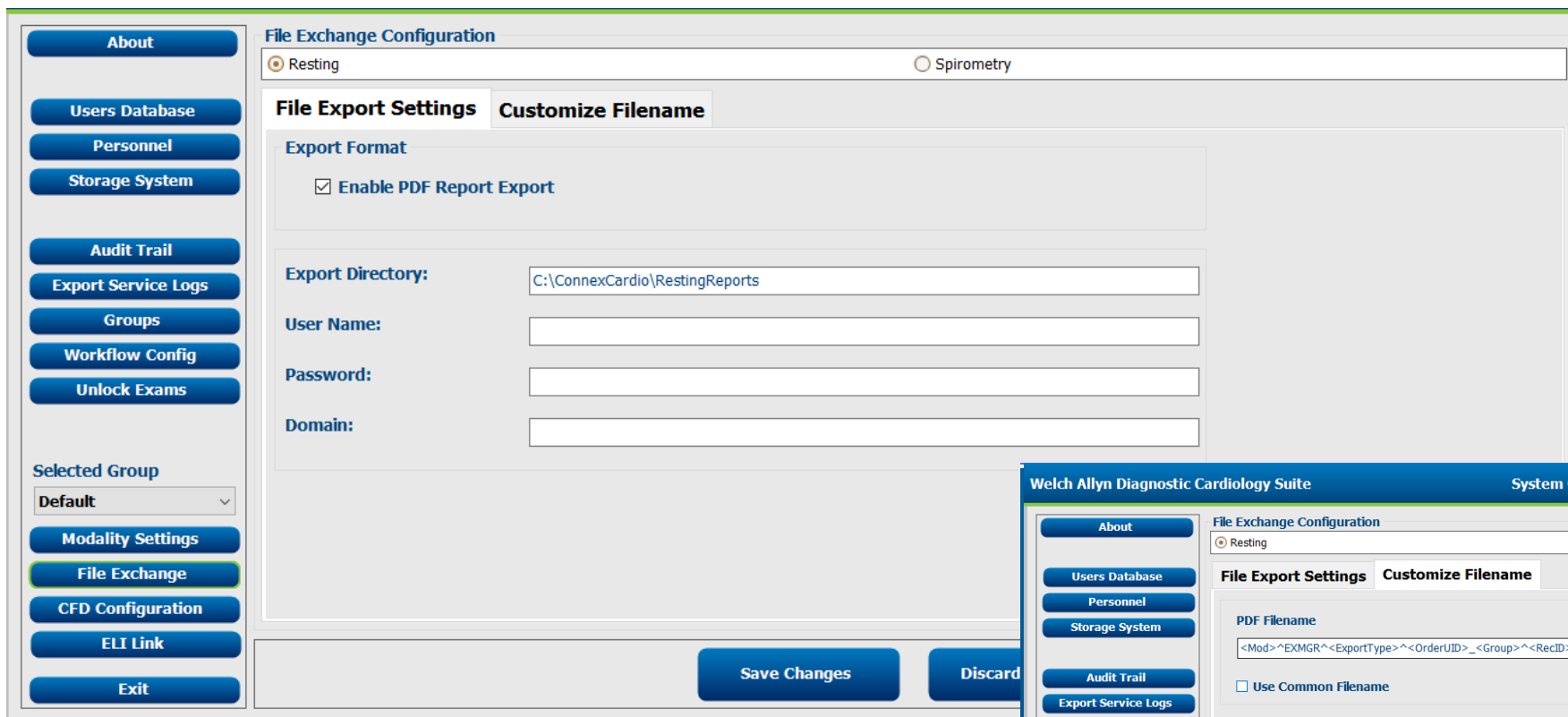
Each module’s version is 2.1.0, but will change as the modules are updated over time

