



Technical Service Bulletin

CARDIOPULMONARY

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Bulletin Type: AS NEEDED

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Subject: TSB- CPWS 1.6.5 SOFTWARE RELEASE

Distribution Scope: Welch Allyn Global Technical Support, Product, Field & Customer Service Teams.
 N/A

Product(s) Referenced: **Material being updated:**

Material#	Description
409422	CPWS V1.6.5 DVD

Affected Products:

Part #	Description
100638	CONNECTIVITY KIT,CPX00 TO CPWS
101442	PCR100 AHA W/INTERP,SPIRO,SYRINGE
101443	PRO ECG IEC W/INTERP,SPIRO,SYRINGE
101444	PCR100 AHA W/INTERP, ABPM
101445	PRO ECG IEC W/INTERP, ABPM
101447	CPWS ABPM AND SPIRO W/SYRINGE
101448	PCR100 AHA,SPIRO,SYRINGE
101449	PRO ECG IEC,SPIRO,SYRINGE
101450	PCR100 AHA, ABPM
101451	PRO ECG IEC, ABPM
101452	PCR100 AHA ,SPIRO,SYRINGE, ABPM
101454	PRO ECG IEC ,SPIRO,SYRINGE, ABPM
101455	PCR100 AHA W/INTERP,SPIRO,SYRINGE,ABPM
101456	PRO ECG IEC W/INTERP,SPIRO,SYRINGE,ABPM
101457	PCE210 AHA STRESS, W/INTERP,PC,TM

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101458	PRO ECG STRESS IEC W/INTERP,CLIP
101860	PCR100 RESTING ECG, NON-INTERP, AHA, 3M
101861	PCR100 RESTING ECG, NON-INTERP, AHA, 5M
102261	CPR100 Rest ECG, AHA, Serial, interp
102262	CPR100 Rest ECG, IEC, Serial, non interp
102263	CPR100 Rest ECG, IEC, Serial, interp
406814	CP50 CONNECTIVITY KIT
703554	SPIROPERFECT KIT, USB, CPWS
ABP	AMBULATORY BP SYSTEM WITH S/W
ABPM-6100C	ABPM-6100 with Chinese SW
ABPM-6100S	ABPM SYSTEM W/6100 RECORDER& SOFTWARE
6100P	ABPM RECORDER & ACCESSORIES IN PKG
6100-24	CABLE,PC CONNECTION,ABPM 6100
6100-24USB	CABLE,USB,PC CONNECTION,ABPM 6100
PC-USB-SER	CONVERTER, USB TO RS232 (DB9)
ABP-SW	ABPM CARDIOPERFECT SOFTWARE
ABP-UK	AMBLTRY BP SYS WITH SOFTWARE UK
CCW-UPCPWR	CPWIN REST.UPGRD WACPW REST. ECG
CCW-UPST	DOS STRESS,UPGRD WACPW STRESS ECG
CP-CON	EMR CONNECTIVITY OPTION
CPE-CN-EB-D	CER100 PDA REST. ECG, NON-INTERP, IEC
CPR12-UN-EB	PRO ECG SYSTEM 1200 HZ WITH
CPR-SN	PRO ECG SYS W/SER INTRFC EXCL. PAT CBL
CPR-UI5-EB-D	PRO ECG 5M USB,INTERP,CABLE DISP ELECT
CPR-UI-EB	PRO ECG SYS W/ USB INTERP & INTRFC,ADULT
CPR-UI-EB-D	PRO ECG SYSTEM WITH USB INTERP
CPR-UI-UB-D	PRO REST SYS
CPR-UN	PRO ECG SYS600 HZ W/USB INTRFC EXCL.PAT
CPR-UN5	PRO RESTING ECG SYSTEM W/ 5MT
CPR-UN5-EB-D	PCR100 RESTING ECG,NON-INTERP,IEC (5M)
CPR-UN-EB	PRO ECG SYS W/USB INTRFCE INCL.PAT CBL
CPR-UN-EB-D	PCR100 RESTING ECG,NON-INTERP,IEC
CPR-UN-UB-D	CARDIOPERFECT PRO REST SYS
CPR-UN-UB-D-1200	CARDIOPERFECT PRO REST SYS
CPR-UPG-LTU	UPGRADE FROM RESTING ECG
CPR-UPG-MD-1	UPGRADE FROM MDR TO CPR-UN
CPR-UPG-POR-1	UPGRADE FROM POR TO CPR-UN
CPR-UPG-POR-3	UPGRADE FROM POR TO CPR-UN
CPSL-UN	PRO EXER ECG LGHT SYS 600HZ W/USB INTRFC
CPSP-UN-UC-D	PCE210,STRESS,NON-INTERP,AHA,NO PC,NO TM
CPSP-UN-UC-D-P	PCE210,STRESS,NON-INTERP,AHA,PC,NO TM
CPSP-UN-UC-D-PT	PCE210,STRESS,NON-INTERP,AHA,PC,TM

