PeriGen, Inc.

PeriCALM® Patterns™ User Guide

Version 02.08.02

Record ID: PATT 020802 – DMR-2769

Revision: 01.00

Issued: 2017-10

PeriGen

Advanced
Perinatal Systems

Copyright notice

Release date

2017-10

Product

PeriCALM Patterns 02.08.02

Publication number

PATT 020802-DMR-2769

Manufactured by

PeriGen Solutions Ltd.
Sderot Nim 2,
PO Box 110,
Rishon LeTziyon, 7510002,
Israel

Customer Support

(+1)-866-321-6788, (+1)-888-866-5339, support@perigen.com

Reader comments

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

Trademarks

PeriCALM Tracings, PeriCALM Curve, 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® 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. About PeriGen

PeriGen, Inc. is an innovative provider of perinatal clinical decision support systems employing patented, pattern-recognition and obstetrics technologies that empower perinatal clinicians to make confident, real-time decisions about the mothers and babies in their care. Our customer-centric team of clinicians and technologists builds the most advanced systems available to augment obstetric decision-making and improve communications among the clinical team at the point of care, while supporting data flow between healthcare IT systems.

PeriGen's unique fetal surveillance products provide dynamic visual cues that direct clinicians to the most essential patient information displayed on the screen. Unlike legacy fetal monitoring devices and software from non-specialist companies, PeriCALM® Patterns™ provides an instant view of the mother's and baby's current status and trends over time to prevent errors, increasing patient safety and reducing risk for clinicians and hospitals.

PeriGen's advanced perinatal systems have received 31 US and international patents.

2. This Guide

2.1. Versions

The **PeriCALM Patterns** *User Guide* is provided:

- As a hard copy,
- As a PDF (Portable Document Format) file available in the **PeriCALM Patterns** server installation folder, and
- As a PDF (Portable Document Format) file, accessible through the hosting system's links or menus.

2.2. Conventions

In order to clearly identify items that have been incorporated in the *User Guide*, we have inserted the following stylistic elements and icons to insure proper understanding and references.

Bold	Used to identify view menus, options, and screen titles.
<u>Blue underline</u>	Used to identify hypertext links; cross-references, email addresses, and web pages. These apply only to the electronic version of the guide.
Italics	Used to reference other related documents.
⚠	This image applies to important warnings; users must pay close attention to the associated message.
◇	This image applies to recommendations.
📝	This image applies to additional information, both procedural and conceptual.

2.3. Additional Documentation

The *PeriCALM Patterns User Guide* provides information that is related to the PeriCALM Patterns application. For additional information related to the PeriCALM suite of products, please refer to the following.

- *PeriCALM Curve User Guide* – provides information about using the PeriCALM Curve application.
- *PeriCALM Curve Release Notes* – Provides information on what is new in this release and the application's limitations.
- *PeriCALM Patterns Release Notes* – Provides information on what is new in this release and the application's limitations.
- *PeriCALM Tracings User Guide* – provides information about using the PeriCALM Tracings application.

3. Overview

PeriCALM Patterns is an application that assists in the timely identification and display of fetal heart rate patterns that may be associated with an increased risk of birth-related injury. From data collected through a fetal monitor, **PeriCALM Patterns** detects and analyzes fetal heart rate accelerations, late, early, variable and prolonged decelerations, as well as uterine contractions, and displays these as colored markings. **PeriCALM Patterns** can zoom out the tracing view to view up to 12 hours of tracings to facilitate identification of trends in heart rate patterns and contractions. Furthermore, **PeriCALM Patterns** can calculate baseline, baseline variability, Montevideo units and contraction interval averages in a sliding window, as well as warn against persistence in uterine tachysystole, as defined by the institution.

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

Key Benefits

- Represents fetal heart rate events and uterine contractions in a visually intuitive manner.

- Calculates several important clinical metrics in real-time.

- Summarizes specific measurements using configurable rule(s).

- Displays 15 or 30-minute, 4 hour and 12 hour views of tracings.

- Brings standard definitions such as NICHD guidelines to the bedside.

- Depending on the configuration, provides either near real-time analysis and notification to better communicate to the care provider the possibility of a combination of fetal heart rate patterns as defined by the institution, or displays the institution's definition of uterine tachysystole in a graphical and numerical manner.

- Provides constant educational reinforcement to minimize the impact of inexperience.

- Provides a user enabled EMR integration capability by exporting detected features to an electronic medical record following user confirmation or editing of the data to be exported.

⚠️ Evaluation of FHR during labor and patient management decisions should not be based solely on the **PeriCALM Patterns** annotations.

🔶 **PeriCALM Patterns** is intended to be used as an adjunct to a fetal surveillance system that provides standard alerts when fetal heart rates are out of bounds.

3.1. The PeriCALM Patterns Interface

The following shows the main components of the **PeriCALM Patterns** interface.

1. The **Expanded Tracing View** shows 15 or 30 minutes worth of fetal tracings including events and contractions.

2. The **Compressed Tracing View** shows 4 or up to 12 hours of compressed fetal tracings including events and contractions.

3. The **Trend Panel**, which is a 4 hour (or up to 12 hours) graph that plots contractility over time and displays a site-defined color coded system to indicate the PeriCALM CheckList level based on the presence or absence of 6 specific EFM features over a 30 minute period. Alternatively, for clients that do not use the **Trend Panel**, a **Persistent Contractility Index** panel is available, indicating the patient's level of contractility, and when it exceeds user-defined limits.

4. The **Slider Window** allows a specific 30-minute section of tracing to be summarized within the **30 Minute Summary** box, and viewed in the **Expanded Tracing View**. A toggle button located above the **Slider Window** allows the user to alternate the view between the first and second 15 minute periods of the 30-minute section when using the 15 minute **Expanded Tracing View**.

5. The **Export Panel** enables users to export 30 minute or 15 minute summaries of the Tracing View into the hosting application screen.

6. The **Toolbar** is used to access many features of **PeriCALM Patterns** and display any messages about the status of the application.

The screen contents may vary according to the installation setup and configuration at a particular facility.
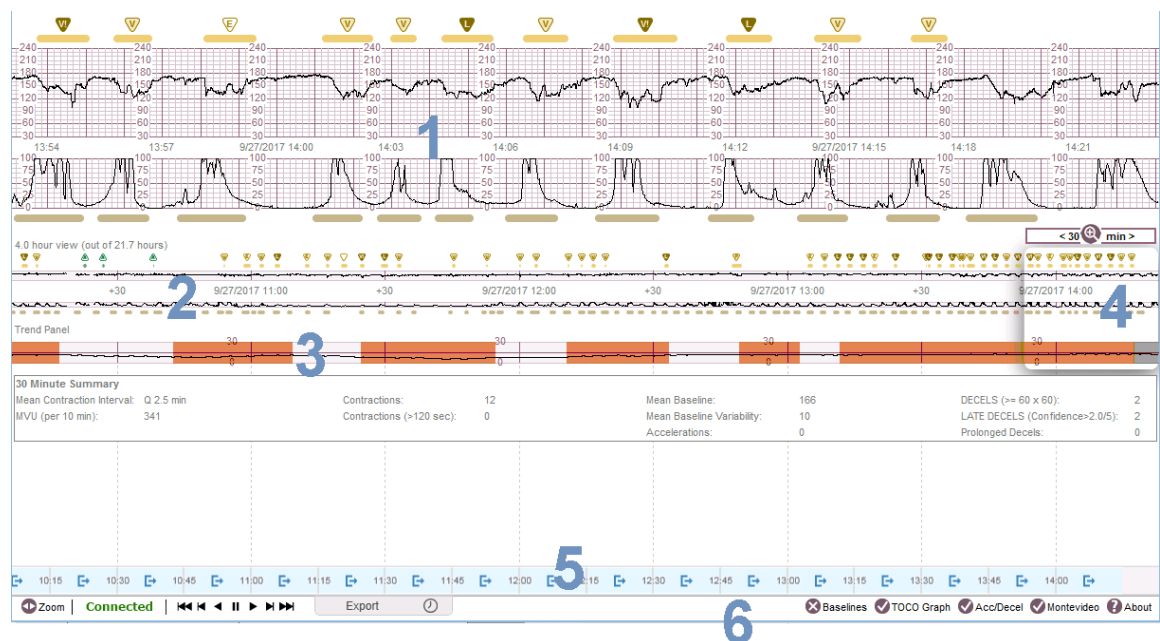
⚠️ **PeriCALM Patterns** requires at least 700x515 of screen space in order to display tracings and events properly and not have any of its data truncated. Should **PeriCALM Patterns** detect that the available screen space is inadequate, the following screen will be displayed.

This functionality requires a minimum of 700x515 pixels of screen space to display correctly, please contact your system administrator for help.

4. Fetal Tracing Display

4.1. The Expanded and Compressed Tracing Views

PeriCALM Patterns displays the equivalent of a paper fetal strip on the computer monitor. The application shows this strip in two levels of detail: an Expanded View, which shows 15 or 30 minutes of tracing, and a Compressed View, which shows 4 hours of tracing. Both the 15/30 minute Expanded View and 4 hour Compressed View are displayed in the same aspect ratio as seen on a typical paper strip.