A spirometry tab was added to modality settings

Manager can now export PDF reports **without use of ELI Link**

ELI Link settings remain for resting ECG, but are not required for PDFs

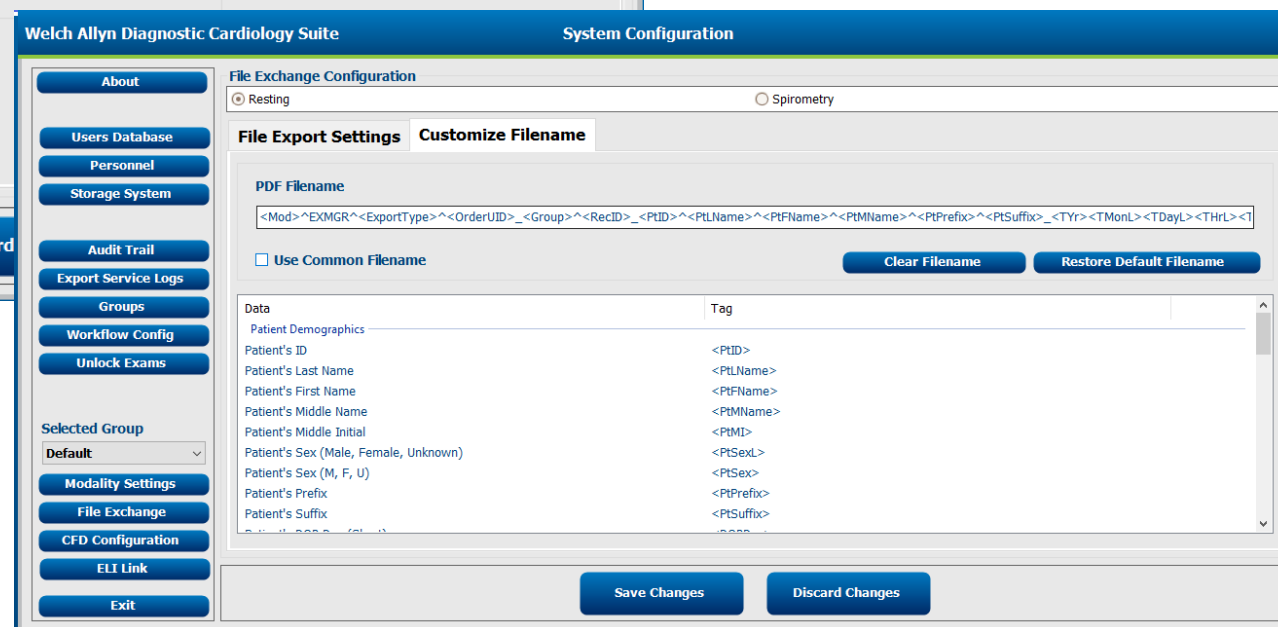
PDF Export made Easier



Use the File Exchange Setting to modify PDF path location.

To drop to a network location, IT will enter system credentials allowing export to that path.

The file naming convention can be modified by clearing the name and double clicking the tags in the order which the customer would like them to appear.