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CPSP-UN-UC-D-T	PCE210,STRESS,NON-INTERP,AHA,TM
CPS-UN	PRO EXR ECG SYS 600HZ W/USB INTRFCE EXCL
CPS-UN5	PRO STREE ECG SYSTEM W/ 5MT
CPS-UN-EC	PCE200,STRESS,NON-INTERP,IEC,CLIP
CPS-UN-EP	PCE200,STRESS,NON-INTERP,IEC,PUSH
CPS-UPG-LTU	SW UPGRD WACPW LITE TO FULL STRESS
CPS-UPG-MDS-1	UPGRADE FROM MDS TO CPS-UN
PE-PROCM-LNK-GB	UPGRADE SET FOR CPR TO CPE SYS
REC-SW	WACP WORKSTATION EVENT ECG
RE-SW-ECG	CARDIOPERFECT PRO CP WORKSTATION SW TEST
RE-SW-HRV	HEART RATE VARIABILITY OPTION FOR WACPW
RE-SW-MEANS	CARDIOPERFECT PRO REST ECG INTERPRET SW
RE-SW-PEDIA	PEDIATRIC AUTO RST-ECG INTERP
RE-SW-VCG	VECTORCARDIOGRAM (RECONSTR.12
SE-UPG-USB	UPGRD MD SYSTO EXER TEST USB INTERFACE
SPIRO-NS	CPWS PC SPIRO NO SYRINGE
SPIRO-NS-RS232	CPWS PC SPIRO NO SYRINGE, RS232
SPIRO-S	CPWS PC SPIRO W/ SYRINGE
SPIRO-S-RS232	CPWS PC SPIRO W/ SYRINGE, RS232
SP-SW	WACP W/STN SP SOFTWARE (SP-SW)
SW-CCW-CD	CCW CD-ROM(FOR SERVICE PACK)
SW-CCW-LIC	WACPW SOFTWARE LICENSE
SW-CCW-LIC-UPD	CCW SOFTWARE VIEWING LICENSE UPDATE
SW-CCW-TELEM	CARDIOPERFECT PRO TELEMED OPTION
SW-UPD-1	UPDATE TO CCW
SW-UPD-2	UPDATE TO CCW
SW-UPD-3	UPDATE SOFTWARE CCW
SW-UPD-4	UPDATE SOFTWARE CCW
SW-UPD-5	UPDATE SOFTWARE CCW

SW Version: CPWS version 1.6.5.1140
 DVD Volume name: CPWS 1.6.5.1140 Rev-B

Serial No. / Starting Serial Number: 176401
Lot Code:

