

PeriGen, Inc.

PeriCALM[®] Tracings[™] System Requirements

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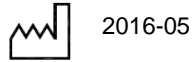
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Empowering Clinicians. Advancing Perinatal Systems.

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Intended Use

PeriCALM Tracings is intended for use as a central monitoring system with signal analysis and display functions and remote repeaters in the perinatal clinical environment. It interfaces with standard fetal and maternal monitors and provides fetal surveillance, monitoring of labor progress, charting, reporting and data analysis, display and archiving functions.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.



Please refer to the User Guides prior to the first use.
Rx only.

Various aspects of the PeriCALM software suite are subject to issued and pending patents in several jurisdictions. Issued patents include:

USA	6,907,284
USA	7,113,819
USA	6,423,016
European Patent	1,505,903
European Patent	1,289,416
Canada	2,311,029
Canada	2,384,516
Canada	2,379,733

Table of Contents

Server requirements	4
2x PeriCALM Tracings – Surveillance Primary/Standby Server(s) (Virtual supported)	4
PeriCALM Tracings – Surveillance Acquisition Server(s)*	4
PeriCALM Tracings - Test/Training Server (Virtual supported)*	5
Enterprise Interface Server (Primary and Test/Backup)	5
Offline Archive Storage	5
Client / Workstation Requirements	5
Citrix	6
Network	6
Supported Tracing acquisition concentrators per networking closet	6
Virtual Environment Support	7
Fetal Monitor Compatibility.....	8

Server requirements

The Server Requirements below cover the standard system offering (<5000 births per year). A Custom configuration is required for additional interfaces and sites with >5000 births.

2x PeriCALM Tracings – Surveillance Primary/Standby Server(s) (Virtual supported)

(Secondary standby is optional and applicable for physical servers only, for virtual deployments, only one server is required when using a High Availability configuration (VMware HA, or HyperV using Windows Server failover clustering). See “Virtual Environment Support” section later in the document)

- 1x Intel Quad Core E5620 or better
- One of the following storage options:
 - Physical: 2x 146GB Raid 1 (OS) + 3x146GB Raid 5 (Application/Data)
 - SAN: 80 GB (OS) + 100 GB (Application/Data):
- 8GB of RAM
- Redundant power supplies
- Dual port Gigabit Ethernet for physical servers only (used with data replication option)
- Microsoft Windows 2008 R2 Service Pack 1 (for all 03.18.xx versions) or Windows Server 2012 R2 (only supported with 03.18.04)
 - Internet Information Services (IIS) installed
 - Common Features and files
 - IIS Manager, World Wide Web Service
 - ASP and ASP.NET
 - Windows Authentication
- The following ports should be free and available for use:
 - PeriCALM Tracings, PeriCALM Patterns: 91, 92, 2506, 7100 and 7802
 - PeriCALM CheckList: 7200, 7803.
 - MSMQ\RPC: 135, 1801, 2101, 2103, 2105
 - Windows File sharing: 137, 445
 - Digi Terminal Servers: 771
 - Moxa Terminal Servers: 4001

If not found, the following components will be automatically installed by the Tracings installation program:

- VC++ 2008 SP1 Redistributable, VC++ 2010 SP1 Redistributable
- .Net 3.5 SP1, .Net 4.5.2 Full
- MSXML 4.0 SP2, MSXML 6.0 SP1

Note: It is important that Windows 2008 R2 SP1 or Windows 2012 R2 be used for all servers. No other OS will be approved for a Production/Test/Training environment

PeriCALM Tracings – Surveillance Acquisition Server(s)*

*Number of server(s) depends on site layout, number of areas and network resiliency. This server can be consolidated with the main server for small site configurations.