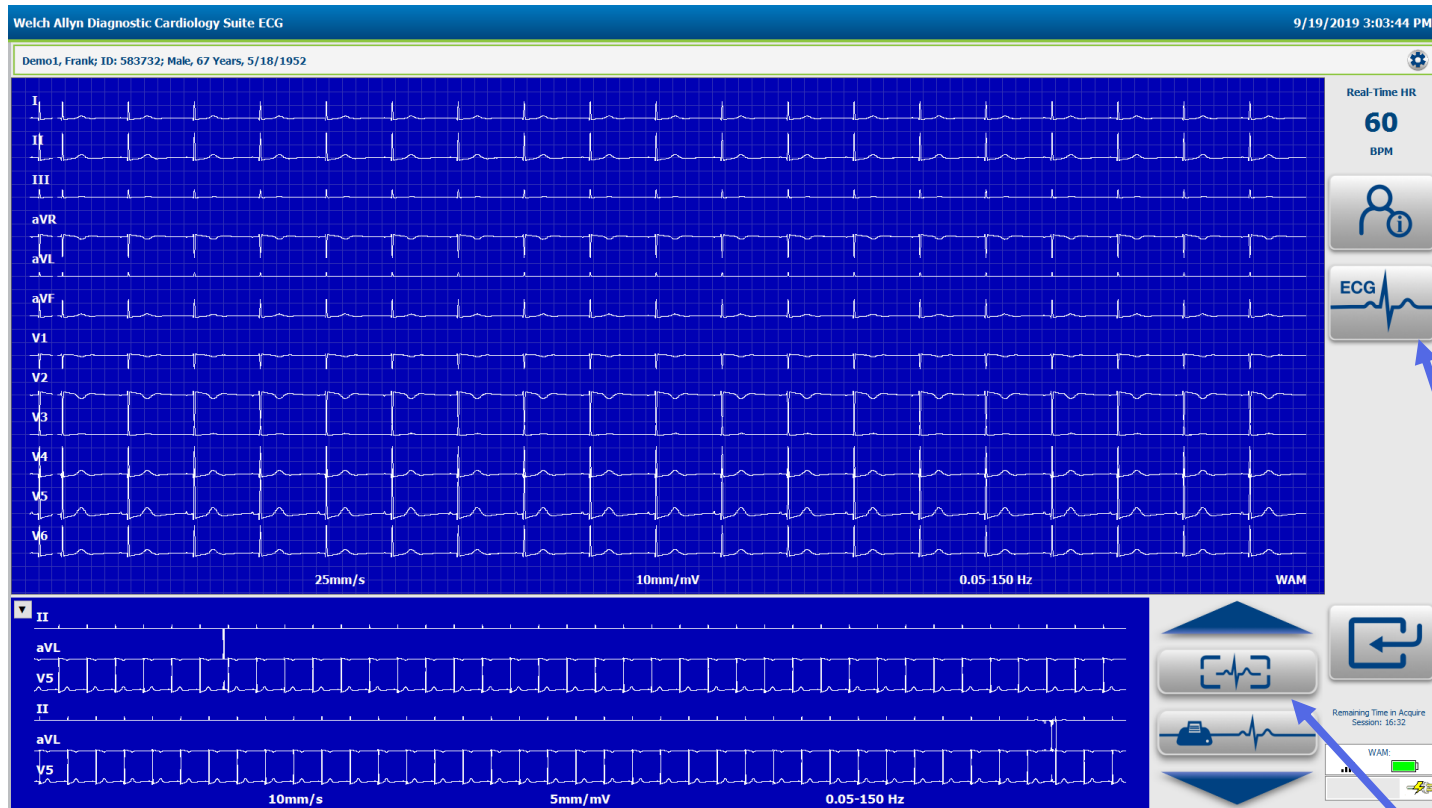




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**Welch Allyn®
Diagnostic Cardiology Suite
ECG Modality**