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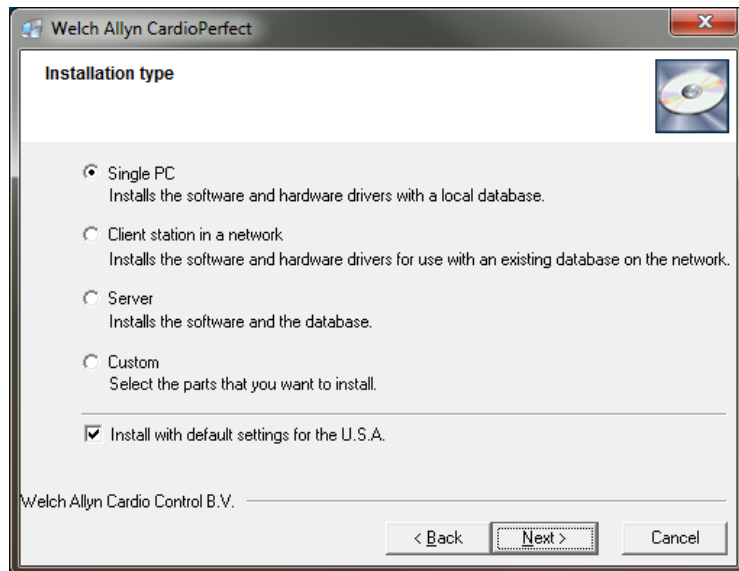
Summary: The Welch Allyn Cardiopulmonary category team is pleased to announce a new version of software for the CardioPerfect Workstation (CPWS). This version 1.6.5 of the software incorporates several enhancements and fixes that are outlined in this bulletin.

This newest version incorporates Windows 8 Standard and Windows 8 Pro compatibility, the introduction of a USB cable and driver solution for ABPM 6100 connectivity, Microsoft SQL Server 2008 R2 Express installation with 10 GB of storage, and various improvements and bug-fixes.

The software can be ordered as an update or upgrade for existing CardioPerfect users and will be distributed via DVD on all new orders starting June 18, 2013.

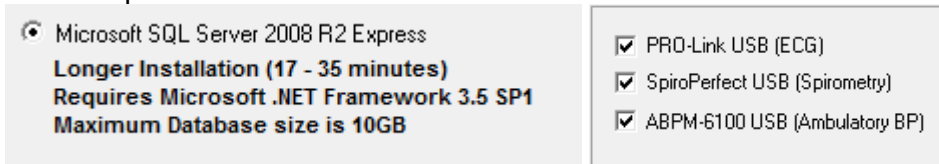
Issue: Software changes & enhancements:

- **Software Installation:**
The software installation process has a new, more intuitive user interface. With the exception of the Custom install, choosing the appropriate installation type allows for the installation of all necessary components by default with no further interaction needed until the “Finish” button appears.



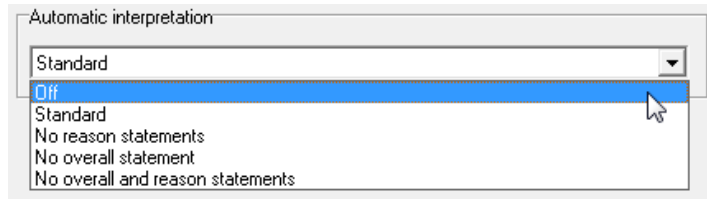
The ability to select or deselect the installation of default settings for the U.S.A. can be done on this screen. This box is checked by default in the U.S.

The Custom installation provides the installer with the traditional, step-by-step process that allows the installer to choose the install directory, MSSQL server type, component driver installation... etc. The added choices of the MSSQL Server 2008 R2 and the ABPM-6100 USB cable driver are visible through the custom option.

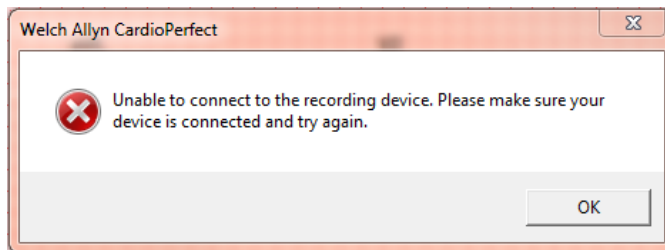


- **Resting ECG:**

- The General tab of the Resting ECG settings has added the ability to adjust the interpretation information that is displayed on new ECGs only.. The interpretation can also be turned On and Off without changing the software Release Code.



