

PeriGen Inc.

PeriCALM[®] Patterns[™] Release Notes

Version 02.06.00

Document ID: PATT 020600 – DMR-2401

Revision: 01.00

Issued: 2016-04



PeriGen[®]

Empowering Clinicians. Advancing Perinatal Systems.

Copyright notice

Copyright © 1997-2016. PeriGen, Inc. All rights reserved.

Publication date



April 2016

Product

PeriCALM[®] Patterns[™], Release 02.06.00

Publication number

PATT 020600 – DMR-2401

UDI number

+B087PATT02061/\$\$70206001

Manufactured by



PeriGen Solutions Ltd.
4 Negev St., Airport City
POB 176, Ben-Gurion Airport
7010000 Israel

Customer Support

(+1)-866-321-6788,

(+1)-888-866-5339, support@perigen.com

Trademarks

PeriCALM Tracings, PeriCALM Curve, PeriCALM Patterns and PeriCALM CheckList are trademarks of PeriGen Incorporated. All other product and brand names are trademarks or registered trademarks of their respective companies.

Intended Use

PeriCALM[®] Patterns[™] is intended for use as an adjunct to qualified clinical decision-making during antepartum or intrapartum obstetrical monitoring at ≥ 36 weeks gestation to obtain annotation of the FHR for baseline, accelerations and decelerations.

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

WARNING: Evaluation of FHR during labor and patient management decisions should not be based solely on PeriCALM[®] Patterns[™] annotations.



Please refer to the User Guide 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

1.	What's New in Version 02.06?	5
1.1.	User enabled EMR integration capability	5
1.2.	30 minute slider window	5
1.3.	Variability changed to integer	5
1.4.	Unique Device Identifier (UDI) number	5
1.5.	Deployment of new active X	5

1. What's New in Version 02.06?

1.1. User enabled EMR integration capability

A user enabled option to export detected features to **PeriCALM Tracings** following user confirmation/modification of the data that is to be exported has been added. This data can then be streamed into a 3rd party EMR using the EMR interface.

This option is not available for PeriCALM Tracings NIEC-Mode clients.

1.2. 30 minute slider window

PeriCALM Patterns expanded tracing view and slider window now show a period of 30 minutes instead of 17 minutes, and the compressed tracing view now shows 4 hours instead of 2 hours.

1.3. Variability changed to integer

Variability is now displayed as an integer number (without a fractional component) throughout the system.

1.4. Unique Device Identifier (UDI) number

A Unique Device Identifier (UDI) number was added to the About Box of the application.

1.5. Deployment of new active X

When **PeriCALM Patterns** is open at a workstation and a newer version of **PeriCALM Patterns** is installed on the server, a message will now pop up indicating that "A new **PeriCALM Patterns** version was identified. The **PeriCALM Tracing** application will close in 60 seconds. Once closed please reopen it via the Windows Start button." A button on the message box enables the user to close the application immediately as well.