Software Overview... ECG Module



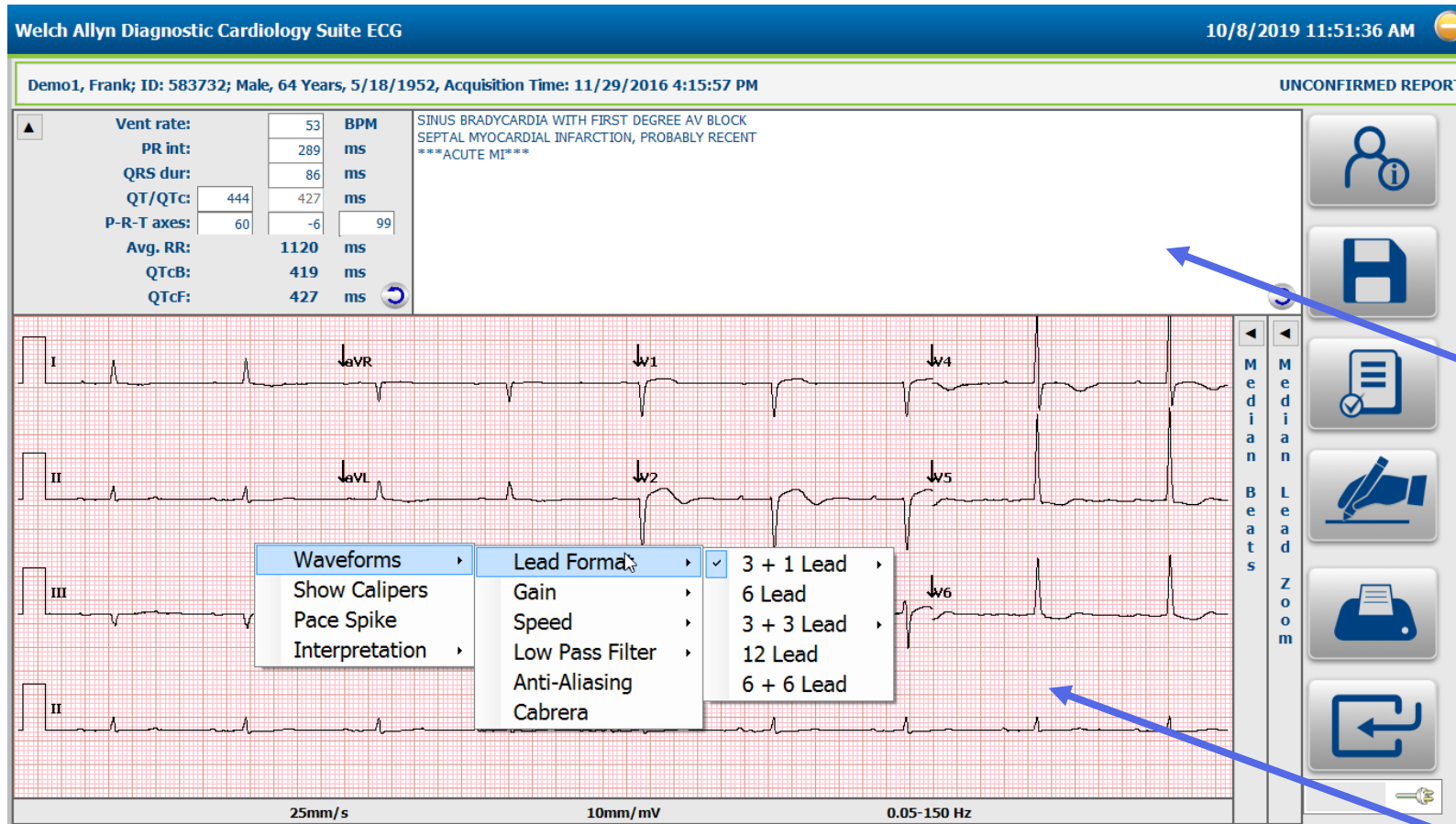
The ECG module uses either the Welch Allyn Wireless Acquisition Module or the Welch Allyn AM12 Acquisition Module, specific to the Diagnostic Cardiology Suite. **No other devices are compatible.**

The wireless module comes with a USB Transmitter Key (UTK) that needs to be paired prior to use using the settings menu.



Technicians have the ability to use the Best 10 feature or the full disclosure buffer to select the ECG with the least amount of noise.

Software Overview... ECG Module



Once an ECG is acquired, it can be saved, reviewed, or signed, depending on the role of the user. Only the buttons that a user has permission to access are presented to the user.

The application uses the VERITAS interpretation algorithm to generate automatic interpretation statements.

Physicians have the ability to edit the automatic statements and measurements, assisted by tools including calipers, launched by right clicking anywhere on the ECG.



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**Welch Allyn®
Diagnostic Cardiology Suite
Spirometry Modality**

New Spirometer Overview



The Diagnostic Cardiology Suite uses a new spirometer that is weighted, so it sits firmly on the desktop as a patient is performing efforts.

Although the spirometer is new, the flow tubes are the same that are used with the CP150.