- The Invalid WDM Handle error has been replaced with:

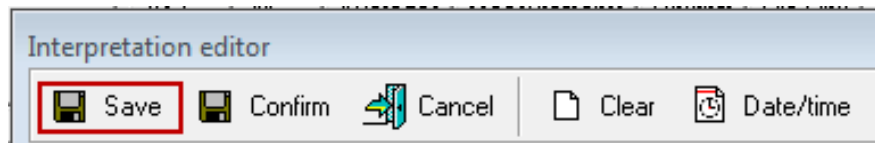


- Unconfirmed interpretations no longer advise "MD SHOULD REVIEW."

1.6.5:
UNCONFIRMED INTERPRETATION

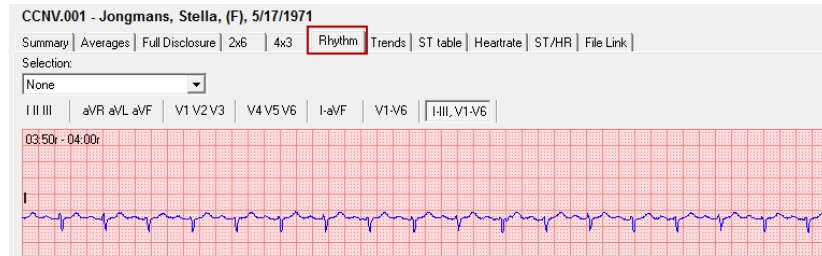
Previous:
UNCONFIRMED INTERPRETATION **MD SHOULD REVIEW**

- Save interpretation (besides Confirm).



- **Stress ECG:**

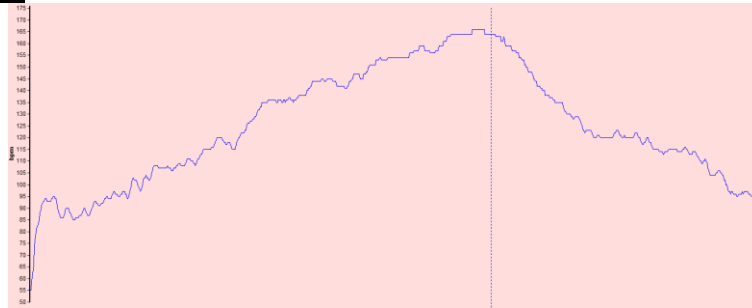
- A Rhythm tab has been added which allows the choice of 7 different rhythm views from any point during the test.



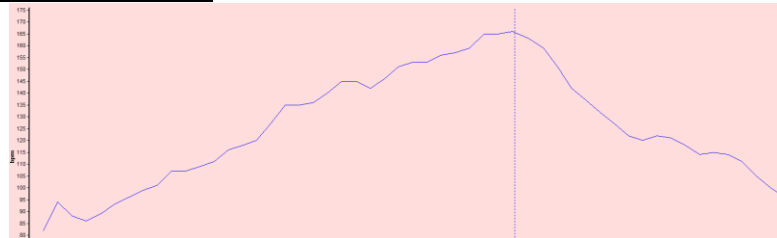
- **Heart-rate Tab:**

- Removed the HR smoothing, which caused discrepancy in max HR reporting.

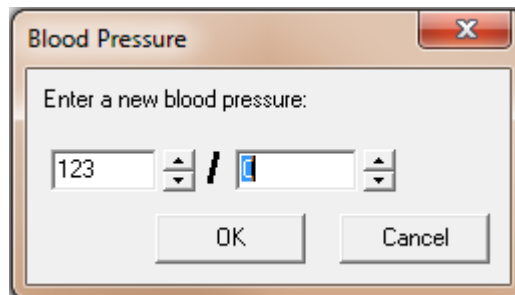
1.6.5



Previous versions



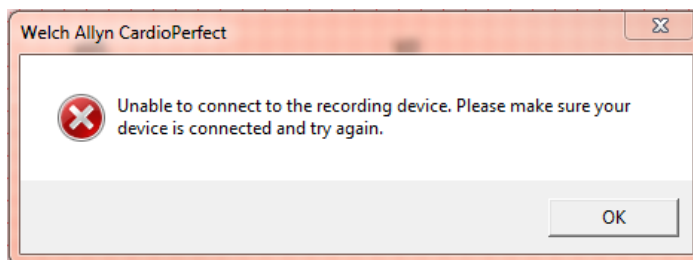
- BP prompt automatically advances from Systolic to Diastolic after 3 digits have been entered.



