

PeriGen, Inc.

PeriWatch™ Cues™ Version 02.08.02

PeriCALM® Patterns™ Version 02.08.02

PeriWatch™ Curve™ Version 02.08.02

PeriCALM® Curve™ Version 02.08.02

Release Notes

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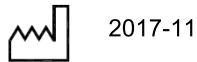
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Reader comments

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

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Intended Use

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 02.08.02?

1.1. PeriWatch – Streaming of Toolbar buttons' settings between fetuses

In PeriWatch, when a patient has multiple fetuses, all toolbar buttons that control what is shown or not on the Cues screen now stream their selection between fetuses. These include: Baselines, Montevideo, Accels/Decels, Toco graph, and Zoom.

1.2. PeriWatch – Contraction Frequency

In PeriWatch Cues, when performing an Export, Cues will calculate the Contraction Frequency as a range value (minimum-maximum) and present it on the hosting application screen's relevant field.

1.3. PeriWatch – Contraction Duration

In PeriWatch Cues, when performing an Export, Cues will calculate the Contraction Duration as a range value (minimum-maximum) and present it on the hosting application screen's relevant field. By default, the values shown will be rounded to the nearest multiple of 5, but this can be configured to display the original values instead.

1.4. PeriWatch – Internal Intensity

In PeriWatch Cues, when performing an Export, while the Montevideo button is checked on the Toolbar, Cues will calculate the Internal Intensity as a range value (minimum-maximum) and present it on the hosting application screen's relevant field. By default, the values shown will be rounded to the nearest multiple of 5, but this can be configured to display the original values instead.

1.5. PeriWatch – Rounding of MVU

In PeriWatch Cues, when performing an Export, while the Montevideo button is checked on the Toolbar, Cues will, by default, round the MVU value to the nearest multiple of 5, but this can be configured to display the original value instead.

1.6. PeriWatch – Rounding of Baseline FHR

In PeriWatch Cues, when performing an Export, Cues will, by default, round the Baseline FHR value to the nearest multiple of 5, but this can be configured to display the original value instead.

1.7. PeriWatch – Uterine Characteristics


In PeriWatch Cues, when performing an Export, Cues will stream information to indicate whether the Contractions related condition of the Cues algorithm is positive or not to enable setting the value of the Uterine Characteristic field on the hosting application screen to 'tachysystole'.

Note: Unlike other fields that are exported, even if the export time range is set to 15 minutes, this specific information will be based on the number of contractions in the last 30 minutes rather than the 15 minutes of the export range.

1.8. PeriCALM – Export Box

For PeriCALM clients using the Export function, an Export Box with one or more configurable tabs will now replace the previous Export Dialog.

It is possible to configure the number of tabs appearing in the Export Box and their displays, the list of items included on each tab, and the number of columns and their widths these items are organized in on each tab.

The appearance of Montevideo Units (per 10 minutes) and Internal Intensity is dependent on the icon  Montevideo in the Toolbar.

If a concept has a value but it is located on a tab that has not been reviewed by the user, a message will pop up to the user when clicking the Export button requiring the user to review the tab.

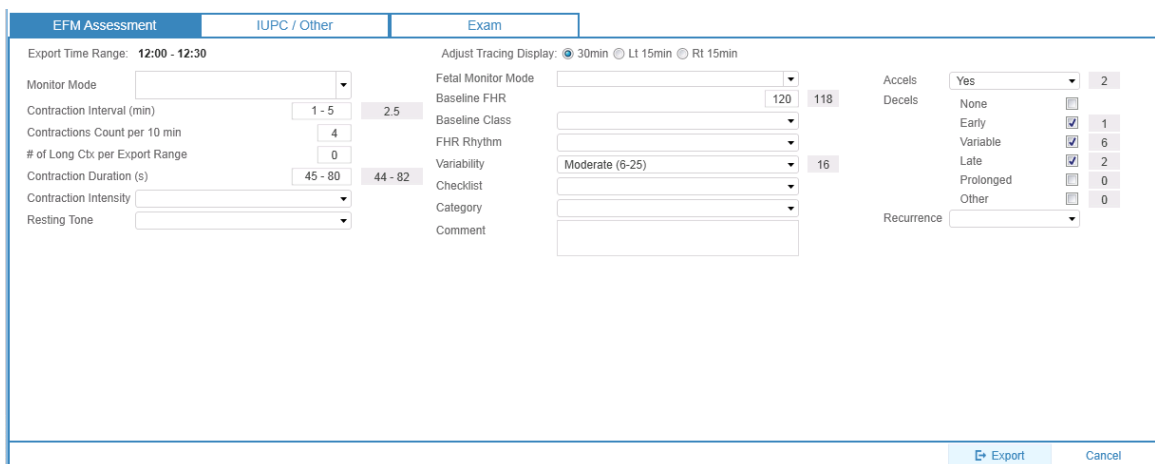
The read-only numerical values (for example those presented for Variability, Accelerations and Decelerations) are not exported and appear for reference purposes only.