Material	Description
410370	Pressure tubing
720705	Disposable Flow Transducers – 25 pack
720706	Disposable Flow Transducers – 100 pack

Software Overview... Spirometry Module



2

Pre-calibration

Selected Flow Sensor: **Connex Cardio Spirometer**

Lot Code: [dropdown]

Calibration Code: [dropdown]

Syringe Volume [Liter]: 3000 ml

Current Calibration Factor: 1

Calibration Error Tolerance: Social Security (1 %) Standard (3 %)

Temperature: 21 °C

Humidity: 52 %

Pressure: 979 mbar

Cancel Next >

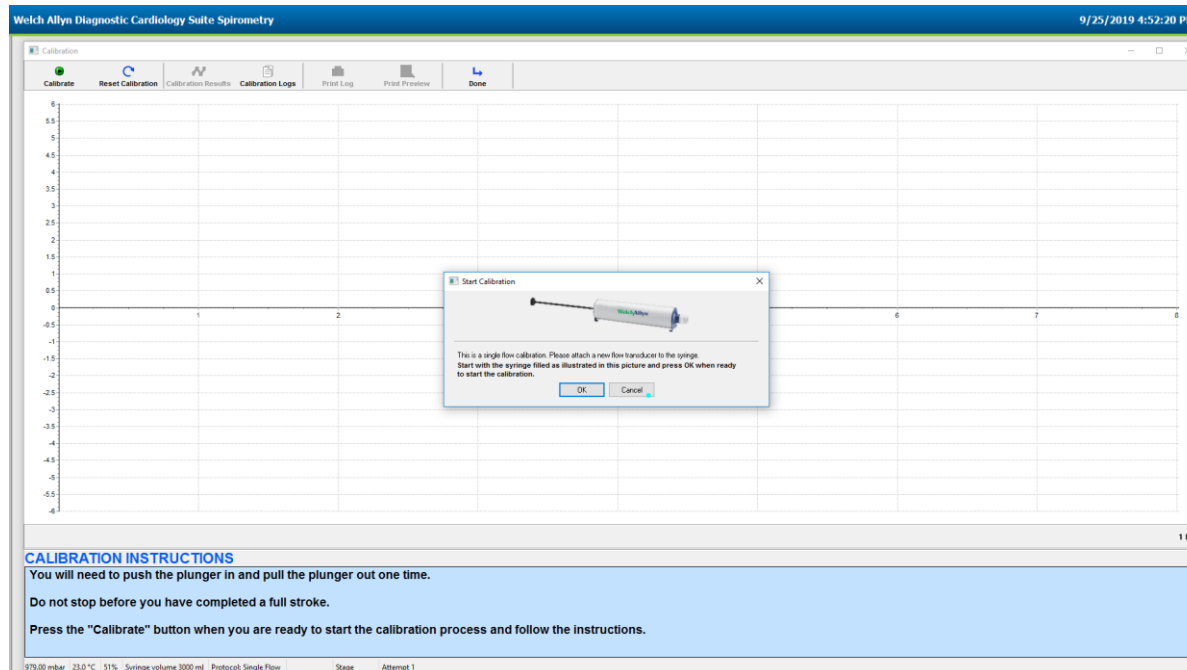


The spirometer used for a spirometry test must be periodically calibrated to ensure correct readings.

A calibration syringe can be ordered with the spirometry kit to perform the calibration.

It is recommended that calibration occur every day.

4



Welch Allyn Diagnostic Cardiology Suite Spirometry 9/25/2019 4:52:20 PM

Calibration

Calibrate Reset Calibration Calibration Results Calibration Logs Print Log Print Previous Done

Start Calibration

This is a single flow calibration. Please attach a new flow transducer to the syringe. Start with the syringe filled as illustrated in this picture and press OK when ready to start the calibration.

OK Cancel

CALIBRATION INSTRUCTIONS

You will need to push the plunger in and pull the plunger out one time.