- Error pop-ups during BP changes and Manual Load Changes no longer occur. Improper values will be highlighted in RED and will not allow the user to continue without correcting the value.

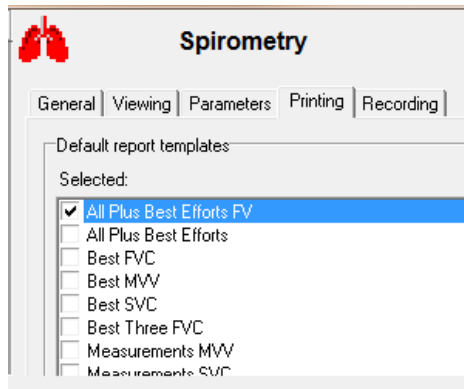


- The Invalid WDM Handle error has been replace with:

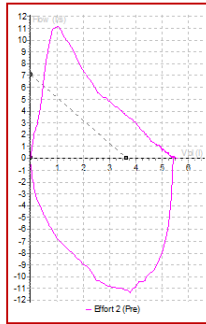
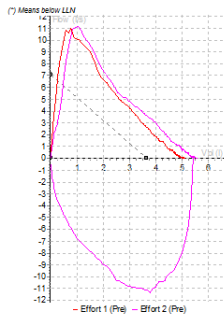


- **Spirometry:**

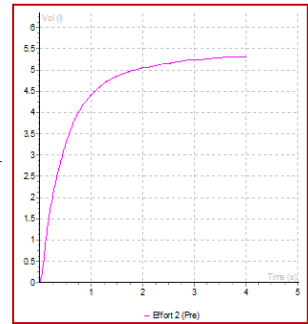
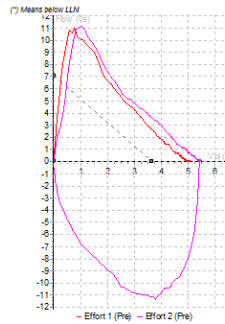
- The choice of “All Plus Best Efforts FV” has been added to the Default report templates



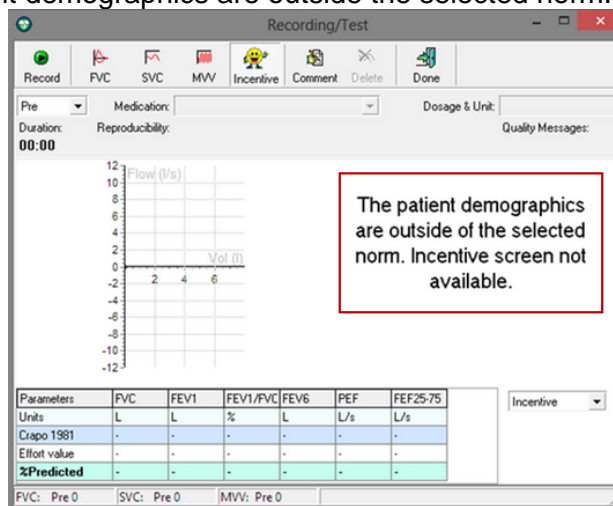
All Plus Best Efforts FV:



All Plus Best Efforts:

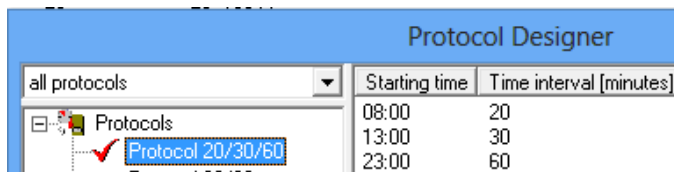


- The Incentive screen will now tell the user that it is not available because the patient demographics are outside the selected norm.



