



## Validation Support Package

Whether you are validating the Ponemah Physiology Platform for the first time or re-validating due to a version upgrade, the Validation Support Package can assist every GLP user's needs in order to comply with 21 CFR Part 11 requirements for computer system validation. DSI recognizes that computer system validation is a time-consuming task, and therefore, is offering the Validation Support Package to assist its customers with validating the Ponemah software and DSI hardware interfaces in order to ease the validation process.

### Validation Documentation

The Validation Support Package is designed to assist the GLP User with Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) phases of the user's validation plan. Test plans will assist with validating the installation and functionality testing of the Ponemah software within the User's environment.

### Vendor Audit

FDA regulations state that the User should qualify the vendor to ensure the quality of the product; the User should perform an audit to evaluate the vendor's software development activities and product quality. The DSI design and development team welcomes its users to perform a vendor assessment.

### Upgrade Assistance/Change History

A change history summary (release notes) will be provided indicating changes performed with each new version of the software. This will assist the customer in determining if there is a need to perform re-validation of the Ponemah software when the user upgrades to a newer version.

### *Features*

- Test Plans
- Vendor Audit
- Change History
- Upgrade Assistance

# Technical Data Sheet

## Model PNM-XXXX

### Validation Support Package

#### Core Components

Alarms/Digital Displays  
Binary Data Convert  
Data Manager  
Data Reduction  
Data Review  
Data Security Option  
Data Storage Scheduler  
DSI Reporting  
ECG PRO (Template)  
Experimental Protocol Header  
Graph Pages  
Groups and Events  
Hardcopy (Print RAW Data)  
Mail Slot  
ODBC Interface  
Settings  
Study Protocol Option (Tox, Non-Tox)  
Video

#### Acquisition Interfaces

ACQ-16 (EPP and USB)  
ACQ-7700 (EPP and USB)  
ACQ-7700 Signal conditioners  
Data Sciences™ OpenART™  
JET™ (Jacketed External Telemetry)  
12 Lead ECG Amplifiers

#### Analysis Modules

Action Potential  
Blood Pressure  
Cardiac Volume  
Coronary Blood Flow  
Cystometry  
Electrocardiogram (Single and Multiple Lead)  
Electrocardiogram (Rate Only)  
Electromyogram  
Left Ventricular Pressure Analysis  
Pulmonary Air Flow  
Pulmonary Compliance and Resistance and Pressure  
Pulsatile Tissue and Gut Motility  
Respiration from Blood Pressure  
Systemic Blood Flow  
Unrestrained Plethysmography

**NOTE: As new versions of Ponemah software are released, new modules may be added or deleted. This list may not include all current features of the Ponemah software that can be validated per the Validation Support Package.**

#### ORDERING INFORMATION

Part Number	Description
PNM-VPS7	Validation Support Package for Ponemah/OpenART Systems
PNM-VSP-A2P	Validation Support Package for Data quest to Ponemah OpenART Upgrade

  

Accessories	
Part number	Description
PNM-PXP-T22	On-Site Validation Assistance per day with validation package (2 day minimum)
PNM-PXP-T11	On-Site Validation Assistance per day (2nd person)
PNM-ESC-01	Ponemah Escrow Agreement-1 year

*Specifications are current at publication.  
Due to DSI's continuing product improvement program,  
specifications may change without notice.*

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