15 min view
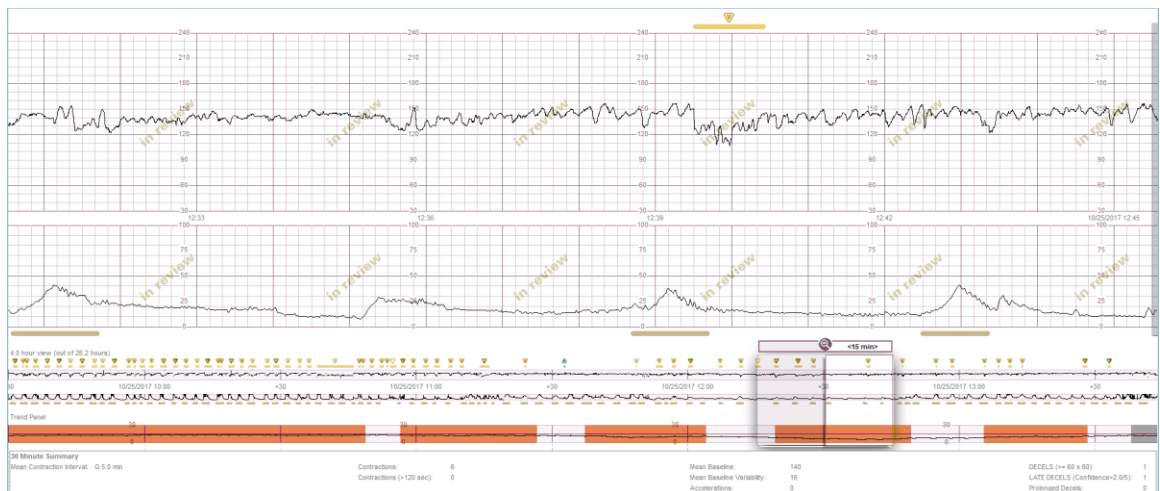
30 min view
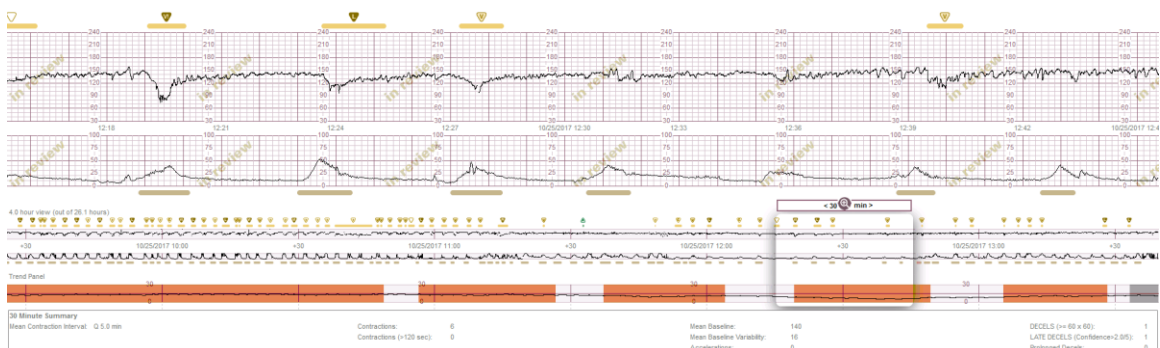
> To ensure that the aspect ratio of the tracings on the computer monitor corresponds to the aspect ratio of an actual paper strip, please ensure that your computer monitor is set to its native resolution.
>
> **PeriCALM Patterns** also requires a minimum amount of space in order to display tracings, should the application not have the space it requires, an informational message will appear and no tracings will be visible. Should this occur, contact a system administrator.

When a patient is selected, the most recent tracing for that patient is loaded on the screen. If less than 15 minutes of tracing exists for the selected patient, a portion of blank tracings will be visible on the left hand section of the Expanded View. Likewise, if less than 4 hours of tracing exists for the selected patient, a portion of blank tracings will be visible on the left hand section of the Compressed View.

By default, if the selected patient is currently acquiring fetal tracings both the Expanded and Compressed views will display live tracings and slowly scroll towards the left in real-time as new tracing is displayed.

If the selected patient is not currently acquiring fetal tracings, an "unplugged" icon will be visible over the tracings and the last recorded 30 minutes will be shown. Additionally, the text "**in review**" will appear as a watermark behind the tracings. If the fetal monitor is turned back on for this patient, both the unplugged icon and the watermark will disappear and live tracings will be shown.

When **PeriCALM Patterns** detects a discrepancy of 10 seconds or more between the timestamp on the tracing received and the time according to the **PeriCALM Patterns Server**, it will display a **Tracing Delayed** watermark on the tracing.
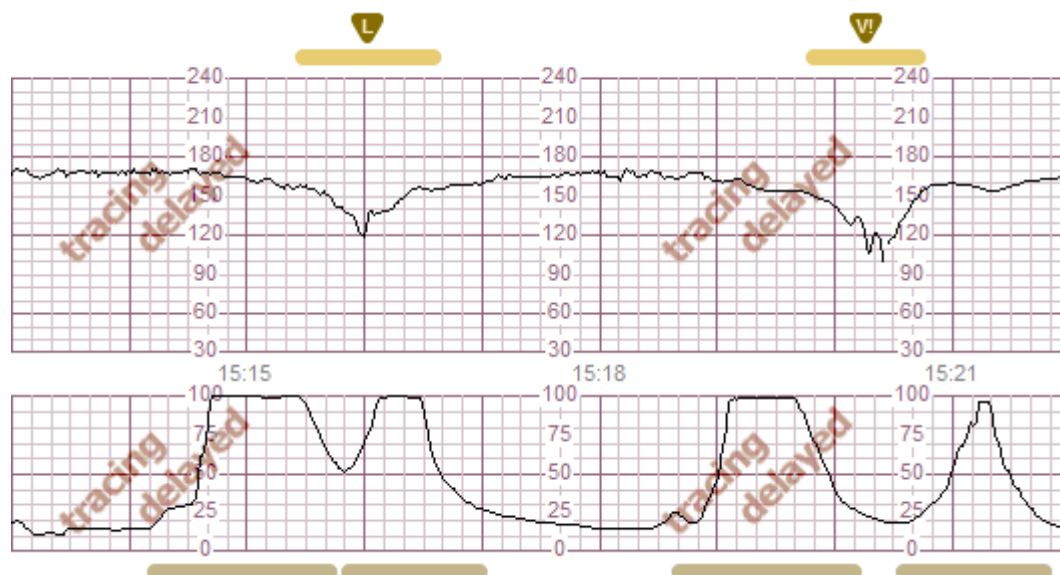
The presence of this watermark does not reduce any of the functionality of **PeriCALM Patterns**; it merely serves to provide a visual indicator that the tracing being displayed on screen is not near real-time.

The 10 second delay threshold is a configurable value and may differ from the current system configuration.

The delayed tracing condition is generally temporary and occurs when the system is under high load.

Should the **Tracing Delayed** watermark be persistently present, the system administrator should be contacted to further investigate the matter.

4.2. Navigating Through the Tracings Views

Both the **Expanded** and **Compressed Tracing Views** can be scrolled in order to review tracings. Left clicking and dragging the mouse directly on top of either tracing view scrolls both tracings to the left or right. The scrolling will stop once the strip has been dragged all the way to either the beginning or the end of the tracing.

The tracing views can also be moved via the **Slider Window** (see The Slider Window) and the **Navigation Buttons** (see The Navigation Buttons).

Each time **PeriCALM Patterns** is opened for a patient the tracings are automatically scrolled to the right, to show the most recent part of the tracing.

4.2.1. The Slider Window

The **Slider Window** is a component of the **Compressed Tracing View** which identifies the 15 or 30 minute **Expanded View** section, and highlights the section which corresponds to the calculated values presented within the **30 Minute Summary** box.
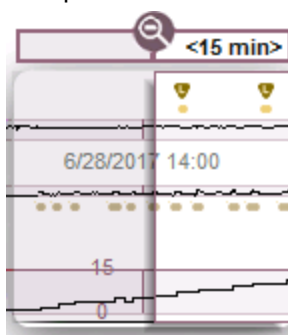
When the **Compressed View** is dragged, the **Slider Window** moves, so that the appropriate 15 or 30 minute window on the **Compressed View** is always displayed (see figure below). Conversely, dragging the **Slider Window** itself will cause the 15 or 30 minute **Expanded View** to scroll.
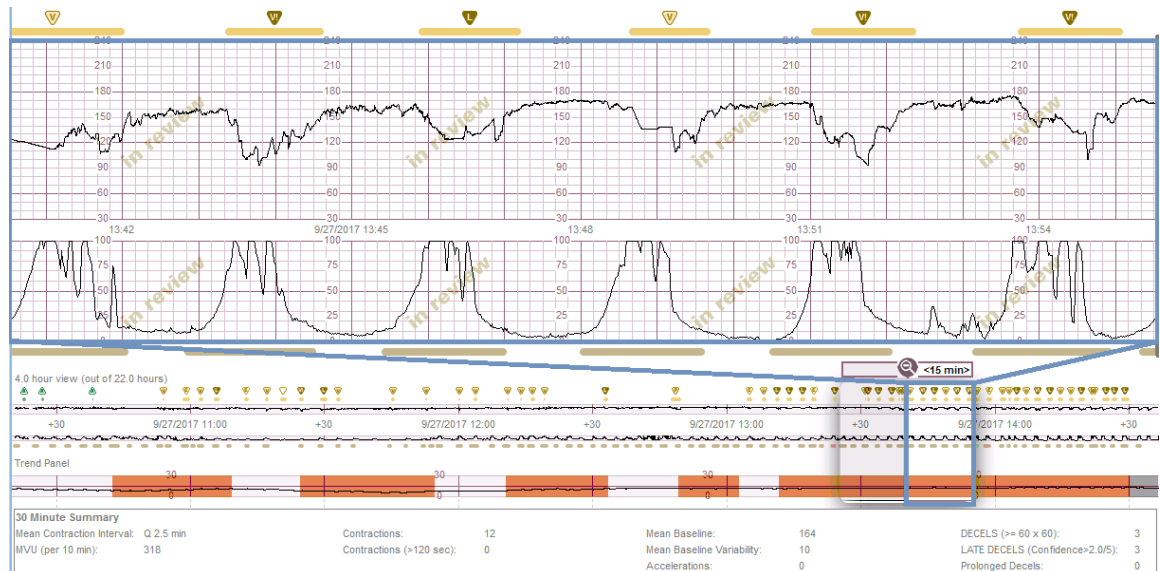
When set to show 15 minutes, the **Expanded View** adapts to display the matching 15 minute range. An internal window within the **Slider Window** shows which 15 minute section is actually being displayed in the **Expanded View**. The toggle button above the **Slider Window** allows the user to toggle between the two 15 minute sections. By default, the second (i.e. rightmost) 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 **Patterns** screen and then reopening it changes the **Expanded View** display back to its default 15 minute setting.

Clients using the Export function will be able to perform the toggling directly from the Export Box using the **Adjust Tracing Display** radio buttons.

The Navigation Buttons

The tracing views can also be scrolled via the **Navigation Buttons** located in the toolbar.

▶◀◀ ◀◀ ◀ ❚❚ ▶ ▶❙ ▶▶❙

These buttons are described in the following table.

▶	Auto-scroll the **Slider Window** from past to present. Note: clicking the button more than once increases the auto-scrolling speed.
▶❙	Skip forward to the next 30 minute window of tracings.
▶▶❙	Jump to most recent tracing.
❚❚	Stop the auto-scrolling of the **Slider Window**. Note: clicking on any part of either tracing view will also stop the auto-scrolling.
◀	Auto-scroll the **Slider Window** towards the past. Note: clicking the button more times increases the auto-scrolling speed.
❙◀	Skip backward to the previous 30 minute window of tracings.
❙◀◀	Jump to the beginning of the tracing.

4.3. Zooming the Compressed Tracing View

The 4 hour **Compressed View** can be zoomed out to display a maximum of 12 hours of tracing by clicking on the **Zoom** ⏸Zoom icon.

Viewing this larger segment of tracing can give clinicians a clearer picture of trends, such as the degree and duration of FHR patterns and uterine contractility, over a length of time.
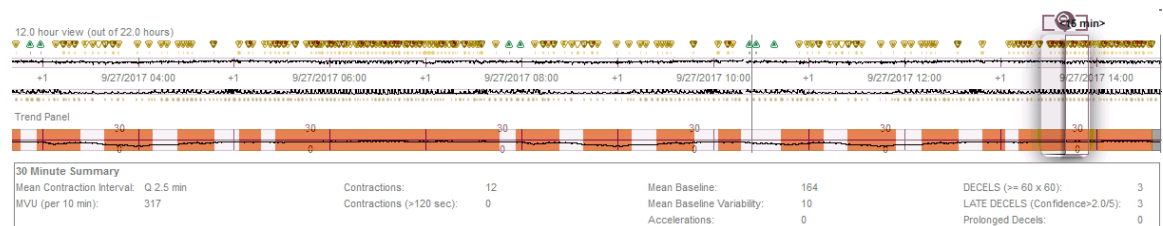
> ⚠️ In the 12 hour view, tracings are compressed horizontally and are no longer in an aspect ratio that is equivalent to a paper strip. The horizontal compression is roughly 3-fold.

The **Compressed View** can be toggled between the 4 and 12 hour view by clicking the **Zoom** icon at any point. The 12 hour view indicates the width of the related 4 hour view using 2 gray vertical lines as displayed below.

4 hour view
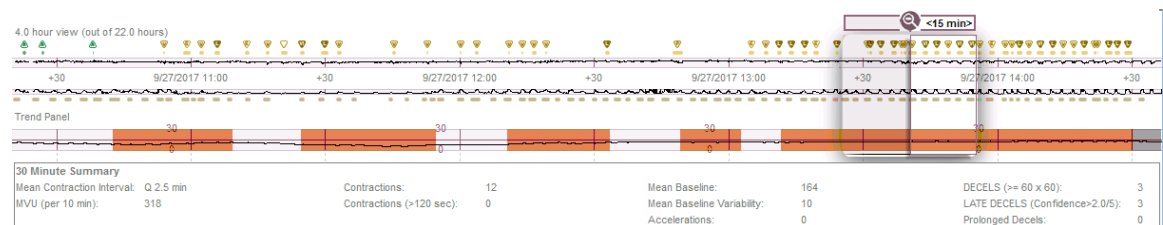
12 hour view

> 📝 When less than 12 hours of tracings are available, the 12 hour view compresses all available tracings into the view.

Additionally, the **Compressed View** is automatically zoomed in from 12 to 4 hours when the **Slider Window** is dragged and then released.

4.4. Export Panel

The **Export Panel** is an optional function that allows users to export 30 minute or 15

minute summaries of the Tracing View into the PeriGen Computer Assisted Labor Monitoring (PeriCALM Tracings) system, or to 3rd party Electronic Health Records. The Export Panel appears directly above the Toolbar and is shown if the Compressed Tracing View displays a 4 hour view.

The Export Panel easily displays to the user which Tracing View sections were already exported and which sections were not yet exported by displaying different Export icons.

When clicking on an Export icon of a specific section on the Export Panel, the Slider Window moves to the corresponding section on the Tracings View, and if the section was not yet exported, an **Export Box** with one or more configurable tabs appears with a summary of the contractions and fetal heart rate for the specific time range as calculated by **PeriCALM Patterns**, and additional documentation fields that can be filled in and exported.

Note: 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 icon] 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 fields that are exported are first rounded to the nearest 0 or 5. This rounding behavior is optional, as well as configurable. Sites may choose to export the original calculated numbers, or use an alternative rounding value, 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.

When the peak of an acceleration is located at the boundary of the 30 minute interval there may be a difference of 1 between the number of calculated Accelerations displayed on the Export dialog and the number of calculated Accelerations displayed in the Summary beneath the slider window.

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

The user can modify values within the Export Box or document additional items before confirming the box and streaming its content into PeriCALM Tracings or to a 3rd party Electronic Health Record.

The Export Panel displays fixed time range intervals. By default these intervals are 30 minutes long. The user can modify the time range by hovering over or clicking the toolbar's Export Button and selecting a different time range in the menu that opens (e.g.

15 minutes). All subsequent Export intervals on the Export Panel will be affected by the change until an additional change in time range is done by a user.
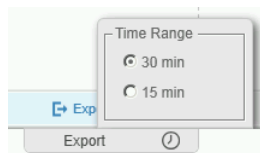
Note: Vertical blue bars appear on the Expanded Tracing View to indicate the start time and end time of the actual 30 minute or 15 minute export range in focus. When exporting a 30 minute time range, use the toggle button on the hosting application screen in order to review the 30 minute time range in its entirety.

5. The PeriCALM Patterns™ Engine

PeriCALM Patterns is powered using the **PeriCALM Patterns** pattern detection engine, which uses advanced mathematical models to analyze a tracing's fetal heart rate and uterine pressure values, in order to identify and calculate:

- Baseline and baseline variability
- Fetal heart rate features
- Uterine contractions
- Mean contraction interval
- Montevideo units

5.1. Baselines and Variability

5.1.1. Baselines

PeriCALM Patterns identifies baselines within the FHR tracing – the approximate mean fetal heart rate in relatively flat segments of the fetal tracing – and excludes accelerations, decelerations, periods of marked fetal heart rate variation and artifacts.

The baselines are used as a source for several other calculations (see next sections).

Baselines are not displayed by default. By clicking the **Baselines** icon ⊗ Baselines , horizontal lines will appear over the FHR tracing, indicating the different areas where baselines are identified. A number corresponding to the baseline fetal heart rate value (in beats per minute) will be displayed below the horizontal lines. **PeriCALM Patterns** does not label baselines as abnormally high (tachycardia) or low (bradycardia).
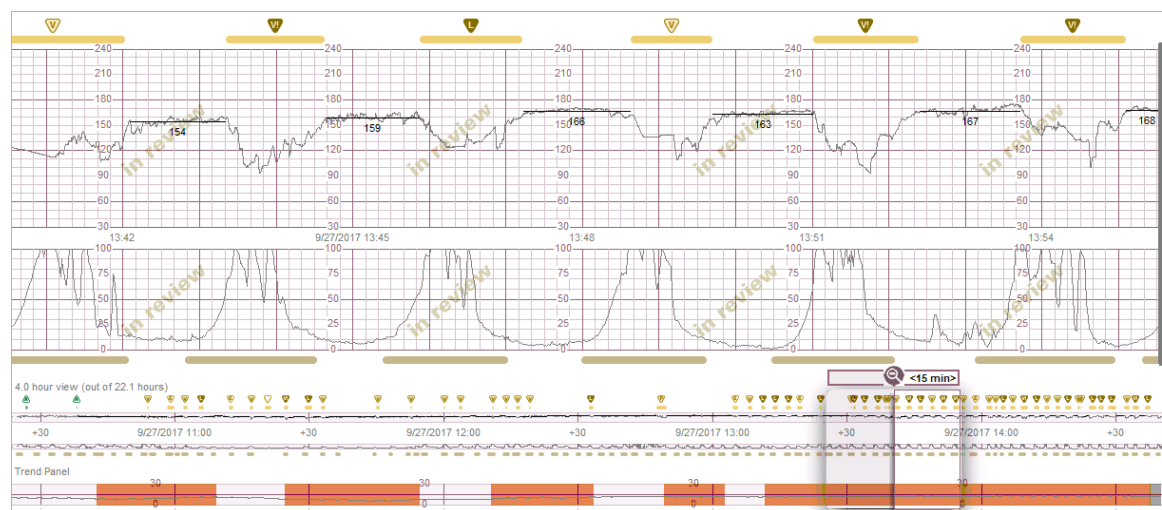
Clicking the **Baselines** icon ✓ Baselines a second time hides the baselines.
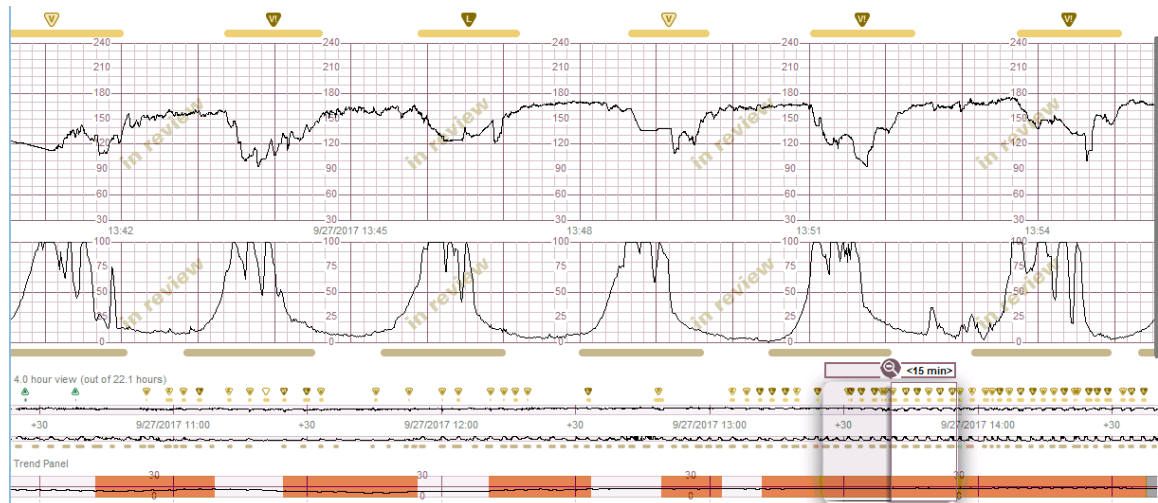
5.1.2. Variability