ABPM:

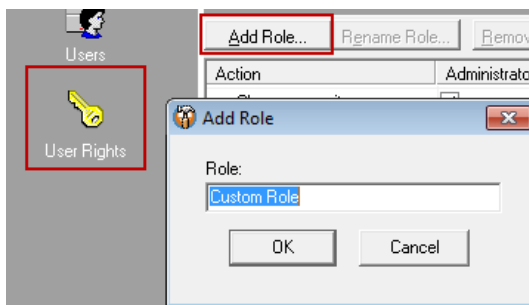
- New USB/Serial communication cable
A single USB cable replaces the PC Communication Serial Cable and the Keyspan adapter.
- New ABPM Default Protocol and Naming Convention lets the user know the time intervals without having to open the protocol editor.



- Added % successful readings:

General	Overall
Nr. measurements	47
% Succeeded	100%
Total time	22:42:00
Average	141 / 99 mmHg
SD	12.8 / 12.6 mmHg
Pulse pressure	42.3 mmHg

- **Recollect:**
 - The issue with Recollect card format tool has been fixed.
- **Administrator Tool**
 - Ability to create additional, customized user roles:



- The Users list does not populate with all of the users automatically...need to click "Search" first. (This is better for long lists of users.)
- **Bug-fixes:**
 - Fixed "Data Execution Prevention" issue with Replicator.
 - Fixed issue that sometimes caused crash after printing.
 - Solved problem with ProLink USB and hibernation.
 - Fixed printing issue with long interpretation text.
 - Stress Summary: Graphs were sometimes missing on the print-out and the sections were shown even if empty. You can now add order number.
 - Spirometry:
 - Best 3 FVC sometimes printed more than 3 efforts.
 - Fixed axis scaling issue
 - ABPM: Fixed issue caused by ABPM device determining leap years incorrectly
 - PerfectLink: Fixed sporadic communication through an RDP session.

- **Database changes:**

Supported Operating Systems and SQL Server versions.

On the Client (thick client)	On the Server	MS SQL database engine
XP SP2 or higher	Windows 2003 Server	SQL 2000
Vista Business SP1 or higher	Windows 2008 Server	SQL 2005
Windows 7 Home Premium, Professional, Ultimate	Windows 2008 Server R2	SQL 2008
Windows 8, Pro	Windows 2012 Server	SQL 2008 R2
32- & 64-bit supported	32- & 64-bit supported	32- & 64-bit supported

NOTE: Server 2012 is not supported for thin-client.

- **PerfectLink Improvements:**

- Support for vWorkspace thin-client environment.
 - **NOTE:** Server 2012 is not supported

- **FileLink:**

- The “Save current test to selected file formats” button on the FileLink tab has been replaced:



- Updated TIF and PDF drivers for Windows 7, Windows 8 and Server 2012 compatibility.
- API improvements for some EMRs like EMIS.

- **Supported thin-client operating systems.**

Client OS	32-bit	64-bit
Windows XP	x	x
Windows XP Embedded	x	
Windows Vista	x	x
Windows 7	x	x
Windows 7 Embedded <u>NOTE: Currently experiencing an installation issue</u>	x	x
Windows 8	x	x

Windows 8 Embedded

x

x

- **Other Changes:**
 - DbBuilder: Added checkbox for US defaults.
 - Additional measurements in SCP export (HR, QT, QTc now exported to MUSE).
 - Improvements that impact EMR interfaces.
 - API improvements for some EMRs like EMIS.
-

Action: Use appropriate CPWS Update DVD part number(s) for customers when needed.

Known Issues:

Administrator Tool:

- HIPAA not logging when you remove a Spiro effort.
- HIPAA log prints off the edge of the paper.
- Need for Chinese translation correction in the Admin Tool / User Rights section.
- Manually creating a back-up in the Admin Tool to the root of any drive, and while using MSSQL 2005 Express, the user may get an error that states that there is not enough disk space and the back-up will fail. Creating a folder for the back-up location resolves this issue.
- Chinese language setting: The error "Failed to add the role. A role with this name already exists." does not translate to Chinese but remains in English.