The Contractions Count per 10 min field is a rounded average calculated from the overall number of contractions within the export range.

Some of the calculated read-only fields have editable values associated with them that are rounded to the nearest multiple of 5, and these editable values are those that are exported. This rounding behavior is optional. Sites may choose to use only the calculated numbers instead. Examples include: Contraction Duration (minimum – maximum), Internal Intensity (minimum – maximum), Montevideo Units, and Baseline FHR.

Clients may choose to export the Contraction Interval in range form (minimum – maximum), or export the Mean Contraction Interval instead.

The Adjust Tracing Display radio buttons allow users to toggle the Expanded Tracing View directly from the Export Box.



The screenshot shows the 'Export Box' interface with three tabs: 'EFM Assessment', 'IUPC / Other', and 'Exam'. The 'EFM Assessment' tab is active, displaying various configuration options:

- Export Time Range:** 12:00 - 12:30
- Adjust Tracing Display:** Radio buttons for 30min (selected), Lt 15min, and Rt 15min.
- Fetal Monitor Mode:** Dropdown menu.
- Baseline FHR:** Input field with values 120 and 118.
- Baseline Class:** Dropdown menu.
- FHR Rhythm:** Dropdown menu.
- Variability:** Dropdown menu with value Moderate (6-25) and 16.
- Checklist:** Dropdown menu.
- Category:** Dropdown menu.
- Comment:** Text input field.
- Accels:** Yes (selected) with value 2.
- Decels:** None, Early (checked, 1), Variable (checked, 6), Late (checked, 2), Prolonged (0), Other (0).
- Recurrence:** Dropdown menu.

At the bottom right, there are 'Export' and 'Cancel' buttons.

EFM Assessment	IUPC / Other	Exam
Export Time Range: 12:00 - 12:30		Adjust Tracing Display: <input checked="" type="radio"/> 30min <input type="radio"/> Lt 15min <input type="radio"/> Rt 15min
Internal Intensity (mmHg)	<input type="text" value="20 - 100"/> <input type="text" value="18 - 100"/>	Tracing Annotation
Internal Resting Tone (mmHg)	<input type="text"/>	
Montevideo Units (per 10 min)	<input type="text" value="195"/> <input type="text" value="197"/>	
Position	<input type="text"/>	
Activity	<input type="text"/>	
Oxytocin (mU/min)	<input type="text"/>	
Interventions	<input type="text"/>	
		<input type="button" value="Export"/> <input type="button" value="Cancel"/>

EFM Assessment	IUPC / Other	Exam
Export Time Range: 12:00 - 12:30		Adjust Tracing Display: <input checked="" type="radio"/> 30min <input type="radio"/> Lt 15min <input type="radio"/> Rt 15min
Dilatation	<input type="text"/>	Amnioinfusion <input type="checkbox"/>
Effacement	<input type="text"/>	IUPC Inserted <input type="checkbox"/>
Station	<input type="text"/>	FSE Applied <input type="checkbox"/>
Fetal Presentation	<input type="text"/>	Membrane Status <input type="text"/>
Fetal Position	<input type="text"/>	Amniotic Fluid Quantity <input type="text"/>
Cervical Position	<input type="text"/>	Amniotic Fluid Color <input type="text"/>
Cervical Consistency	<input type="text"/>	Amniotic Fluid Odor <input type="text"/>
		Bleeding Flow <input type="text"/>
		Blood Clots <input type="text"/>
		<input type="button" value="Export"/> <input type="button" value="Cancel"/>

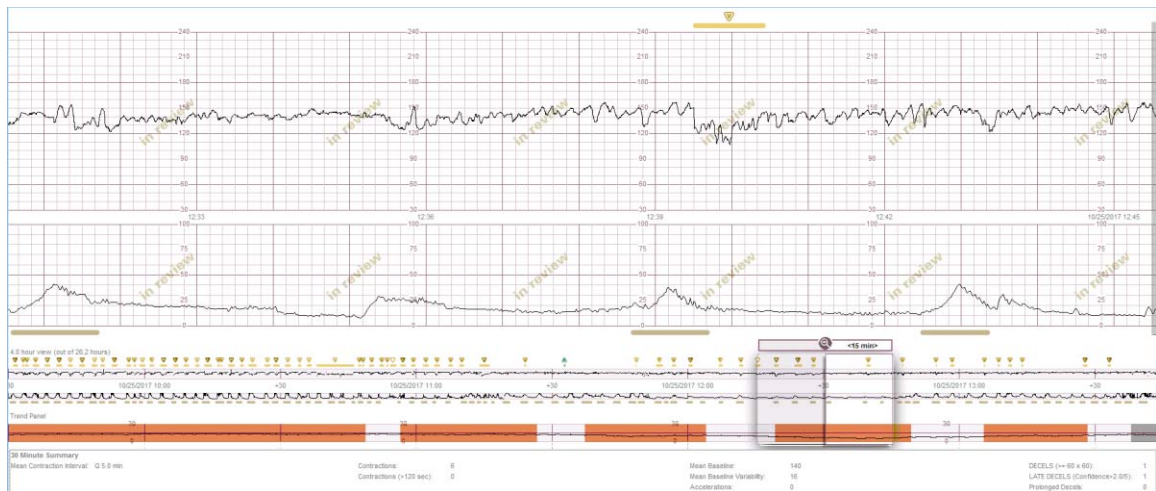
1.9. CheckList – Optional setting allows closing the Notification Dialog without opening the tracing view