Variability refers to a measurement of the variation in fetal heart rate values in a baseline segment. **PeriCALM Patterns** defines the baseline variability as the number that corresponds to plus or minus 2 standard deviations of the fetal heart rate values around the baseline segments.
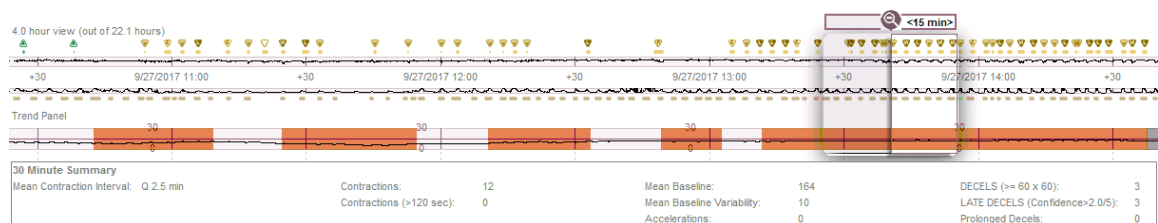
Using the baselines detected, **PeriCALM Patterns** calculates **Mean Baseline** and **Mean Baseline Variability** over a 30-minute window. These values are displayed in the **30 Minute Summary** box beneath the **Slider Window** (shown above). **Mean Baseline** and **Mean Baseline Variability** are calculated in real-time as new tracing becomes available. Additionally, moving the **Slider Window** over existing sections of tracing updates these two calculations dynamically. For clients using the Trend Panel, when values exceed the **PeriCALM CheckList algorithm** criteria for an FHR feature, its name is displayed in all capital letters.

5.2. Fetal Heart Rate Events

An event is a feature in the fetal heart rate tracing that corresponds to either an acceleration or a deceleration. Events marked by **PeriCALM Patterns** are labeled according to standard nomenclature[1].

When **PeriCALM Patterns** detects an event, an **Event Marker** will be displayed on the tracing. **Event Markers** are thick green or beige lines displayed above the fetal heart rate

---

[1] Electronic Fetal Heart Rate Monitoring: Research Guidelines for Interpretation. Published simultaneously by the Journal of Obstetric, Gynecologic, and Neonatal Nursing (J Obstet Gynecol Neonatal Nurs 1997; 26: 635-640) and the American Journal of Obstetrics and Gynecology (Am J Obstet Gynecol 1997; 177: 1385-90).

tracing (see below). The left and right extremities of the line respectively indicate the beginning and end of the event. A pictogram above the **Event Marker** indicates the specific type of event detected.
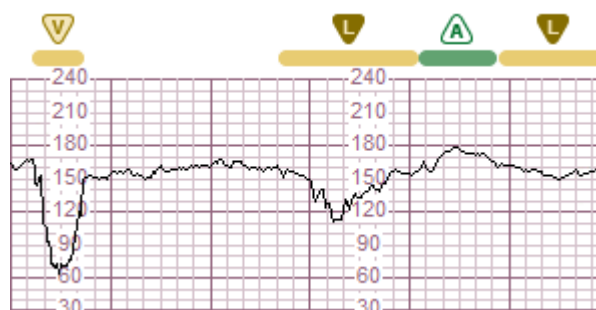
> Event detection is always disabled for patients whose gestational age is below 36 weeks or who have more than one fetus.

5.2.1. Signal Quality

To properly interpret events, **PeriCALM Patterns** must receive FHR signals from the fetal monitor at least 50% of the time span represented by the event. If a valid signal is received for less than this amount of time, no events will be displayed. Lack of an adequate signal is a function of the fetal monitor's ability to detect the fetal heartbeat.

Sometimes an incomplete signal provides enough information for **PeriCALM Patterns** to suspect an acceleration or a deceleration. When this occurs the event markers will have a question mark within the triangle and the event will be labeled Non-Interpretable. A Non-Interpretable event can be confirmed or struck out by the user. See Confirming a Non-Interpretable Event and Striking Out an Event.

5.2.2. Accelerations

Accelerations refer to episodic increases in the fetal heart rate that are at least 15 beats above the baseline and last for at least 15 seconds. **PeriCALM Patterns** does not sub-classify accelerations according to length.

For clients using the Trend Panel, using the accelerations detected, **PeriCALM Patterns** dynamically displays the total number of accelerations counted over a 30-minute window in the **30 Minute Summary** box beneath the **Slider Window**. When values exceed the **PeriCALM CheckList algorithm** criteria for an FHR feature, its name is displayed in all capital letters.

Accelerations are represented by **green** event markers and pictograms in the shape of upwards pointing triangles.

A   **Acceleration**

A visually apparent abrupt increase (onset of acceleration to peak in < 30 seconds) in FHR that is at least 15 beats above the baseline and lasts for at least 15 seconds.

?   **Non-Interpretable Acceleration**

PeriCALM Patterns recognizes that an event with the shape of acceleration has occurred, but portions of the tracing are missing, therefore **PeriCALM Patterns** will not

give a definitive label unless the event is confirmed by a user.

5.2.3. Decelerations

In **PeriCALM Patterns**, variable decelerations have a minimum depth of 15 bpm, a minimum duration of 15 seconds and a maximum duration under 2 minutes. With respect to the NICHD guidelines, decelerations are divided into three broad categories, which are also defined based on their shape and relationship to contractions.

- A **Gradual** deceleration has a gradual onset. Note that in periods of very low variability the decrease may be less than 15 bpm.
- A **Variable** deceleration has an abrupt onset.
- Irrespective of its shape, a deceleration is classified as **Prolonged** if it is longer than 2 minutes and less than 10 minutes in duration.

It is important to note that the NICHD definitions of decelerations are not mutually exclusive nor do not they cover all possibilities. Some decelerations will meet parts of more than one type of NICHD definition. For example, a deceleration may have an abrupt onset yet also be delayed in timing with respect to the onset, peak and end of an associated contraction. In such cases the **PeriCALM Patterns** will assign a label, based on what template this deceleration best fits using the many measurements available for this particular deceleration. Some decelerations will not fit any NICHD deceleration definition. For example, a shallow symmetrical deceleration with a gradual onset but without association with a contraction cannot be classified as **Early** or **Late** or **Variable**.

For clients using the Trend Panel, using the decelerations detected, **PeriCALM Patterns** dynamically displays the total number of Late Decelerations (with a confidence factor greater than 2.0/5), Decelerations >= 60 x 60 (i.e. any decelerations that are not late whose duration is greater than 60 sec and depth is greater than 60 bpm below baseline), and Prolonged Decelerations (with a depth >20 bpm below baseline) counted over a 30-minute window in the **30 Minute Summary** box beneath the **Slider Window**. When values exceed the **PeriCALM CheckList algorithm** criteria for an FHR feature, its name is displayed in all capital letters.

> Late Decelerations' confidence factor threshold level and Prolonged Decelerations minimal depth below baseline threshold level can be configured by a system administrator.

The following illustrations show the pictograms that appear in **PeriCALM Patterns**, as well as the basic definitions. Because of the ambiguities in the NICHD definitions as described above, **PeriCALM Patterns** uses statistical methods, not rule based methods, to assign the label. Thus every labeled deceleration may not exactly fit every part of the definition.

In **PeriCALM Patterns**, decelerations are represented by **beige** event markers and pictograms in the shape of downwards pointing triangles. The clinical relevance of a deceleration is represented by the shade of the beige color, which becomes progressively darker as the relevance increases.

Early Deceleration

A visually apparent gradual decrease (onset of deceleration to nadir > 30 seconds) and return to baseline FHR associated with a uterine contraction. In most cases, a

deceleration that begins with a contraction and ends before or near the end of the contraction is classified as **Early**.

Non-Interpretable Deceleration

PeriCALM Patterns recognizes that an event with the shape of a deceleration has occurred, but portions of the tracing are missing, therefore **PeriCALM Patterns** will not give a definitive label unless the event is confirmed by a user.

Non-Associated Deceleration

PeriCALM Patterns recognizes that a deceleration with gradual onset has occurred, but there is no associated contraction; therefore **PeriCALM Patterns** will not give a label of **Early** or **Late** or **Variable**.

Variable Deceleration

A visually apparent abrupt decrease (onset of deceleration to nadir < 30 seconds) in FHR below the baseline, which may or may not be associated with a uterine contraction. When variable decelerations are associated, onset, depth, and duration commonly vary with successive uterine contractions.

Prolonged Deceleration

A visually apparent decrease in FHR below the baseline that persists > 2 minutes but < 10 minutes from the onset to return to baseline.

Late Deceleration

A visually apparent gradual decrease (onset of deceleration to nadir > 30 seconds) and return to baseline FHR associated with a uterine contraction. In most cases the onset, nadir, and recovery occur after the beginning, peak and end of contraction, respectively.

Variable Deceleration with Specific Features

A Variable deceleration with any one of the following :

- **Loss of Variability** within the deceleration. Note this does not refer to baseline variability.
- Rule of **60's** (passes 2 of 3 following criteria: 60 seconds in duration, down 60 beats from the baseline; and/or nadir of deceleration is 60 beats/min or less) [2,3,4]

---

[2] Royal College of Obstetricians and Gynecologists. Electronic fetal monitoring: The use and interpretation of cardiotocography in intrapartum fetal surveillance. Evidence-based Guideline number 8. http://guidance.nice.org.uk/CGC

[3] Practice bulletin no. 116: Management of intrapartum fetal heart rate tracings. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2010 Nov;116(5):1232-40

[4] Intrapartum fetal heart rate monitoring. VIII. Atypical variable decelerations. Krebs HB, Petres RE, Dunn LJ.Am J Obstet Gynecol. 1983 Feb 1;145(3):297-305

P! **Prolonged Deceleration with Specific Features**

A visually apparent decrease in FHR below the baseline that persists > 2 minutes but < 10 minutes from the onset to return to baseline and is characterized by one of more of the following features:

- **Loss of Variability** within the deceleration. Note this does not refer to baseline variability.
- Rule of **60's** (passes 2 of 3 following criteria: 60 seconds in duration, down 60 beats from the baseline; and/or nadir of deceleration is 60 beats/min)[2,3,4,5]

X **Struck-out Event**

This symbol will be displayed for both acceleration and deceleration events that have been struck out manually.

5.2.4. Displaying Events

PeriCALM Patterns can display or hide events. In either case, this can be changed at any time by clicking the **Acc/Decel** button located in the toolbar.

When the button displays a checkmark ✔ Acc/Decel , events are currently displayed and clicking the button will hide events.

When the button displays an "**X**" ✖ Acc/Decel , events are currently hidden and clicking the button will show events.

> While **PeriCALM Patterns** detects events in real-time, several minutes of tracing may be required to confidently identify and display an event or a baseline.

5.2.5. Selecting Event Markers

An event can be selected by clicking on or hovering over the event marker or pictogram.
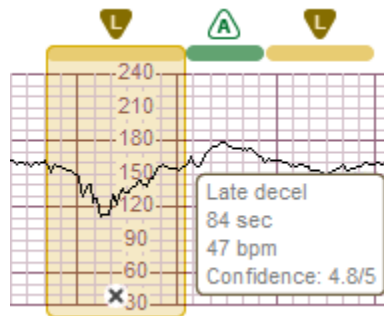
A highlighted box will surround the portion of the heart rate tracing where the event was detected and an associated information box will show:

---

[5] Variable Decelerations: Do Size and Shape Matter? Hamilton EF, Warrick PA, O'Keeffe D. Journal of Maternal- Fetal & Neonatal Medicine , 2012 Jun;25(6):648-53

- **The type of event and any specified features** (see Accelerations, Decelerations).
- **The duration of the event**: The time (in seconds) from the beginning to the end of the event.
- **The depth or height of the event**: The increase or decrease of the heart rate (in bpm) during the event.
- **The confidence of detection**: The degree to which the **PeriCALM Patterns** detection engine is confident that the event detected is indeed an actual event. This value is expressed as a score on 5 points, where 0 indicates that the **PeriCALM Patterns** is only "somewhat confident" and 5 indicates that it is "very confident".

5.2.6. Striking Out an Event

In some cases, a clinician may not agree with an event that **PeriCALM Patterns** detected. In such an instance, it is possible for the clinician to strike out a detected event.

1. Click on or hover over the event marker in question.
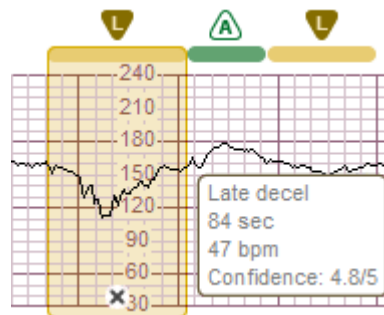
2. Click on the "**X**" icon located at the bottom of the highlighted area. A message is displayed, warning that an event will be struck out.
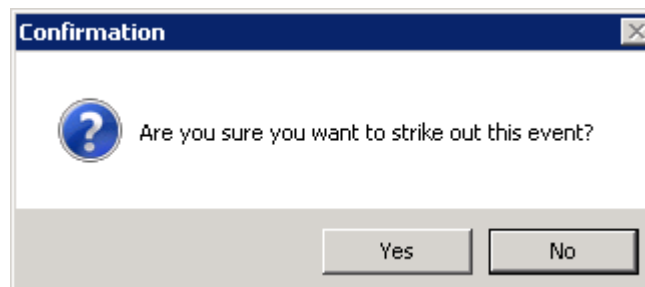
3. Click **Yes**. The event marker turns white with an "**X**" above it, indicating that the event has been struck out (see below).
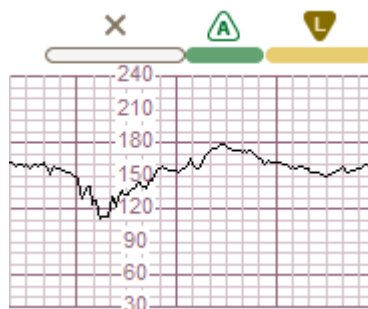
5.2.7. Restoring an Event

In some cases, a clinician may not agree with an event that was struck out. In such an instance, it is possible for the clinician to restore the event.

1. Click on or hover over the event marker in question.

2. Click on the arrow icon located at the bottom of the highlighted area. A message is displayed, indicating that an event will be restored.
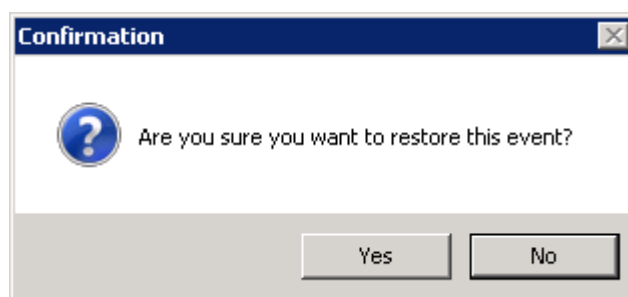
3. Click **Yes**. The event marker returns to its original, pre-strike out marked and interpreted state.
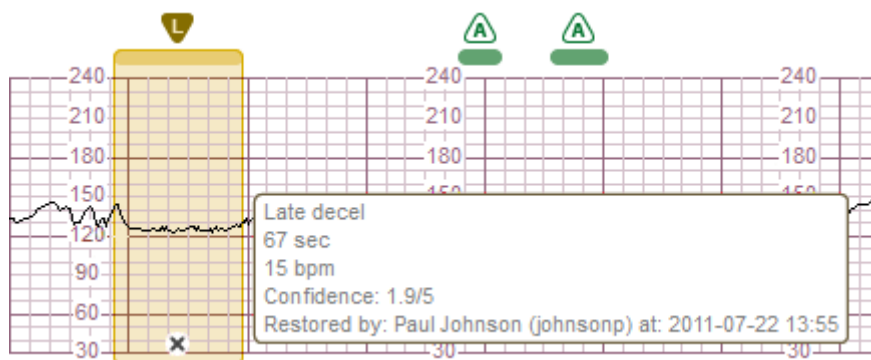
5.2.8. Confirming a Non-Interpretable Event

When **PeriCALM Patterns** identifies a potential event, but portions of the tracing are missing, the event is classified as non-interpretab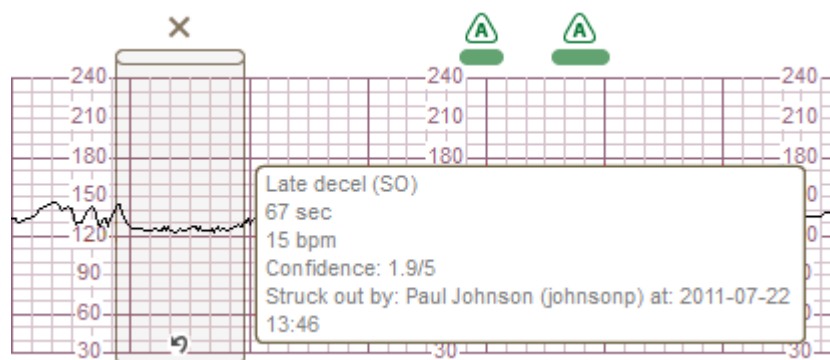le and a **Non-interpretable Deceleration** ⬙? or a **Non-interpretable Acceleration** △? pictograph is displayed, as applicable (see Signal Quality for additional information on non-interpretable events).

If the clinician is confident that an event has indeed occurred over the given area of tracing, the non-interpretable event can be confirmed.

