

Horizon XVu System Version 1.1 Release

Appendix A

Mennen Medical Ltd. is now updating the New Horizon XVu CathLab System Software Version 1.0 with the new XVu software version 1.1

This document will describe the new features and changes that will be available.

1. Introduction

Further to our previous documentation for the version 1.0 release, some features that were not available have now been included, new software therefore being equivalent to the V2.7 SE Horizon software (Ultra 25 computer) and V2.6b SE Horizon software (Blade computer).

Glossary

	Definition
FFR	Fractional Flow Reserve
ECG	Electrocardiogram
BP	Intrinsic Blood Pressure
LV	Left Ventricle
AO	Aorta
Pd	Distal Coronary Blood Pressure
Pa	Aortic Blood Pressure
CFE	XVu physiological front end
GUI	Graphical User Interface
HR	Heart Rate

2. These new features are based on the Horizon SE ver. 2.7:

2.1 Option that enables translation of the user interface into various languages including Hebrew. (Default language will remain English)


2.2 Fractional Flow Reserve (FFR) calculations.

This value is measured by calculating the ratio between the mean pressure at a given point in the coronary tree (usually distal to the stenosis) Pd, and the mean Aortic pressure Pa. **FFR = Pd/Pa.**

This value is helpful in deciding on the proper intervention treatment

The FFR option requires having

- The pressure wire (Pd) in **BP3**
- The Pa in **BP1**


The FFR option should be activated in **System Option**, by clicking the **FFR** checkbox  in the **System Options Parameters** panel.

Procedure Initialization :

- a. Both wires should be positioned in the Pa.
- b. BP1 and BP3 should be zeroed.
- c. The BP1 (Pa) mean values are then equalized by the XVu system to that of BP3 (Pd) mean value.
- d. The user is prompt to advance the Pd tip to it's correct location (distal to the stenosis). The offset between the Pa mean pressure and the Pd mean pressure is displayed.
- e. Maximum hyperaemia will be sustained by Intravenous Adenosine or Intracoronary Papaverine or Intracoronary Adenosine.
- f. A drop in pressure will be recorded in the pressure wire
- g. The FFR value is displayed continuously on the screen.
- h. Pressing a location on the coronary diagram will enter a note to notes list with the location + value of the FFR.
- i. A pull back curve can be recorded and repeated as needed.

2.3 Displaying and charting ST values.

ST segment characteristics are indicators of heart muscle ischemia and infarction. The level of the ST segments with respect to the iso-electric baseline and the orientation of the ST segments are of special interest to physicians as an indication of the severity and location of ischemia and infarcts caused by Ischaemic Heart Disease.

- 2.3.1 **Calculation:** The CFE automatic ST region for calculation is defined as follows: The iso point is on the iso electric line between the P wave and the QRS. The ST point is 80 msec after the QRS.
- 2.3.2 The continuous ST segment analysis option should be activated in System Option, by clicking the ST Checkbox ST in the System Options Parameters panel.
- 2.3.3 There is an option for setting an ST alarm at a user configurable value. This is accessed by clicking **System Configuration** menu in the XVu footer area.
- 2.3.4 The software permits a manual adjustment of the ISO and ST measuring points
- 2.3.5 When ST is selected to be displayed, the following actions occur:
 - ❖ The ECG filter is changed to ST filter (0.05 to 40 Hz), The new filter ST is displayed in the waveforms screen bottom part
 - ❖ The ST results as calculated for the **current lead used for HR calculations** are displayed in the main waveform window in the following format

 - ❖ The default display color is **yellow**, but if the ST value exceeds the value selected as the ST alarm value the color is changed to **red**
- 2.3.6 ST data can be selected & charted in Graphic Trends and Vital signs numeric Charts by clicking the ST check box ST in Vital Sign Charting panel.
- 2.3.7 Collected data can be saved in the Notes Window under VITAL_SIGN category.

2.4 Automatic LV-AO Pullback.

This feature eliminates the user's need to state the catheter site while performing LV-AO Pullback. The Xvu automatically recognizes the positioning of the catheter in the LV. When the catheter is pulled back to the AO, the Xvu system automatically recognizes the new site and analysis is available.


This option requires the **vsAnalysis** option to be on. In this mode the waveform is colored in magenta and the pullback channel BP label is replaced by **LV**.

If the catheter is not yet in the LV, the LV label is flagged with an asterix. When the catheter is advanced into the LV, or is already in the LV site the LV label is not flagged.

The system expects to detect at least 3 consecutive LV beats

When the catheter is pulled back to the **AO** the Xvu system automatically recognizes the new site. The waveform is colored in red and the pullback **LV** label is replaced by **AO**. After clicking Analysis, a regular **LV → AO** Pullback window pops up.

This option will be currently available only for those layouts with the coronary heart diagram.

The default state of the Pullback button is selected in the **Clinical Parameters Setup**, by clicking the Automatic Pullback checkbox  in the Analysis Parameters Setup panel. When the Checkbox is unchecked this means a regular pullback procedure is the default Pullback button state.

The pullback is terminated by Analysis, Stop, or Cancel button as any regular pullback analysis can be terminated

2.5 F1 Quick key added for Backward Post-Pullback performance.

This is a utility for cases where the user missed the DR's pullback session, and wants to analyse post-pullback-procedure. The system collects the BP1 waveform in the background, even when the waveform was not labelled by any site name.

When the system is not in acquisition mode, hitting **F1** key results in the pop up of the analysis window of pullback, containing up to 200 seconds backward of BP1 waveform snapshot, labelled as **CV**. The user may label the snapshot as required and run an analysis on it.

2.6 Edit and create for user-defined sites.

This feature allows modification of Mennen default pediatric and peripheral sites. The main menu of *System Setup* was changed to include a new entry "Edit Sites".

2.7 Foreign languages Support

Italian, french and Hebrew are available as an option.

3. The Software upgrade is not mandatory and is available for the following systems:

- ❖ The Horizon XVu with console
- ❖ The Horizon XVu Lite without console
- ❖ The Compact Horizon XVu with console (To be released in Q3 2009)
- ❖ The Compact Horizon XVu without console (To be released in Q3 2009)

4. Limitations:

- ❖ The XVu software ver 1.1 is available for the SUN Ultra 25 computer and UNIX Solaris 10 operating system.
- ❖ A Software/Upgrade programme is available.
- ❖ The XVU software version 1.1 is parallel to the SE s/w ver 2.7 (Ultra 25 computer) and V2.6b SE Horizon software (Blade computer).