# PeriGen Inc.

## PeriCALM® Patterns™ User Guide
## Version 1.16

## Copyright notice



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# 1. About PeriGen

**PeriGen, Inc.** is a technology-enabled professional services company specializing in risk reduction and clinical quality improvement in obstetrics. A pioneer in clinical decision support, PeriGen provides innovative, real-time solutions and a full suite of complementary professional and consulting services that reduce risk and improve clinical outcomes.

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# 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 installation folder, and
- as an online help system, accessible from within the PeriCALM Patterns application.

## 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. |
| Blue underline | 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; close attention must be paid 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 Patterns Release Notes* – Provides information on what is new in the release and the application's limitations.
- *PeriCALM Tracings User Guide* – Provides information about using of the PeriCALM Tracings application.
- *PeriCALM Administration User Guide* – Provides information about the configuration of the system and includes HL7 specifications, System Logs and Chalkboard Configuration.
- *PeriCALM Tracings Release Notes* – Provides information on what is new in the release and the application's limitations.

# 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.

Key Benefits

- Represents fetal heart rate events and uterine contractions in a visually intuitive manner.
- Calculates several important clinical metrics in real-time.
- Displays 17-minute, 2 hour and 12 hour views of tracings.
- Brings standard definitions such as NICHD guidelines to the bedside.
- Displays the institution's definition of uterine tachysystole in a graphical and numerical manner.
- Improves communication.
- Provides constant educational reinforcement to minimize the impact of inexperience.
- Adds the convenience of automatic data input for your confirmation.

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.

Evaluation of FHR during labor and patient management decisions should not be based solely on 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. What's New in Version 1.16?

- Compatibility with PeriCALM Tracings Version 3.16
- PeriCALM Patterns is now supported on Windows 7 32 and 64 bit, Windows Server 2008 R2 64 bit and Windows Server 2008 R2 SP1 64 bit

## 3.2. Features Carried Forward from Previous Versions

- Compatibility with the NIEC (Non-Integrated External Charting component) mode of PeriCALM Tracings
- Detection of contractions and calculation of contraction interval
- Detection of fetal heart rate accelerations
- Detection and classification of fetal heart rate decelerations (Early, Late, Variable, etc.)
- Detection of baselines and calculation of baseline variability
- Display of persistent contractility, as defined by the institution
- Integration with PeriCALM Tracings
- Ability to archive discharged visits and to view these visits in a viewer application
- Detection of Events with Non Reassuring Features (Loss of variability within deceleration, 60s and Biphasic shape)
- Calculation of Montevideo units
- Ability to launch PeriCALM Patterns with a specific bed pre-selected
- Simultaneous display of an expanded 17-minute view of the tracing and a compressed 2-hour view
- Ability to zoom out the 2-hour view to up to 12 hours in order to facilitate the identification of trends