Do not stop before you have completed a full stroke.

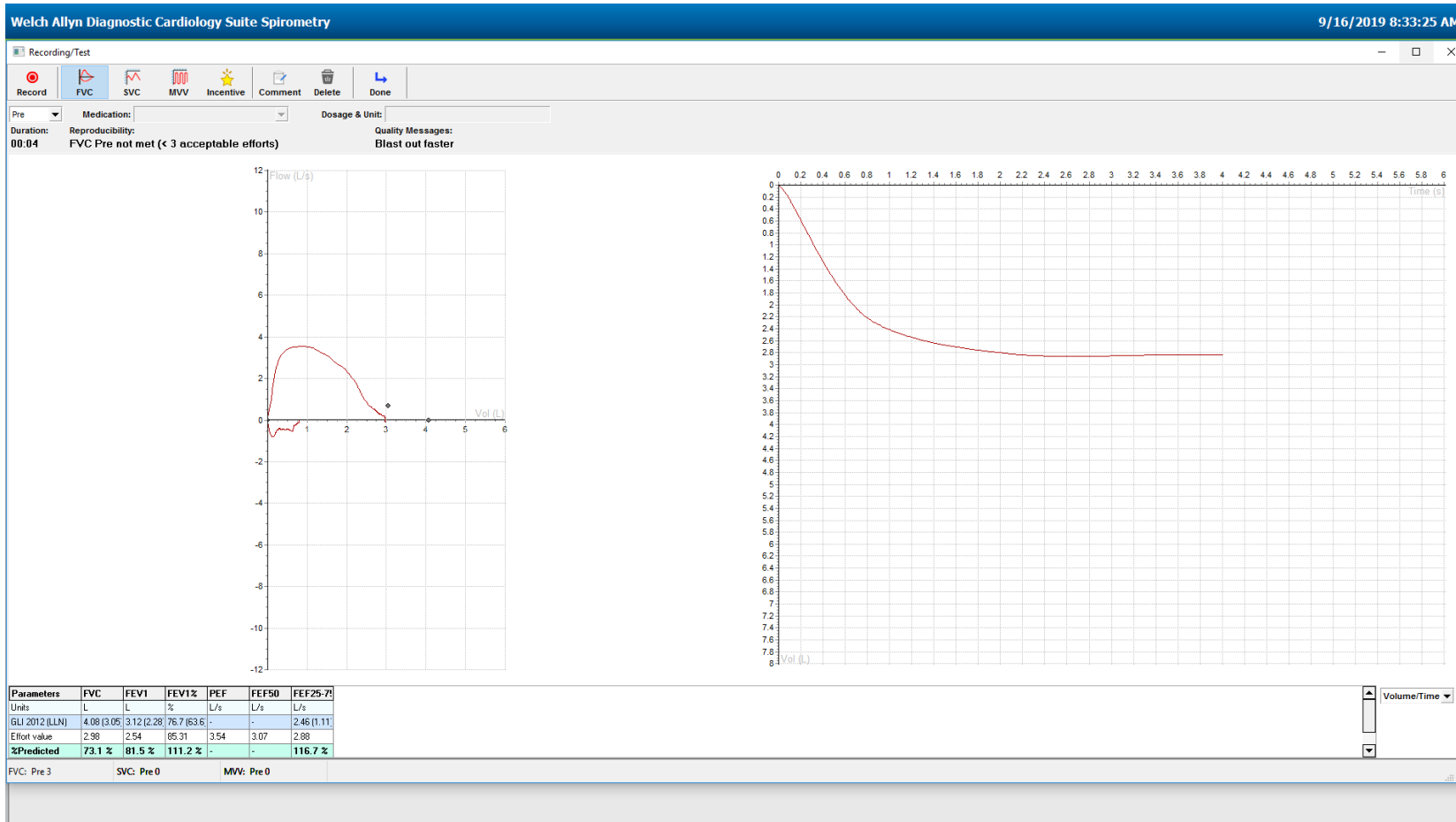
Press the "Calibrate" button when you are ready to start the calibration process and follow the instructions.

979.00 mbar 23.0 °C 51% Syringe volume 3000 ml Protocol: Single Flow Stage Attempt 1

To calibrate the spirometer:

1. Select Calibrate Spirometer from the Manager, or within the Spirometry modality
2. Enter the Lot Code and Calibration Code, located on the label for the flow tubes (mouth pieces)
3. Temperature, pressure, and humidity are automatically detected by the device.
4. Follow the instructions on screen

WADCS Software Overview... Spirometry Module



A spirometry test consists of a series of efforts performed by the patient to determine the amount of air that is inhaled and exhaled. A spirometry test consists of at least 3 good, repeatable efforts.

The module supports three different types of spirometry tests:

- FVC
- SVC
- MVV

The product also supports tests that include initial baseline efforts “pre tests” followed by administration of a bronchodilator, and “post tests” done afterward. This type of test is performed to determine if the presence of therapy improves the symptoms reported.

WADCS Software Overview... Spirometry Module

Welch Allyn Diagnostic Cardiology Suite Spirometry 9/12/2019 9:25:25 AM

Demo1, Frank; ID: 583732; Male, 67 Years, 5/18/1952, Acquisition Time: 8/29/2019 10:47:39 AM Unconfirmed

New Effort Calibrate Calibration Log Interpretation... All efforts

FVC SVC MVV Trend Measurements

Flow/Volume Loop Selected Flow/Volume

Effort	Selected	FVC	FEV1	FEV1%	PEF	FEF50	FEF25-75
Units		L	L	%	L/s	L/s	L/s
GLI 2012 (LLN)		4.08 (3.05)	3.12 (2.28)	76.7 (63.7)	-	-	2.47 (1.11)
Pre 10:49:55 AM	<input checked="" type="checkbox"/>	2.09	1.92	92.0 %	3.65	2.71	2.49
Pre 10:49:28 AM	<input checked="" type="checkbox"/>	2.12	2.02	95.5 %	3.46	2.64	2.53
Pre 10:48:47 AM	<input checked="" type="checkbox"/>	2.12	2.03	96.1 %	3.18	2.63	2.57
Final		2.12	2.03	96.1 %	3.18	2.63	2.57
Final%Pred (z)		52.0 % (-3.16)	65.2 % (-2.10)	125.2 % (2.87)	-	-	104.0 % (0.10)
FINAL		2.12	2.03	96.06	3.18	2.63	2.57

Interpretation:
Pre: FVC= 2.12L FEV1= 2.03L
FEV1%= 96.1% [2.03/2.12 FEV1/FVC]
(8/29/2019 10:48:47 AM), Moderately severe restriction

Comment:
ATS Reproducibility Pre: Criteria Not Met (< 3 acceptable efforts)
ATS Reproducibility Post: Criteria Not Met (< 3 acceptable efforts)

Once a test is acquired, it can be saved, reviewed, or signed, depending on the role of the user. Only the buttons that a user has permission to access are presented to the user.

The application has the ability to enter interpretation text or comments that appear on the final report.

Interpretation/Medication editor

Save Cancel Clear Date/time Best Effort FVC Interpretation Comment

Medications
 - Bronchodilator
 - Corticosteroids
 Interpretation
 - Within normal limits
 - Restrictive abnormalities
 - Mild restrictive abnormality
 - Moderate restrictive abnormality
 - Moderately severe restrictive abnormality
 - Severe restrictive abnormality
 - Very severe restrictive abnormality
 - Obstructive abnormalities
 - Mild obstructive abnormality
 - Moderate obstructive abnormality
 - Moderately severe obstructive abnormality
 - Severe obstructive abnormality
 - Very severe obstructive abnormality
 - Maybe a physiological variant
 - No interpretation possible

Pre: FVC= 2.23L FEV1= 2.07L
FEV1%= 92.9% [2.07/2.23 FEV1/FVC]
(8/30/2019 9:53:05 AM), Moderately severe restriction