1. Select the Non-Interpretable event of interest by clicking on it or hovering over it.
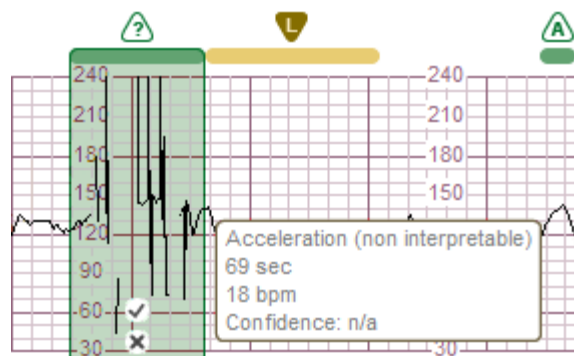
Click on the checkmark icon located at the bottom of the highlighted area. A message is displayed, asking whether the clinician wants to confirm the non-interpretable event.
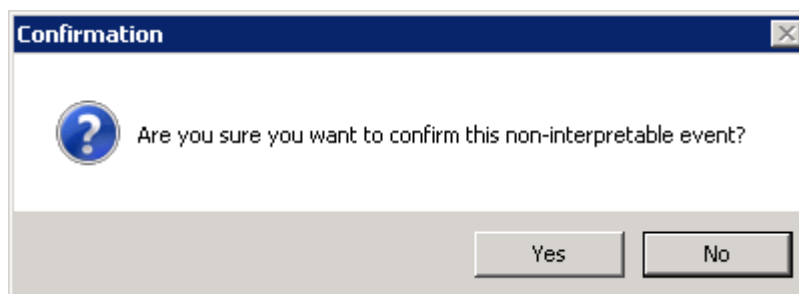
2. Click **OK**. The "?" event pictograph is replaced by the applicable event type pictograph.
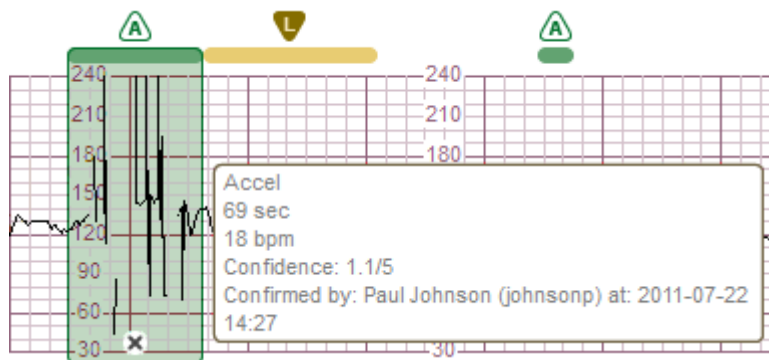
5.3. Contractions

5.3.1. Contraction Markers

PeriCALM Patterns identifies contractions by analyzing the uterine pressure tracing. Detected contractions are displayed by Contraction Markers. These are beige lines displayed beneath the uterine pressure grid (see below). The left and right parts of the lines respectively indicate the beginning and end of each contraction.
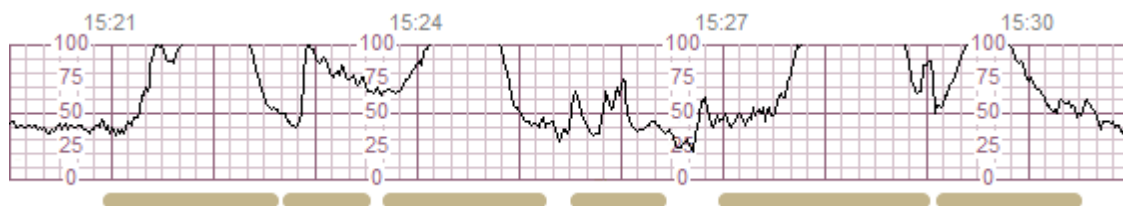
5.3.2. Striking Out a Detected Contraction

In some cases, a clinician may not agree with a contraction that **PeriCALM Patterns** detected. In such an instance, it is possible for the clinician to strike out a detected contraction.

1. Click on or hover over the desired contraction marker. The contraction becomes selected as shown below.
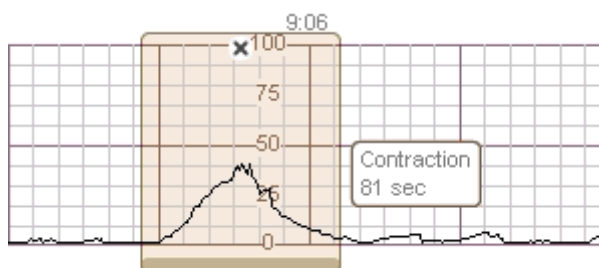
2. Click on the "**X**" icon located at the top of the highlighted area. A message appears, warning that a contraction is about to be struck out.

Confirmation

Are you sure you want to strike out this contraction event?

Yes   No
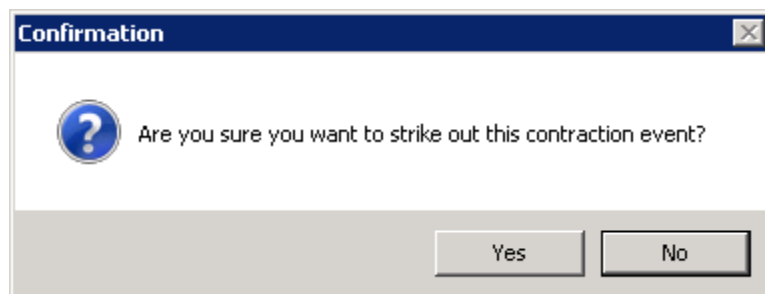
3. Click **Yes**. The contraction marker turns from beige to white, indicating that the contraction has been struck out (see below).
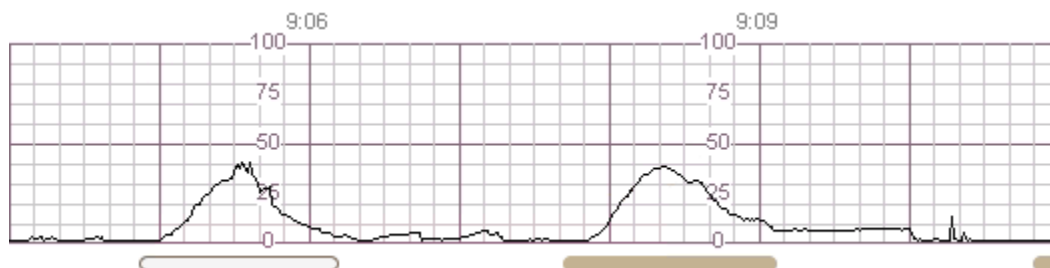
Striking out a contraction will result in the Mean Contraction Interval, Montevideo Units and Contractions being recalculated. Striking out a contraction will not affect the detection of Fetal Heart Rate Events.

5.3.3. Restoring a Struck Out Contraction

In some cases, a clinician may not agree with a contraction was struck out. In such an instance, it is possible for the clinician to restore that contraction.

1. Click on or hover over the desired contraction marker. The contraction becomes selected as shown below.

Contraction (SO)
81 sec
Struck out by: Paul Johnson (johnsonp) at: 8/17/2011 9:21
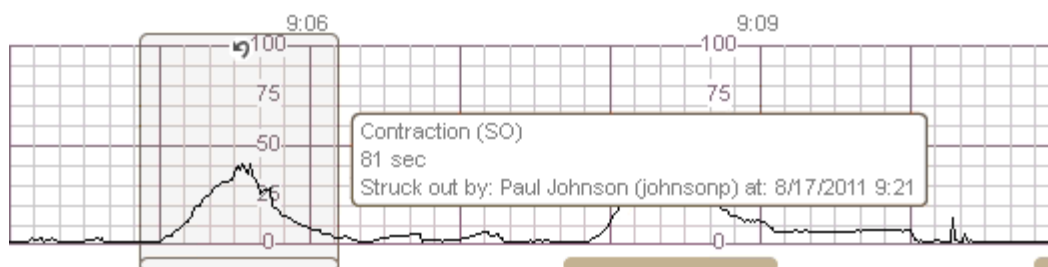
2. Click on the arrow icon located at the top of the highlighted area. A message appears, warning that a contraction is about to be restored.

Confirmation

Are you sure you want to restore this contraction event?

Yes   No
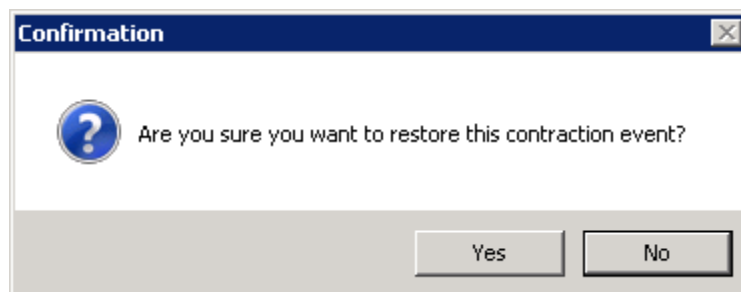
3. Click **Yes**. The contraction marker turns from white to beige, indicating that the contraction has been restored (see below).
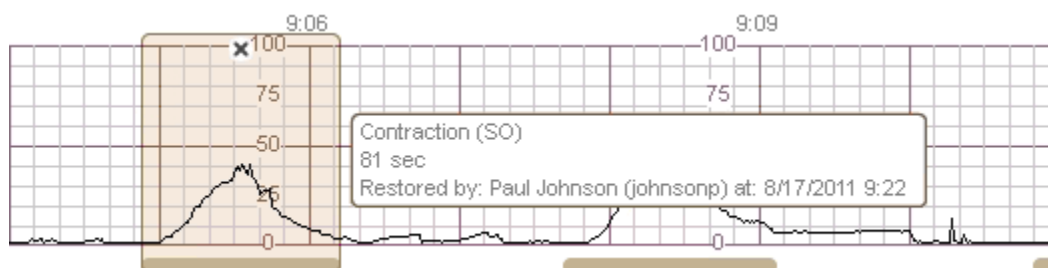
Contraction (SO)
81 sec
Restored by: Paul Johnson (johnsonp) at: 8/17/2011 9:22

Restoring a contraction will result in the Mean Contraction Interval, Montevideo Units and Contractions being recalculated. Restoring a contraction will not affect the detection of Fetal Heart Rate Events.

5.4. Mean Contraction Interval

Using the contractions detected, **PeriCALM Patterns** calculates the average time between contractions within a 30 minute window. Similarly to **Mean Baseline** and **Mean Baseline Variability**, these values are calculated and displayed dynamically in the **30 Minute Summary** box beneath the **Slider Window**.

| 30 Minute Summary					
Mean Contraction Interval:	Q 2.5 min	Contractions:	12	Mean Baseline:	164	DECELS (>= 60 x 60):	3
		Contractions (>120 sec):	0	Mean Baseline Variability:	10	LATE DECELS (Confidence>2.0/5):	3
				Accelerations:	0	Prolonged Decels:	0
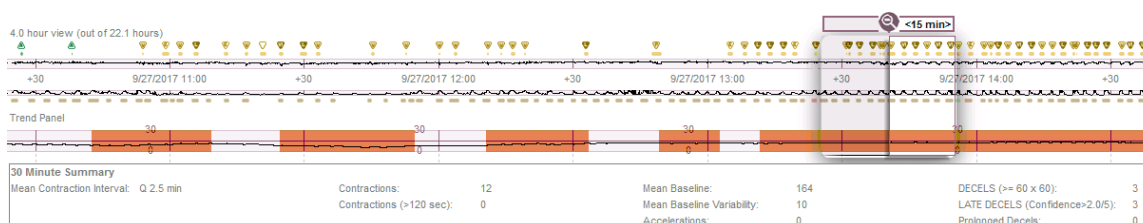
5.5. Trend Panel

In addition to the two fetal strip tracing views, **PeriCALM Patterns** optionally displays a **Trend Panel**, which is a 4 hour (or up to 12 hours) graph that plots the **PeriCALM CheckList algorithm** results over time. By clicking the **TOCO Graph** button ✓TOCO Graph , this graph can be displayed in either a **Simple** or **Multifaceted** version.

In the **Simple** view, a site-defined color coded system is employed to indicate the PeriCALM CheckList level based on the presence or absence of 6 specific EFM features over a 30 minute period.

> The threshold criteria for each EFM feature can be configured by a system administrator.

- **Off-white** – None of the values measured for all EFM features exceed the institutional criteria.
- **Orange** – The value measured for one or more features exceeds the institutional criteria.
- **Grey** – The status is unknown, for example the CheckList recognition algorithms are processing but not yet finished the analysis of that segment of tracing.

In the **Multifaceted** view, in addition to the color coded system, the actual number of contractions in the 30 minute period is plotted.
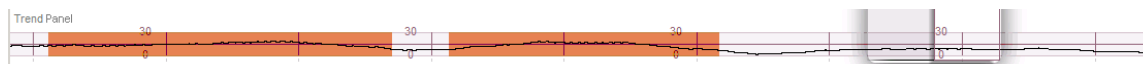
In both views, the following items are configured by site:

Table 1

Default Parameters		
Rule over past 30 minutes	**Threshold***	**Color Code**
Mean Baseline Variability (and no 15X15 accelerations)	< 6 bpm	
Late Decelerations (greater than a minimal confidence factor)	>=2 (confidence >70%, i.e. >2/5)	
Any Decelerations (that are not late) 60secX60bpm below baseline (Decelerations >= 60 x 60)	>=3	
1 Late Decelerations and 1 or more Deceleration (>= 60 x 60)	>=2	
1 Late Decelerations and 1 or more Prolonged Deceleration (greater than a minimal depth below baseline)	>=2 (>20 bpm below baseline)	
Contraction Count	>=16	
Contractions (>120 sec)	>=2	
None of the above		
Cannot Calculate		
* These threshold values are provided as an example of a typical or commonly accepted configuration. The actual threshold values to be used will be configured by your site in accordance with hospital policies.		

> During initial 30 minutes, once Decelerations or Contractions criteria have been exceeded, the Trend Panel will be positive even if less than 30 minutes have elapsed.

For reference purposes, the **PeriCALM CheckList Algorithm** rules calculating the color coded **Trend Panel** are accessible from the **PeriCALM Patterns About Box**. Click on the **?** icon on the **PeriCALM Patterns Toolbar** to open the **PeriCALM Patterns About Box** and then click the **Algorithm** link to open the **PeriCALM CheckList Algorithm** dialog on which the rules calculating the algorithm, as well as the site configured threshold values used within the algorithm calculation, are listed.

5.6. Contractility

For clients that do not use the Trend Panel, **PeriCALM Patterns** displays a **Persistent Contractility Index**, which is a 4 hour (or up to 12 hour) graph that plots contractility over time. By clicking the **TOCO Graph** button , this graph can be displayed in either a **Simple** or **Multifaceted** version.

In the **Simple** view, a site-defined 3-color system is employed to indicate the level of contractility.

- **Off-white** – contractility is below the threshold levels set by the site. The contractility threshold is defined by both a number of contractions and a time interval. In this example 5 contractions per 10 minutes. Both factors are configurable by the site at the time of installation.
- **Beige** – contraction rates exceed the contractility threshold levels set by the site, but persist for a period of time less than that determined by the site for its persistency threshold.

This is referred to as stage 1 and these threshold levels can be configured by a system administrator.

- **Orange** – refers to contraction rates that exceed both a persistency threshold and previously defined contractility thresholds. Persistency refers to an uninterrupted duration where contractions exceed the contractility threshold. The persistency threshold is also set by the institution at the time of installation. For example, a persistency threshold is commonly chosen to be 30 minutes. In this example Orange would appear when contractions are above 5 per 10 minutes and this rate has been present for the last 30 minutes. The Orange color would continue as long as these conditions are met.

This is referred to as stage 2 and this threshold level can be configured by a system administrator.

In the **Multifaceted** view, in addition to the 3-color system, the actual number of contractions in the site-defined persistency timeframe is plotted. The maximum value of the y-axis (e.g. 10 contractions per 10 minutes) and the value of an intermediate line (e.g. 5 contractions per 10 minutes) are configurable by a system administrator as well.

In both views, the following items are configured by site:

- The number of minutes over which contractions are being summarized (e.g. 10 minutes)

- The threshold to distinguish high uterine contraction rates from normal (e.g. greater than 5 contractions in 10 minutes)
- The time frame for evaluating persistency of high contractility (e.g. 30 minutes)

5.7. Montevideo Units

PeriCALM Patterns also calculates **Montevideo Units**. They can be displayed by clicking the icon ⊗ Montevideo in the toolbar. This turns the "**X**" in the icon into a checkmark ✔ Montevideo and **Montevideo Units** appear in the **30 Minute Summary** box beneath the **Slider Window**. Additionally, for clients who are using the Export function, the MVU and Internal Intensity fields will be shown on the Export Box only when the Montevideo icon in the toolbar is checked.

After the Montevideo icon in the toolbar is checked, it remains checked each time the **PeriCALM Patterns** screen is subsequently opened, until a user unchecks it. Such changes will not be reflected, though, on other workstations in which the **PeriCALM Patterns** screen is already open at the time.
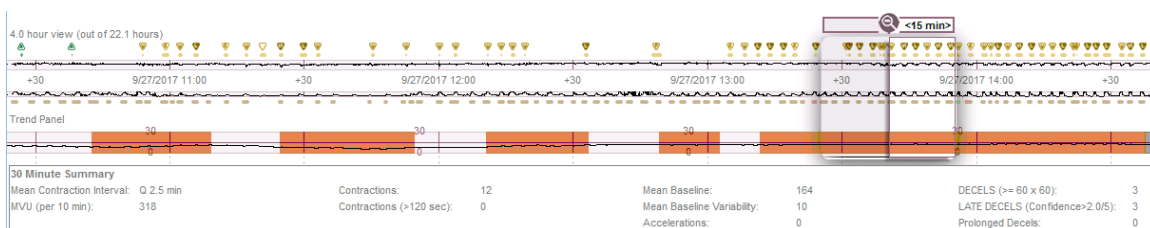
While **Montevideo Units** are calculated over the 30 minute span of the **Slider Window**, the value is averaged and expressed as a number per 10 minutes. In the above figure, for example, an average of 272 **Montevideo Units** is calculated for 10 minutes while the 30 minutes of the Slider Window would actually correspond to a higher total of **Montevideo Units**.

A contraction is considered within the 30 minute window if its peak is within the 30 minute window.

PeriCALM Patterns does not detect probe status to determine if an external Tocodynamometer (TOCO) or an Internal Uterine Pressure Catheter (IUPC) is in use. Please be aware that **Montevideo Unit** calculations are only valid if an IUPC is in place.

6. System Connection Status

On the left hand side of the toolbar, to the right of the **Zoom** icon, **PeriCALM Patterns** displays its current state. Should an issue occur with the application, the state can be clicked to display an informational message which provides additional details related to the application's current state.

Internally the software checks a number of factors; when all factors are complete and consistent with each other, there are no issues to report. Otherwise special messages will appear reflecting the state of the application.

6.1. Possible System Connection States

6.1.1. Connected State

PeriCALM Patterns displays the green **Connected** state | **Connected** | when the application has no issues to report.

6.1.2. Error State

PeriCALM Patterns displays the red **Error** state | **Error** | when the application has connection issues to report. When this state occurs, the **PeriCALM Patterns** screen is blank and patient data is not available. Clicking on the icon will display an informational message detailing the cause of this state.

6.1.3. No Data State

PeriCALM Patterns displays the orange **No Data** state | **No data** | when the application cannot access the patient's episode of tracing. When this state occurs, the **PeriCALM Patterns** screen is blank and patient data is not available. Clicking on the icon will display an informational message detailing the cause of this state.

6.1.4. Recovery State

PeriCALM Patterns displays the orange **Recovery** state | **Recovery** | when the application needs to calculate and display events for large amounts of historical data instead of the usual punctual display and calculations; typically this occurs after a period of **PeriCALM Patterns** down time. Clicking on the icon will display an informational message detailing the cause of this state. Once **PeriCALM Patterns** has completed the recovery of data, it will return to the **Connected** state.

Additionally, recovered patient data is highlighted above the grid in light gray as per the following image.
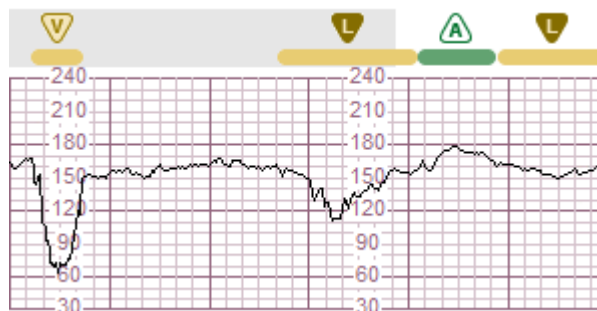
	While **PeriCALM Patterns** is in recovery mode, it is possible to navigate the tracing and perform actions on it; however it should be noted that large blocks of tracing data and events will periodically appear on the grid until all of the applicable historical tracing has been processed and displayed, at which point the **Connected** status will be displayed.

7. Using PeriCALM Patterns

7.1. Important Notes

- <u>None</u> of the information generated within **PeriCALM Patterns** will update the patient record in the hosting clinical system. **PeriCALM Patterns** only reads information from the hosting system.

- By selecting the hosting system's configured link or menu item, **PeriCALM Patterns** will be launched for the currently selected patient and will use the currently logged-in user credentials to track changes.

- **PeriCALM Patterns** requires that the following fields be charted in order to calculate and display events: **Estimated Delivery Date** (EDD), and **Number of Fetuses**.

A modification to a patient's **Estimated Delivery Date**, **Number of Fetuses**, **Patient Name** or **Patient ID** in the hosting system will require up to 60 seconds to be reflected in **PeriCALM Patterns**.

- The maximum length (usually 1 day) of episodes of tracing that can be displayed is configurable and includes any gaps in the tracing within that period.

- Past episodes of tracing can only be viewed within a period of time after the patient is discharged, as they are permanently deleted after a configurable number of hours (usually 72 hours after discharge).

- This version of **PeriCALM Patterns** provides no print or archiving capability.

Confirmation message boxes and the **About** window will disappear automatically after a configurable period of time in seconds in order not to cause conflict with the host system's auto-log off feature. When this occurs, no changes will be made to the **PeriCALM Patterns** data, i.e., no events or contractions will be struck out or confirmed.

Appendix: Development and Testing

Developing the Pattern Detection Algorithms

The medical literature includes several reports measuring how well clinicians agree with each other on accelerations and decelerations. In these reports clinician agreement levels ranged from 27-60%. Neither industry nor national professional associations have a formal set of labeled tracings that can be used as a standard against which new analysis techniques can be compared. Therefore a standard was constructed by a panel of experienced clinicians. This test set is referred to as the Clinical Panel Standard.

Tracings were collected from a sample of patients with outcomes ranging from normal to abnormal so that examples of all types of features were available. The clinical aspects of the patients from whom these tracings were collected are summarized in Table 2.

Table 2

Patients in the Clinical Panel Standard								
Mother's Age (years)	Gestational Age		Birth Weight (g)	APGAR		Arterial Cord Gases		Method of Delivery	Indication for Intervention
	Wks.	Days		1 min	5 min	pH	Base excess		
29	36	5	2982	3	5	6.96	-15.6	Cesarean Section	Poor Variability
31	40	0	2585	2	6	7.06	-13.3	Mid Forceps	Failed Vacuum
29	39	1	2869	9	9	7.24	-3.7	Spontaneous Vertex	N/A
35	37	5	2912	2	4	7.25	-8	Low Vacuum	N/A
20	39	6	3995	9	9	7.31	0.6	Spontaneous Vertex	N/A
24	39	1	3242	9	9	7.35	-5.8	Spontaneous Vertex	N/A

The Clinician Panel comprised 5 experienced Obstetricians who used specialized software to review and mark the tracings. They were instructed to label the tracings according to the NICHD guidelines, which were provided. The software allowed them to scroll forwards and backwards, to measure length and depth of selected segments and to affix and edit their labeling. They were unable to see each other's marks. The results were compared, and the Clinical Panel Standard was defined as those features marked with agreement by a majority opinion. The Clinical Panel Standard included 41.8 hours of tracings, with 152 accelerations and 182 decelerations.

Performance

Baseline

The **PeriCALM Patterns** assessment of baseline was highly correlated with the baseline values of the clinical experts in the Clinical Panel Standard. The Correlation Coefficient was 0.987.

Each version of **PeriCALM Patterns** is evaluated to verify that good correlation is maintained between measured Baseline and visual estimates.

Baseline Variability

PeriCALM Patterns defines FHR variability as two standard deviations of FHR values in baseline segments. Each version of **PeriCALM Patterns** is evaluated to verify that good correlation is maintained between measured Baseline Variability and visual estimates.

Accelerations and Decelerations

Performance testing is summarized in Table 2, Table 3 and Table 4.

- **Number in Test** is the number of specific FHR features in the Clinical Panel Standard.
- **Detected** is the number of features in Clinical Panel Standard that were also identified by the **PeriCALM Patterns**.
- **Missed** is the number of features in Clinical Panel Standard that were not detected by the **PeriCALM Patterns**.
- **False positives** are the number of features that were identified by the software but were not identified in the Clinical Panel Standard. A false positive may have been identified by none, one, or two of the five clinicians.
- **Sensitivity** is the percentage of Clinical Panel Standard features that the software detected. Mathematically it is defined by ratio of (detected) / (number in test).
- **Proportion of Agreement** refers to the percentage of all the **PeriCALM Patterns** identified features that were confirmed by the majority on the clinical panel. Mathematically it is defined by the ratio of (detected) / (detected and false positives).
- Reported proportions of agreement amongst clinicians for accelerations are around 55% and between 24% and 60% for decelerations[i,ii,iii,iv,v]. A single report of the performance of another commercially available software for electronic fetal monitoring (EFM) pattern recognition showed proportions of agreements of 55% for accelerations and 46% for decelerations[vi].

Table 3

Overall performance for FHR Events and Contractions						
Feature	Sensitivity	Proportion of Agreement	Number in Test	Detected	Missed	False Positives
Accelerations	71.05%	90.76%	152	108	44	11
Decelerations	92.31%	77.42%	182	168	14	49
Contractions	79.6%	95.4%	553	440	113	21

Classification

When a deceleration was detected, it was further classified as to type. The performance regarding detection for each deceleration type is summarized in Table 4 and Table 5.

Table 4

Performance for detection of specific deceleration types						
Deceleration Type	Sensitivity	Proportion of Agreement	Number in Test	Detected	Missed	False Positives
Variable deceleration	93.5%	83.7%	93	87	6	17
Late deceleration	95.8%	67.6%	48	46	6	21
Early deceleration	73.7%	77.8%	19	14	5	4
Gradual decelerations unassociated with contractions	95.5%	82.6%	22	21	1	5
Prolonged decelerations	90.9%	83.3%	11	10	1	2

Table 5

Performance for detection and typing of decelerations				
Deceleration Type	Number in Test	Detected	Agreement with Type	Agreement with Type (%)
Variable deceleration	93	87	73	73/93 (78.5%)
Late deceleration	48	46	34	34/48 (70.8%)
Early deceleration	19	14	14	14/19 (73.7%)
Gradual decelerations unassociated with contractions	22	21	15	15/22 (68.2%)
Prolonged decelerations	11	10	5	5/11 (45.5%)

Limitations

The following limitations are present in the application:

- **PeriCALM Patterns** does not mark features in areas where the tracing is absent or very intermittent.
- **PeriCALM Patterns** does not identify sinusoidal fetal heart rate patterns.
- **PeriCALM Patterns** does not sub-classify accelerations by duration, i.e., it will not identify accelerations as prolonged.
- **PeriCALM Patterns** does not label baselines as abnormally high (tachycardia) or low (bradycardia), although it provides the numerical value of the baseline.
- **PeriCALM Patterns** does not identify fetal cardiac arrhythmias.
- When tested on a set of FHR tracings that had been evaluated by a panel of experts, **PeriCALM Patterns** detected 92% of decelerations and 72% of accelerations. Because not all features present on a tracing are identified by **PeriCALM Patterns**, it is essential that a qualified clinician review the tracings.

---

[i] Ayres- de-Campos D, Bernardes J. Early, variable and late decelerations: can a consensus be reached in their identification? Int J Gynaecol Obstet 1999;**65**:305-6

[ii] Bernardes J, Costa-Pereira A, Ayres-de-Campos, Van Geijn HP, Pereira-Leite L. Evaluation of interobserver agreement of cardiotocograms. Int J Gynaecol Obstet 1997;**57**:33-7

[iii] Donker DK, Van Geijn HP, Hasman A. Interobserver variation in the assessment of fetal heart rate recordings. Eur J Obstet Gynaecol Reprod Biol 1993;**52**:21-8

[iv] Taylor GM, Mires GL, Abel EW, Tsantis S, Farrell T, Chien PFW et al. The development and validation of an algorithm for real time computerized fetal heartrate monitoring in labor. Br J Obstet Gynaecol 2000;**107**:1130-7

[v] Todros T, Preve CU, Plazzotta C, Biocalti M, Lombardo P. Fetal Heart rate tracings:observers versus the computer assessment. Eur J Obstet Gynecol Reprod Biol 1996;**68**:83-6

[vi] Devoe L, Golde S, Kilman Y, Morton D, Shea K, Waller J. A comparison of visual analyses of intrapartum fetal heart rate tracings according to the new national institute of child health and human development guidelines with computer analyses by an automated fetal heart rate monitoring system. Am J Obstet Gynecol. 2000 Aug;**183**(2):361-6