## 3.3. The PeriCALM Patterns Interface

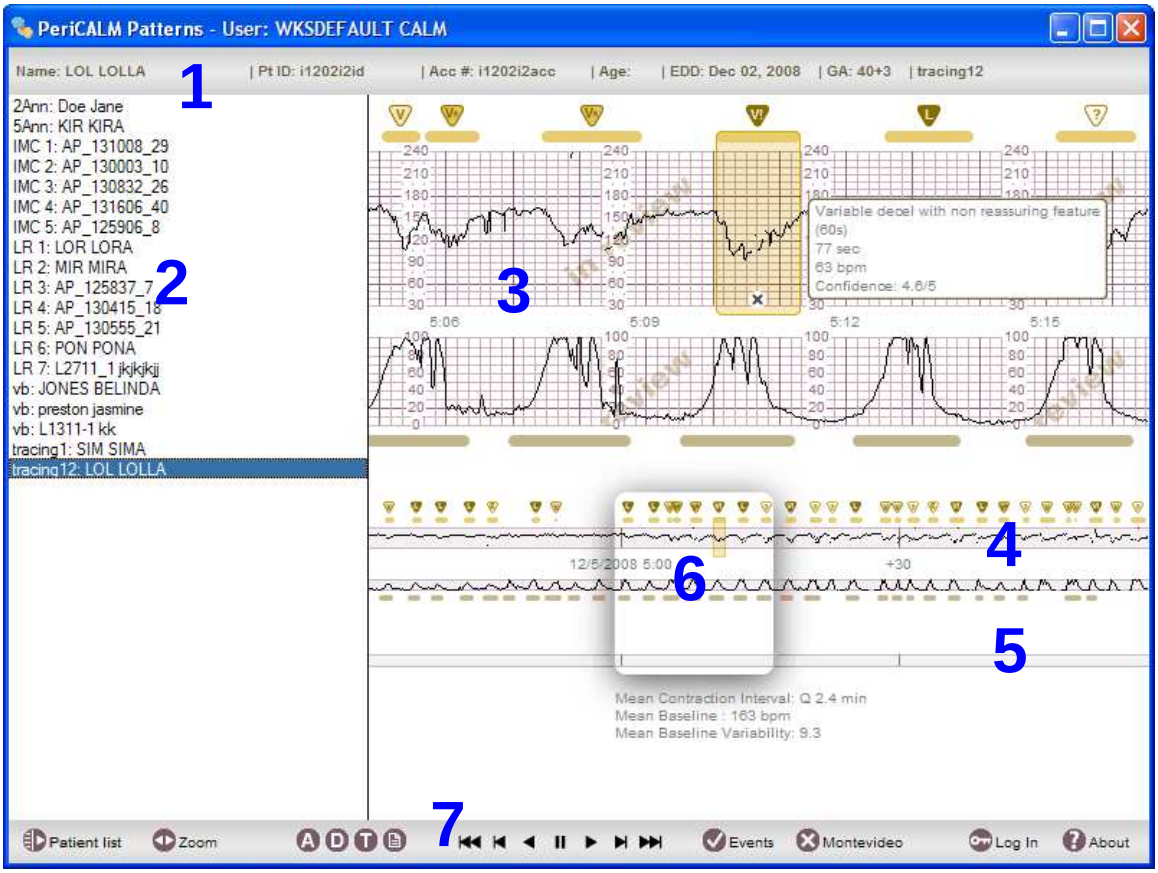
The following shows the main components of the PeriCALM Patterns interface.

1. The **Patient Banner** displays information on the currently selected patient
2. The **Patient List** shows all patients currently admitted

Only available in standalone mode, i.e. when not launched from a central monitoring system.

3. The **Expanded Tracing View** shows 17 minutes worth of fetal tracings including events and contractions
4. The **Compressed Tracing View** shows 2 or up to 12 hours of compressed fetal tracings including events and contractions.
5. The **Persistent Contractility Index** indicates the patient's level of contractility, and indicates when it is excessive.
6. The **Slider Window** allows a specific section of 17 minute section of tracing to be viewed in the Expanded Tracing View
7. The **Toolbar** is used to access many PeriCALM Patterns features.

The available buttons vary according to the installation setup and configuration.



# 4. Accessing PeriCALM Patterns and Selecting Patients

PeriCALM Patterns is designed to run on sites that have PeriCALM Tracings installed. To learn how to access PeriCALM Patterns when PeriCALM Tracings is installed, see Using PeriCALM Patterns with PeriCALM Tracings. To learn how to access PeriCALM Patterns without PeriCALM Tracings, see Launching PeriCALM Patterns Directly.

## 4.1. Using PeriCALM Patterns with PeriCALM Tracings

When using PeriCALM Patterns in conjunction with PeriCALM Tracings, patient context between the two applications is maintained. As such, charting can be done in PeriCALM Tracings while heart rate and contraction analysis for the same patient is done in PeriCALM Patterns.

### 4.1.1. Launching PeriCALM Patterns from PeriCALM Tracings

Follow the steps below to launch PeriCALM Patterns from PeriCALM Tracings.