ECG Module:

- Events in ECG Printouts not matching displayed positions on printed tests when printing with Calibration pulse.
- ECG Settings for Default Chart-speed and Default Sensitivity are not applied unless the test is refreshed by moving away from the test and returning.
- The first ECG recording may not start correctly on the server, if the client system has multiple recording devices attached.
- Missing Language Sets: Greek and Russian MEANS interpretation language files are not in the software and will give the interpretation in English.
- CPWS loses COM API connectivity when starting an ECG recording through EMR (NextGen) interface. (Cause is unknown and not a confirmed CPWS issue).
- While in live ECG monitoring or recording mode, enabled but disconnected network adapters may interrupt the acquisition and/or the display of the live data. This will result in a "Fatal error 1 detected, monitor will abort" error message.

Stress Module:

- Averaged beats may not align properly.
- Averages stop being calculated while signal is not very bad. MEANS will stop calculating if QRS complexes become too wide.

Spirometry Module:

- Referring Physician is not printed on some Spirometry printouts.
- The “Set Best Effort” function in the Action menu will be disabled (gray) when the test is opened with PRE or POST as the selected test option. Selecting another option and returning to the original option enables the “Set Best Effort” function.
- The New Effort button remains available when an in-progress test is inadvertently left open beyond the software’s 24 hour limit for adding efforts to a test.
- Smoker and Asthma checkboxes only appear on measurements reports
- Calibration log does not show sensor ID.
- Last recorded SVC or MVV effort is still displayed in the monitor when switching from SVC to MVV effort type or visa-versa.
- The colors assigned to the flow results on the graph may not match the colors assigned to the measurement result shown below the graph.
- The list of available reports on the print dialogue is not wide enough. This causes the string for "All Plus Best Efforts FV" to be truncated when in Dutch, Greek, and Polish in the Report list-box of the dialog.

ABPM Module:

- Exceeding Norms graphs follow the settings, not the threshold values in the Summary.

Not Module Specific:

- The error "Invalid character value for cast specification" will occur when a patient’s birthdate is incorrectly entered and the calculated age is over 200 years of age.

FileLink:

- On Server 2008, FileLink requires the server role for Print Management and the Printer Spooler Service to be enabled.
- Slow performance when the system that is running FileLink is connected to a network and is not connected to the internet.

PerfectLink:

- 1.1 Upgrade does not upgrade ECG files. This will require the full un-install of 1.0 and reinstall of the 1.1 PerfectLink drivers.
- The “Repair” function fails after upgrading PerfectLink from 1.0 to 1.1. This will require the full un-install of 1.0 and reinstall of the 1.1 PerfectLink drivers.
- 1.1 PerfectLink drivers do not install on Windows 7 Embedded, 32 bit and 64 bit.

Reference to Standards:

- 21 CFR Part 820, ISO 13485, MPD SOP-0002

Service Strategy: A customer may call that is upgrading to CPWS 1.6.5 from an older version of the software and does not have a DVD-ROM player installed on the PC. The CPWS 1.6.5 software installation media may need to be delivered to the computer through a different means. Please refer to the CPWS REMOTE INSTALL REFERENCE GUIDE, DIR 20012822, Rev B, and follow the TeamViewer delivery method outlined in Steps 4 through 6 on pages 19 & 20.

Procedure: Refer to this TSB and Installation documentation located on the CPWS DVD.

Quality Documents: **All service centers using SAP to record service transactions:** For each product serviced, record the service activity in SAP.
All other service centers and Field Service: For each product serviced, complete and file a service report and attach to the service DHR.

Notes:

1. Contact the Welch Allyn Complaints Department to initiate or process a medical device complaint resulting from this or other issues.
2. Drawings, illustrations, and part numbers in this document are for reference purposes only and subject to change.

End of Bulletin

Revision History					
Version	Description	Change #	Init	Release Date	Appr
A	Initial Release	D*	SMB	D*	D*
D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL					