PeriGen, Inc.

PeriWatch™ HUB™ Version 01.01.00

Release Notes

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Revision: 01.00
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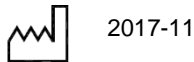## Copyright notice

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Product

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Reader comments

Comments or suggestions regarding this publication are welcome and should be sent to Technical Operations at the aforementioned address.

Trademarks

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

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.

PeriCALM® Patterns™ / PeriWatch™ Cues™ 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.

PeriCALM® Curve™ / PeriWatch™ Curve™ is intended for use as a data analysis system to assess labor progress in singleton, cephalic presentation pregnancies when the gestational age is ≥ 35 weeks.

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™ / PeriWatch™ Cues™ annotations.

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

Various aspects of the PeriCALM® / PeriWatch™ 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

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1. What's New in Version 01.01.00?

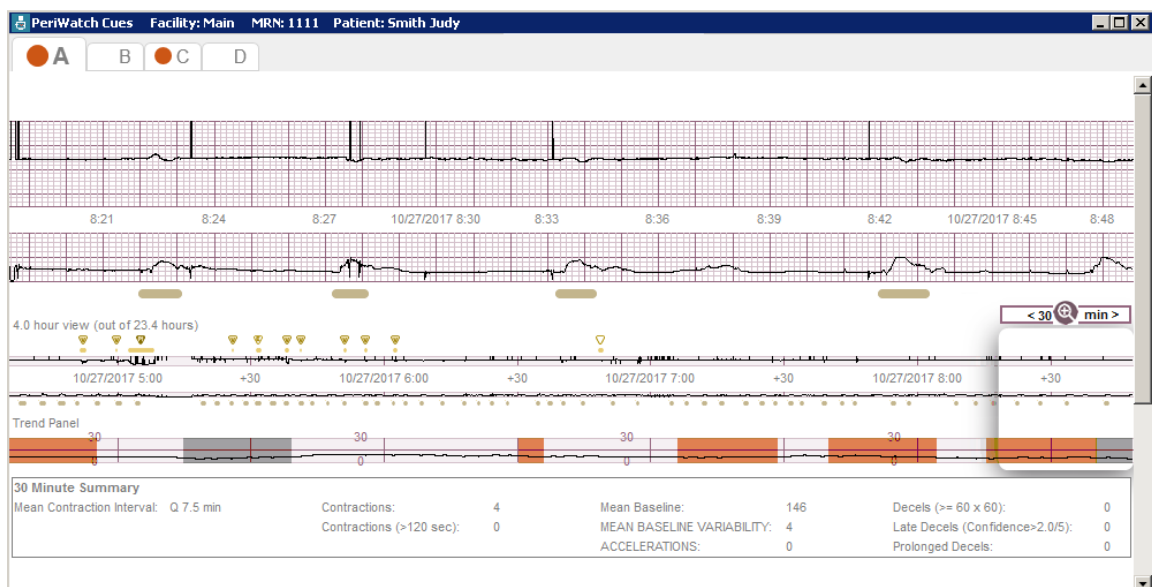## 1.1. Adapt HUB to support presenting data received from PeriWatch

Changes were made to HUB in order to enable it to present data (patient identifiers, facility name, gestational age, # of fetuses, pelvic exam and vital signs) received from the PeriWatch Tracings 2017 R3 application that hosts PeriWatch Cues and/or PeriWatch Curve, and use this data for its cell coloring, sorting and filtering functions.

1.2. PeriWatch – Adapt HUB to support multi-fetus capability

Changes were made to HUB in order to support the PeriWatch multi-fetus capability. As a result, for PeriWatch clients, the following behavior will be encountered on the HUB screen: in patients with multiple fetuses, the Cues State column shows a cumulative status for all fetuses.

- Cues displays as 'Positive' if any fetus is positive;
- Cues displays as 'Negative' if all fetuses are negative;
- Cues displays as 'Unknown' if the patient's gestational age is unknown, or if none of the fetuses are positive and at least one of them is evaluated as 'Unknown';
- Cues displays as 'NA' if the patient's gestational age is < 36 weeks.
- Additionally, the value displayed in the Positive Cues Duration column is the duration of the fetus with the longest active positive Cues state.

Clicking the Cues State for such patients opens the Cues screen with up to 4 tabs in it, displaying each fetus (A-D) separately. Click on the tab to show the Cues screen for the specific fetus. When the Positive Cues Duration value for a specific fetus exceeds configurable threshold levels, a colored icon appears on the tab of that fetus.

1.3. PeriWatch – Adapt HUB to support multi-facility capability

Changes were made to HUB in order to support the PeriWatch multi-facility capability. As a result, PeriWatch HUB can now display facilities' names on the HUB screen, and filter by facility when a single collector supports multiple facilities. The facility displayed here is taken from the "locale" configured in PeriWatch Tracings.

1.4. PeriWatch – Handling of Temperature

In PeriWatch both Centigrade and Fahrenheit values are always available. In PeriCALM only a single unit is in use at a facility. Clients will need to decide on a system-wide temperature unit to use on HUB taking into account this information. A configurable parameter will be selected during installation of HUB in order to define the proper system-wide Temperature unit (Centigrade or Fahrenheit) that is to be used in HUB (i.e. displayed on the HUB screen and used in the cell coloring rules' thresholds).

1.5. Add ability to open Curve from percentile cells even if they have no percentile value

The Curve screen will now open when clicking on a patient's Curve %-ile regardless whether there is an actual calculated numerical value, or 'NA' (indicating that the patient's gestational age is < 35 weeks, or that the number of fetuses is >1), or '-' (indicating that there is no calculated Curve).

If Curve is not installed at a site then the cells remain empty and the Curve screen cannot be opened from those cells.

1.6. PeriCALM CheckList/PeriWatch Cues control

PeriWatch HUB now opens a PeriCALM CheckList/PeriWatch Cues control that includes features added into PeriCALM Patterns 02.08.02 (PeriWatch Cues 02.08.02).

1.7. Upon launching of HUB, display content without Patient Identifiers

Upon launching of PeriWatch HUB, the HUB screen now opens, though it does not display patient identifiers and does not allow the user to perform actions such as filter, comments, opening of Cues or Curve, and sorting until the user logs in. After log in the patient identifiers are displayed and the actions are enabled.

1.8. Parity added to G, TPAL column

PeriWatch HUB now additionally includes Parity in the column presenting the OB Formula. The column, now called G,P / TPAL, displays Gravidity, Parity, Term, Preterm, Abortions, and Living children.

2. Limitations

2.1. PeriCALM Tracings Version Supported

PeriWatch HUB version 01.01.00 only supports clients using at a minimum PeriCALM Tracings version 03.18.04.