1. Launch PeriCALM Tracings and log in.
2. From the default screen and if not already displayed, select the **Chalkboard** icon  on the left-hand side vertical icon bar. The application displays the **Chalkboard**.
3. From the **Chalkboard**, select the patient of interest. PeriCALM Tracings highlights the selected row.
4. Click on the PeriCALM Patterns icon  . The application will launch PeriCALM Patterns. Once launched, PeriCALM Patterns will display the patient that is currently selected in PeriCALM Tracings.

When PeriCALM Patterns is launched from PeriCALM Tracings, patient context is synchronized between the two applications. Changing patients can only be done from PeriCALM Tracings. To select a different patient to display in PeriCALM Patterns, return to PeriCALM Tracings and select the desired patient from a multi-patient view.

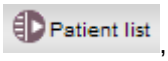
When PeriCALM Tracings is configured to use the NIEC mode (see PeriCALM Tracings documentation for additional details) the standard patient banner is adjusted to reflect the patient in PeriCALM Tracings. The HL7 conflict icon is no longer displayed on screen.

### 4.1.2. Launching PeriCALM Patterns Directly

Even with PeriCALM Tracings installed, it is possible to launch PeriCALM Patterns without first launching PeriCALM Tracings. In such a case, patient selection is done directly within PeriCALM Patterns. This is detailed in the following procedure.


1. Launch PeriCALM Patterns via the PeriCALM Patterns icon on your desktop or Start Menu. The application will launch PeriCALM Patterns. Once launched, PeriCALM Patterns will display an empty tracing with “No patient selected” displayed in the patient banner at the top of the screen. At this point, a **Default User** is logged in. Typically, for security reasons, default users have a limited amount of access or no access at all to functionalities in the application.
2. Log in to PeriCALM Patterns via the **Log In** icon 

in the bottom toolbar.
3. Open the patient list by clicking on the **Patient list** icon 

in the bottom toolbar or by pressing the Escape key on the keyboard. The patient list opens and displays the currently admitted patients.
4. Select the patient of interest by clicking on a patient in the **Patient list**. The patient’s information will be displayed in the patient banner and the tracing will be loaded on the screen.
5. The patient list is closed by either clicking on the **Patient list** icon 

, pressing the Escape key on the keyboard, or simply moving the mouse out of the patient list.

## 4.2. Keeping the Patient List Open

When PeriCALM Patterns is launched directly (i.e., not from PeriCALM Tracings), it is possible to keep the patient list open at all times. This can be useful for central monitoring workstations. When PeriCALM Patterns is launched with this option, the patient list remains opens and is not overlaid on any fetal tracing, as would normally be the case. Instead, fetal tracings are slightly reduced in size and are displayed beside the patient list to avoid any overlap with the patient list. Please contact PeriGen Support to configure your workstation with this feature.

## 4.3. Default Bed

When PeriCALM Patterns is launched directly (i.e., not from PeriCALM Tracings), it is possible to have PeriCALM Patterns open with a specific bed already selected. This can be useful for bedside workstations, where the bed of interest is almost always the bed beside the workstation. When PeriCALM Patterns is configured in this manner, the application automatically logs in with the default user and displays the specified bed. In the default bed mode, many of PeriCALM Patterns’ functionalities are restricted. To re-enable these functionalities, such as being able to select other patients, you must log on as a regular user. When logging out (see Logging Out of PeriCALM Patterns), PeriCALM Patterns will return to the default user and the default bed. To configure PeriCALM Patterns with the Default Bed feature, please contact PeriGen Support.

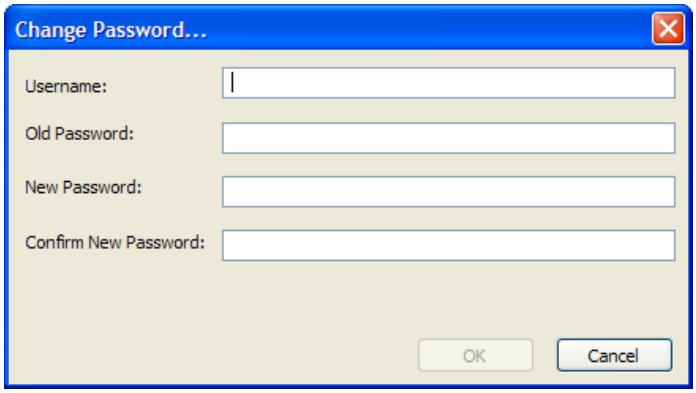
## 4.4. Changing Password

The password used to log in to PeriCALM Patterns can be changed within PeriCALM Patterns. To change passwords, see the procedure below.

Only available in standalone mode, i.e. when not launched from a central monitoring system.


1. Launch PeriCALM Patterns via the PeriCALM Patterns icon on your desktop or Start Menu.
2. Click on the **Log In** icon 

in the bottom toolbar.
3. Click on the **Change Password…** button. This opens the **Change Password** window shown below.




4. Enter your username and existing password in the **Username** and **Old Password** boxes respectively.
5. Enter a new password in both the **New Password** and **Confirm New Password** boxes.
6. Click **OK**. Your password will be saved and you will be logged in to PeriCALM Patterns.

## 4.5. Logging Out of PeriCALM Patterns

If PeriCALM Patterns was launched from PeriCALM Tracings, logging out of PeriCALM Patterns is done by logging out of PeriCALM Tracings.

If PeriCALM Patterns was not launched from PeriCALM Tracings, logging out of PeriCALM Patterns is done via the **Log Out** button 

in the bottom toolbar of PeriCALM Patterns.

Closing Patterns (see Closing PeriCALM Patterns) also results in the user being logged out.

PeriCALM Patterns has an auto log out feature which is activated after a certain period of inactivity. The length of this time period is configurable and is shared between PeriCALM Patterns and PeriCALM Tracings, and configured in the latter.

## 4.6. Closing PeriCALM Patterns

PeriCALM Patterns can be closed by clicking on the **Close** button  in the top right corner of the application. If PeriCALM Patterns was launched from PeriCALM Tracings, closing PeriCALM Tracings will also automatically close PeriCALM Patterns. Closing PeriCALM Patterns also logs out any user that was logged in to PeriCALM Patterns at that moment.

# 5. Fetal Tracing Display

## 5.1. 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 17 minutes of tracing, and a Compressed View, which shows 2 hours of tracing. Both the 17 minute Expanded View and 2 hour Compressed View are displayed in the same aspect ratio as seen on a typical paper strip.

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.

When a patient is selected (either in PeriCALM Tracings or PeriCALM Patterns' Patient List), the most recent tracing for that patient is loaded on the screen. If less than 17 minutes of tracing exists for the selected patient, a certain amount of blank tracings will be visible on the left hand portion of the Expanded View. Likewise, if less than 2 hours of tracing exists for the selected patient, a certain amount of blank tracings will be visible on the left hand portion 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 17 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.

## 5.2. Navigating Through the Tracings Views

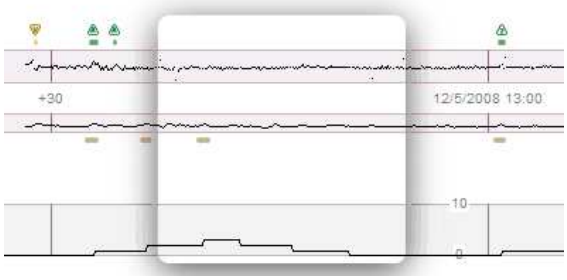
Both the Expanded and Compressed Tracing Views can be scrolled in order to review past tracings. Dragging the mouse directly on top of either tracing view, scrolls the both tracings to the left or right. The scrolling will stop once the strip has been dragged all the way to either the beginning or the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

The tracing views can also be moved via the Slider Window (see The Slider Window), the Navigation Buttons (see The Navigation Buttons) and the keyboard (see The Keyboard)

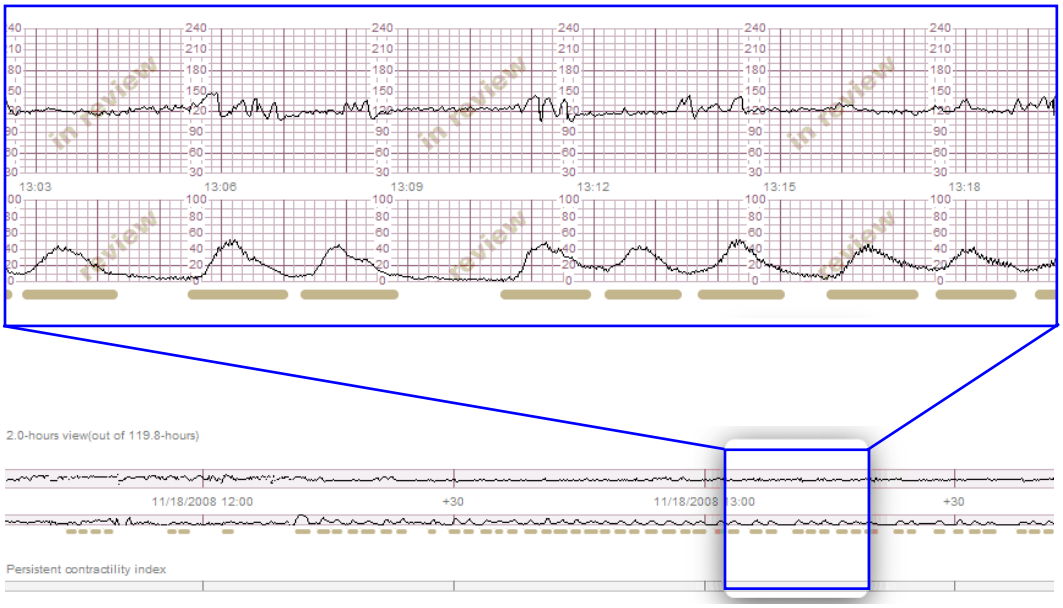
Each time the patient selection is changed, tracings are automatically scrolled to the right, to show the most recent part of the tracing.

### 5.2.1. The Slider Window

The Slider Window is a component of the Compressed Tracing View which identifies the 17 minute overlap between the 17 minute Expanded View and the 2 hour Compressed View.



When the Compressed View is dragged, the Slider Window moves, so that the appropriate 17 minute window on the Compressed View is always displayed (see figure below). Conversely, dragging the Slider Window itself will cause the 17 minute Expanded View to scroll.




## 5.2.2. 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.

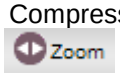
| | |
|---|---|
| ▶ | Auto-scroll the Slider Window from past to present. Note: clicking the button more than once increases the auto-scrolling speed. |
| ⏭ | Skip forward to the next 17 minute window of tracings. |
| ⏭⏭ | Jump to the end of the tracing. |
| ⏸ | Stop the auto-scrolling of the Slider 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 17 minute window of tracings. |
| ⏮⏮ | Jump to the beginning of the tracing. |

### 5.2.3. The Keyboard

The tracing views can be scrolled via the keyboard. The various keyboard shortcuts are described below.

| | |
|---|---|
| → button | Scrolls the Slider Window from past to present. |
| **Ctrl** + → buttons | Skip forward to the next 17 minute window of tracings. |
| **Ctrl** + **Alt** + → buttons | Jump to the end of the tracing. |
| ← button | Scrolls the Slider Window towards the past. |
| **Ctrl** + ← buttons | Skip backward to the previous 17 minute window of tracings. |
| **Ctrl** + **Alt** + ← buttons | Jump to the beginning of the tracing. |

## 5.3. Zooming the Compressed Tracing View

The 2 hour Compressed View can be zoomed out to display 12 hours by clicking on the **Zoom** icon 

or by pressing the Space bar. 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 6-fold.

The Compressed View can be toggled between the 2 and 12 hour view by clicking the **Zoom** icon or Space bar at any point. Additionally, the Compressed view is automatically zoomed in from 12 to 2 hours whenever the Slider Window is dragged and then released.

# 6. The PeriCALM Patterns Engine

At the heart of PeriCALM Patterns is the application's 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:

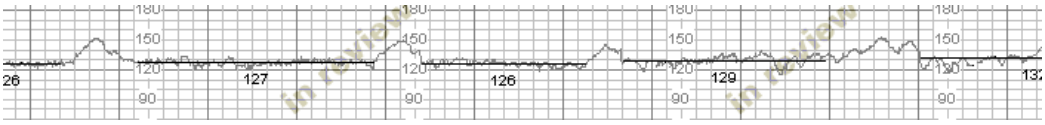
- Baseline and variability
- Fetal heart rate features
- Uterine contractions
- Mean contraction interval
- Montevideo units

## 6.1. Baselines and Variability

### 6.1.1. 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 artifact. The baselines are used as a source for several other calculations (see next sections). Baselines are not displayed by default. By pressing Ctrl-B on the keyboard, 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 BPM) will be displayed below the horizontal lines.

PeriCALM Patterns does not label baselines as abnormally high (tachycardia) or low (bradycardia).




By pressing Ctrl-B again, baselines can be hidden.

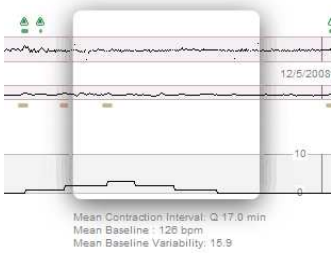
### 6.1.2. Variability

Variability refers to a measurement of the variation in fetal heart rate values in a baseline segment. PeriCALM Patterns defines the baseline variability as 2 Standard Deviations of the fetal heart rate values within the baseline segment.

### 6.1.3. Mean Baseline and Mean Baseline Variability

Using the baselines detected, PeriCALM Patterns calculates Mean Baseline and Mean Baseline Variability over a 17-minute window. These values are displayed beneath the 17-minute Slider Window (shown below). Mean Baseline and Mean Baseline Variability

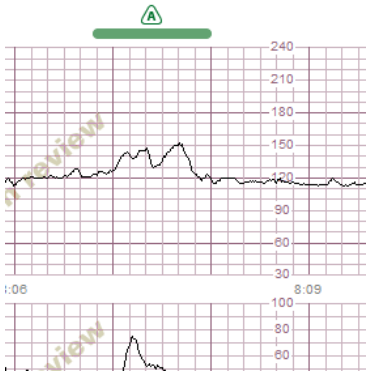
are calculated in real-time as new tracing becomes available. Additionally, the Slider Window can be moved over existing sections of tracing and these two calculations will be updated dynamically.




## 6.2. 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 green or brown lines displayed above the fetal heart rate 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 must be activated in order for events to be displayed. This is a configuration option that must be set when PeriCALM Patterns is installed at your site. When activated, events can be hidden or displayed by clicking the appropriate button at the bottom of the screen.

Event detection is always disabled for patients whose gestational age is below 36 weeks or who have more than one fetus.

[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).

### 6.2.1. Signal Quality

To generate annotations, PeriCALM Patterns must receive FHR signals from the fetal monitor at least 50% of the time during a sliding window of time, which can be set between 60 and 120 seconds. If a valid signal is received for less than this amount of time, no annotations will be generated. 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.

### 6.2.2. 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.

In general, accelerations are represented by green event markers and pictograms in the shape of upwards pointing triangles.


**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.

### 6.2.3. Decelerations

Historically, decelerations were classified and labeled according to a postulated underlying physiology. For example, baroreceptor-mediated fetal heart rate changes are abrupt and head compression or chemoreceptor-mediated changes are gradual in onset.

In PeriCALM Patterns, 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-defined pattern. 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 these cases PeriCALM Patterns will assign a label based on what fits best with 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.

The following illustrations show the deceleration event markers and 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 contraction to associate the deceleration with; 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.
- Biphasic shape
- 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]


**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.
- Biphasic shape
- 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]

**Struck-out Event**

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

[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

### 6.2.4. Displaying Events

PeriCALM Patterns can be configured to be launched with Events displayed or not, by default. In either case, this default setting can be changed at any time by clicking the **Events** button located in the toolbar or by pressing Ctrl-E on the keyboard.

When the button displays a checkmark 

, Events are currently displayed. Clicking the button will hide Events.