Clients can now choose to allow their CheckList Bedside View users to click the 'X' button of the Notification Dialog in order to close it without having the Tracing View automatically open first. Nonetheless, this action will still be regarded as a 'Review' of the notification.

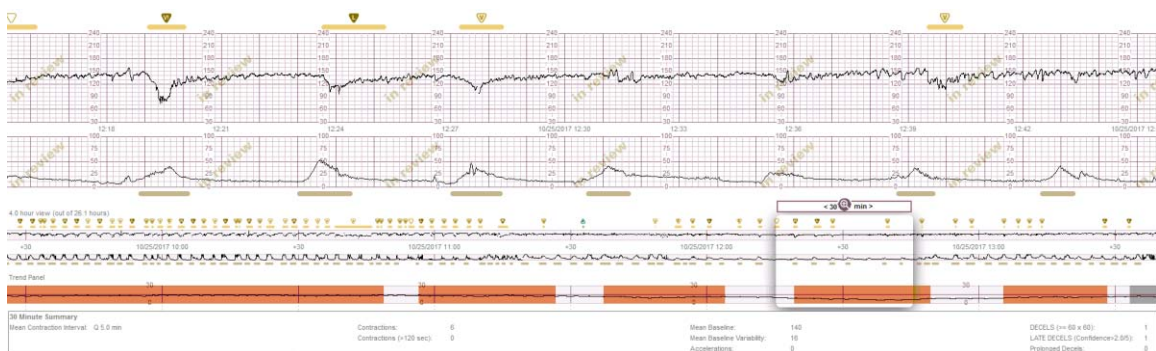
1.10. User control over 15/30 minute Expanded View display

The system now enables users to select between displaying a 15 minute or a 30 minute Expanded View. By default, a 30 minute Expanded View is displayed, but this can be configured by the site to be 15 minutes instead.

15 min view



30 min view



When set to show 15 minutes, the Expanded View displays the Slider Window's 30 minute section 15 minutes at a time. An internal window within the Slider Window shows which 15 minute section is actually being displayed in the Expanded View. Vertical Start Time and End Time markers appear in gray on the Expanded View to mark the boundaries of the entire 30 minute section. The toggle button above the Slider Window allows the user to toggle between the two 15 minute sections. By default, the second section is displayed (except when jumping to the beginning of the trace, in which case the first section is displayed first). The user can alternately select to display the entire 30 minute section in the Expanded View by clicking the magnifying glass icon at the center of the toggle button. Clicking the magnifying glass icon once again changes the view back to 15 minutes. Additionally, closing the screen and then reopening it changes the Expanded View display back to its default setting.

A 30 Minute Summary box located beneath the Slider Window presents the calculated values corresponding to the Slider Window's entire 30 minute section.

For PeriCALM clients the horizontal Baseline FHR lines are no longer displayed by default.

PeriCALM clients using the Export function will be able to perform the toggling directly from the Export Box using the **Adjust Tracing Display** radio buttons. PeriWatch clients will be able to do the same from the hosting application screen.

1.11. Persistence of MVU button after being clicked

When a user checks the Montevideo icon in the toolbar it will now remain checked for that patient each time the PeriWatch Cues screen is subsequently opened, until a user unchecks it. When the Montevideo icon is checked the Montevideo Units appear in the 30 Minute Summary box beneath the Slider Window, and for PeriCALM users who are using the Export function, the MVU and Internal Intensity fields will be shown on the Export Box, whereas for PeriWatch users the MVU and Internal Intensity fields' calculated values will appear within the hosting application screen when performing an Export.

When the Montevideo icon is being checked or unchecked on one workstation, while the PeriWatch Cues screen is already open at a second workstation, the PeriWatch Cues screen in the second workstation will not be affected by these changes.

1.12. VERTEX option added to CephalicCodes in psf file

The option VERTEX was added to the list of default CephalicCodes included in the PSF file.

2. Fixes

2.1. ExportArchiveDB file growth

A bug was found where under some circumstances of error handling, data could be written repeatedly to the database causing uncontrolled database growth.

This bug has been corrected.

2.2. Position of slider window when clicking on the Compressed View

A bug was found in which when clicking on the compressed view the slider window moved to the point of the click, aligned to it at its rightmost edge. This bug has been corrected, and now the slider window is centered at the point of the click.