Comment:


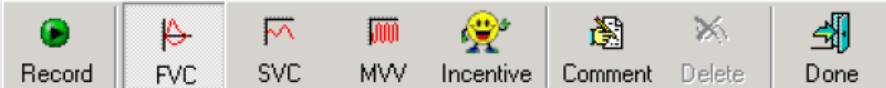
Comparison to CardioPerfect Workstation – Resting ECG

Product Feature	Diagnostic Cardiology Suite	CardioPerfect Workstation
Acquisition Module	Welch Allyn AM12 Acquisition Module Welch Allyn Wireless Acquisition Module	Pro-Recorder
Frequency Response Sampling Rate	0.05 – 300 Hz; 1000 samples/s full range recommended for adults and pediatrics by the AHA, HRS, ACC	0.05 – 150 Hz; 600 samples/s range recommended for adults only by AHA, HRS, ACC
Filters	40 Hz, 150 Hz, 300 Hz display filters 50/60 Hz AC Filter	Muscle, Anti-aliasing Baseline wander (0.5 Hz) 50/60 Hz AC Filter
Frequency Response for Pacemaker Spikes	40,000 Hz	2,000 Hz
Pacemaker Display	Yes, using a pace-spike channel below the captured ECG	Yes, with markers on the captured ECG waveform
Rhythm Printing	Single channel of ECG may be printed for the entire time the patient is connected. Else, individual 10 second snapshots can be acquired, printed in succession to acquire multiple pages of ECG during a single session.	Rhythm ECG can be captured with event marking in the ECG module.

Comparison to CardioPerfect Workstation – Resting ECG

Product Feature	Diagnostic Cardiology Suite	CardioPerfect Workstation
Serial Comparison	Not Supported	Supported through “compare ECG” section; average complexes are superimposed over each other
Quality Indication	Lead fail and lead reversal indication	Leadoff detection and “Bad signal quality” indication on display
Quality Selection	Best 10 setting allows the 10 seconds that is most artifact-free to be selected	No specific feature
Display Options	12x1, 6x2, 3X4 + rhythm lead, 3x4 + 3 rhythm leads, 6x6	3x4 and 6x2
Averages / Median Beat	Averages and zoomed in median lead shown for selected lead	Averages of each lead available
Vector View	Not supported	Optional
R-R View	Not supported	Optional
QTc Calculation	Linear, Bazett and Fridericia	Bazett, Fridericia, Hodges
Interpretation Algorithm	VERITAS	MEANS

Comparison to CardioPerfect Workstation – Spirometry

Product Feature	Diagnostic Cardiology Suite	CardioPerfect Workstation
Age Range Supported	6 years and older	6 years and older
Test types supported	FVC, SVC, MVV Pre/Post Bronchodilation	FVC, SVC, MVV Pre/Post Bronchodilation
Incentive Screen	Yes, same as CPWS	Yes, Fireman
Predictive Norms	See manual for full list, same as CPWS	See manual for full list
Supported Spirometer	Diagnostic Cardiology Suite Spirometer	SpiroPerfect
Ambient Conditions	Automatically detected by spirometer	Must be input manually prior to use
Iconography	 <p>The same buttons are utilized with updated iconography</p>	

Comparison to CardioPerfect Workstation – Connectivity

Product Feature	Diagnostic Cardiology Suite	CardioPerfect Workstation
PDF Export	File Exchange through the Manager	File Link
DICOM Support	Yes, through ELI Link for ECG	No
HL7 Support	Yes, through ELI Link for ECG	Yes
Connectivity Gateway for other ECGs	No	Yes for CP150
Integrated EMR Launch	Yes, ECG and Spirometry	Yes, all modalities
Thin Client Support	Yes, with Connex Link	Yes, with Perfect Link
Telemedicine Option	Not Supported	Optional
Networked Authentication	Yes, Active Directory Supported	Yes, Windows NT supported