- 1x Intel Dual Core or better

- 2x 146GB Raid 1 or better
- 4GB of RAM
- 2 Network Interface Controllers (NIC)
- Redundant power supplies recommended
- Microsoft Windows 2008 R2 Service Pack 1 (for all 03.18.xx versions) or Windows Server 2012 R2 (only supported with 03.18.04)

PeriCALM Tracings - Test/Training Server (Virtual supported)*

- VM is recommended for this server. If not available at the site, a dedicated entry level server or workstation is required:
 - 1x Dual core CPU, Quad core recommended
 - Storage: 40 GB of available storage for application files (excluding OS)
 - 4GB of RAM
 - At least 1 Network controller
 - Microsoft Windows 2008 R2 Service Pack 1 (for all 03.18.xx versions) or Windows Server 2012 R2 (only supported with 03.18.04)

Enterprise Interface Server (Primary and Test/Backup)

- Similar specification to the above Test/Training Server.

Offline Archive Storage

- Network mountable storage (UNC path) for long term archive storage (a local copy is typically maintained on the server).
- Storage requirement formula: 1MB x Annual birth rate. Ex: 2500 births/Year => 2.5GB per year.

Standalone encrypted and compressed files are produced per patient which include the binary representation of all visit and tracing information for each pregnancy.

Client / Workstation Requirements

- Microsoft Windows 7 Professional 32/64-bit (SP1)
- 2GB RAM. 500 MB of available memory should be reserved for PeriCALM Tracings modules.
- Microsoft Internet Explorer 9.0 or better. Ensure that client policies do not restrict the installation of trusted ActiveX controls by end users.
- 1024x768 or 1280x1024 (4:3) is the standard minimal resolution supported by the system. Only native resolution and native aspect ratios are supported (non-native resolutions or aspect ratios will result in a stretched representation of fetal tracings and are not supported)
- .NET Framework 3.5 Service Pack 1
- .NET Framework 4 Full client profile
- Microsoft Visual C++ Redistributable 2008 SP1 and 2010 SP1 (x86/x64).
- Wireless network are not recommended for the PeriCALM Tracings application. If required, PeriGen will collaborate with the customer to confirm that PeriCALM application performs as expected on the site's wireless environment.
- Large Screen displays of non-interactive multi-tracing Surveillance or Chalkboard are supported in full screen in native resolutions only (typically 1920x1080). Native resolutions are the default

recommended resolution for the type of display used that will ensure proper aspect-ratio. Different resolutions may require separate validation procedures and must be verified in advance with PeriGen personnel

For PeriCALM Checklist customers:

- a. All bedside workstations that will be using PeriCALM Checklist must be deployed via Citrix published desktop or thick client.
- b. All other workstations may be deployed via Citrix published application.
- c. Designated central monitored workstations may be deployed as Non-Interactive workstations with PeriCALM installed locally on them.
- d. Availability of ports 7200, 7803 in addition to the ports required by PeriCALM Tracings/Patterns as listed above.

Citrix

- Citrix deployment of PeriCALM Tracings Client Application is supported on dedicated servers only with a maximum of no more than 30 concurrent sessions.
- Server specifications should line up or improve on the above PeriCALM Tracing Surveillance Primary Server minimal requirements.
- It is strongly recommended to use modern multi-core CPUs and account for 200MB of physical memory per concurrent session.
- Precise server and memory recommendations are a function of overall site load. Recommendations will be finalized during system implementation.

Network

- Switched Ethernet network, 100 Mbit or better
- Guaranteed maximum latency of 20ms (worse case) between all components of the system
- CAT5+ dedicated cabling between each monitoring area and networking closet. Cables should be compliant to RS232 data transmission standards. Point-to-point configuration recommended.

Supported Tracing acquisition concentrators per networking closet

From DIGI:

ConnectPort LTS Series (RS232 mode only)

- ConnectPort LTS 32 port (70002411 or 70002412)
- ConnectPort LTS 32 port MEI (70002413 or 70002414)
- ConnectPort LTS 16 port (70002403 or 70002404)
- ConnectPort LTS 16 port MEI (70002405 or 740002406) or Dual power supplies (70001634)
- ConnectPort LTS 8 port MEI (8 port) (70001611 or 70001612)

EtherLite series

- DIGI Etherlite EL-32, 32 port (part # 70001429). (EOL - Not for new implementation)
- DIGI Etherlite EL-160, 16 port (part # 70001427). (EOL - Not for new implementation)

From MOXA :

NPort 6610 Series:

- 8 port (NPort 6610-8, 6610-8-48V)
- 16 port (NPort 6610-16, 6610-16-48V)
- 32 port (NPort 6610-32, 6610-32-48V)

NPort 6650 Series :

- 8 port (NPort 6650-8, 6650-8-48V, 6650-8-T, 6650-8-HV-T) *
 - 16 port (NPort 6650-16, 6650-16-48V, 6650-16-T, 6650-16-HV-T) *
 - 32 port (NPort 6650-32, 6650-32-48V, 6650-32-HV-T) *
- * Supported using RS-232 protocol only

NPort 5610 Series :

- 8 port (NPort 5610-8, 5610-8-48V)
- 16 port (NPort 5610-16, 5610-16-48V)
- 8 port desktop model (NPort 5610-8-DT-J)

NPort 5650 Series :

- 8 port (NPort 5650-8-T, 5650-8-HV-T) *
 - 16 port (NPort 5650-16, 5650-16-T, 5650-16-HV-T) *
 - 8 port desktop model (NPort 5650-8-DT-J) *
- * Supported using RS-232 protocol only

CN2650 Series:

- CN2650-8
 - CN2650-16
 - CN2650-8-2AC
 - CN2650-16-2AC
 - CN2650I-8-2AC*
 - CN2650I-16-2AC*
- * Requires a standard connector between DB9 Male to RJ45 Male according to standard RS232 pin-out and manufacturer guidelines. See OP-SPEC-2388 - CN2650I Equivalent connector specification.

The total number of devices is determined by total number of monitoring areas and distribution across networking closets. Redundant configuration requires double the number of base devices.

Virtual Environment Support

- Virtual servers on VMware vSphere v4.X and v5.X or Microsoft Hyper-V (2012 R2 Host) are supported on equivalent or better server specifications. Other platforms may require extra validation services.
- Resource reservations are mandatory on virtual servers. Certain restrictions may be needed depending on site layout and load.

- Tracing Acquisition servers are susceptible to real-time clock discrepancies on heavily loaded virtual infrastructures. For that reason, the following operations and configurations are mandatory in order to approve the deployment of Tracing Acquisition on customer virtual infrastructures:
 - Strict resource reservation on the Tracing Server VM
 - A host and storage vMotion (VMware) or Live Migration (Hyper-V) validation test demonstrating no substantial impact on tracing acquisition functions.
- Virtual workstations : The following environment is supported:
 - VMware Horizon View 5.x using persistent desktops. (Note: non-persistent desktops may be used but require use of a startup script to reset the MSMQ QMId and restart MSMQ; the configured environment will need to be validated by PeriGen technical staff.)
- NOTE: VM Snapshots are not supported and should be categorically avoided as a mean for backup of a running PeriCALM Tracings VMs. Using snapshots while the system is running will cause interruption of live data acquisition and display for clinical staff.
- NOTE: Time synchronization from the host the PeriCALM guest VM must be disabled.

Fetal Monitor Compatibility

Vendor	Protocol compatibility	Type	Interface card / Firmware	Description
Philips	1371	* 1350A and B * 50XM series	M1350-66532 or M1350-66536 * Firmware: <u>C01.03 and above</u>	24 pin Centronics connector for RS422 digital interface (M1350-66532) OR DB9 pin serial connector for RS232 interface. Firmware software must support option C13.
Philips	1371	Avalon FM20 Avalon FM30 Avalon FM40 Avalon FM50	Firmware: <u>F.0X and above.</u>	DB9 pin serial connector for RS232 interface. Firmware software must support option C13.
Philips	1371	Series 50IP	M1353-69531	24 pin Centronics connector for RS422 digital interface
GE/Corometrics	1371	118	J09-J10	DB9 RS232 serial interface
GE/Corometrics	1371	120/170/250 Series	J09-J10-J11	RJ11 RS232 serial interface

* Philips 1350 A/B and 50XM are presently out of support by Philips. Although the serial protocol is still supported, PeriGen cannot be held responsible for known issues with these fetal monitors with firmware versions lower than **C01.03**. Known issues include a very high frequency of SPO2 measurements sent to the electronic tracing when the paper recorder door is open and no paper is in the tray.