When the button displays an "X" 

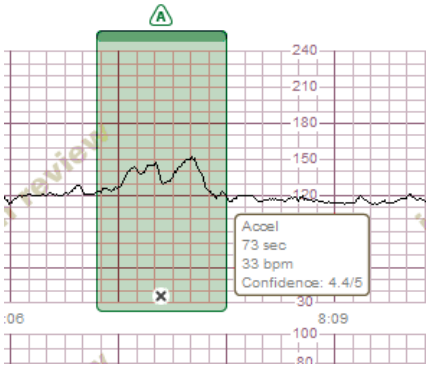
, Events are currently hidden. Clicking the button will show Events.

While PeriCALM Patterns detects events in real-time, several minutes of tracing may be required by the event detection engine before PeriCALM Patterns can confidently identify and display an event or a baseline.

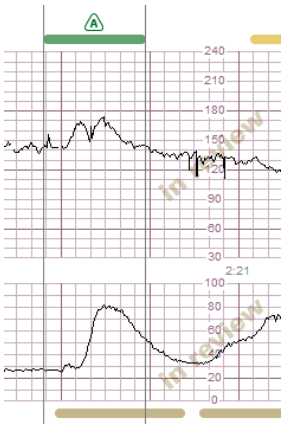
### 6.2.5. Selecting Event Markers

An event can be selected by clicking on the Event Marker (shown below). A highlighted box will surround the portion of the heart rate tracing where the event was detected and an associated information box will show:

- **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, and
- **The confidence of detection**: The degree at 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 PeriCALM Patterns is "somewhat confident" and 5 indicates that PeriCALM Patterns is "very confident".



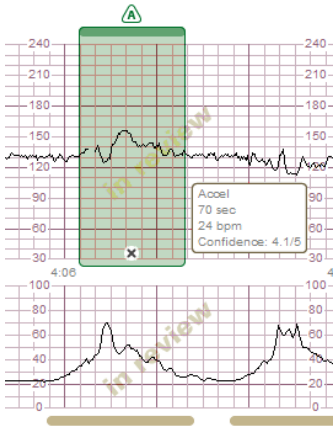
In addition to being able to select an event, a clinician can also hover the mouse over an event without clicking. In this case, vertical lines representing the start and end points of an event will traverse the tracing to assist in determining pattern association and timing with uterine contractions (shown below).




## 6.2.6. Striking Out an Event

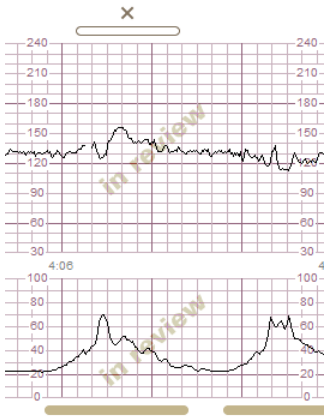
In some cases, a clinician may not agree with an event that PeriCALM Patterns detected. In such an instance, it is possible for the clinician to strikeout a detected event.

1. Click on the event marker in question.



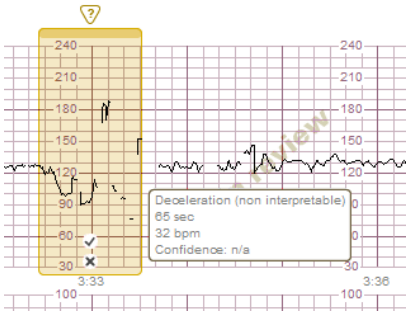

2. Click on the "**X**" icon inside the highlighted area. A message is displayed, warning that an event is about to be struck-out.

3. Click **OK**. The event marker turns white with an “X” above it, indicating that the event has been struck out (see below).




## 6.2.7. Confirming a Non-Interpretable Event

When PeriCALM Patterns identifies a potential deceleration, but portions of the tracing are missing, the deceleration is classified as non-interpretable and a **Non-interpretable Deceleration** icon is displayed. If the user is confident that a deceleration has indeed occurred over the given area of tracing, the non-interpretable deceleration can be confirmed.

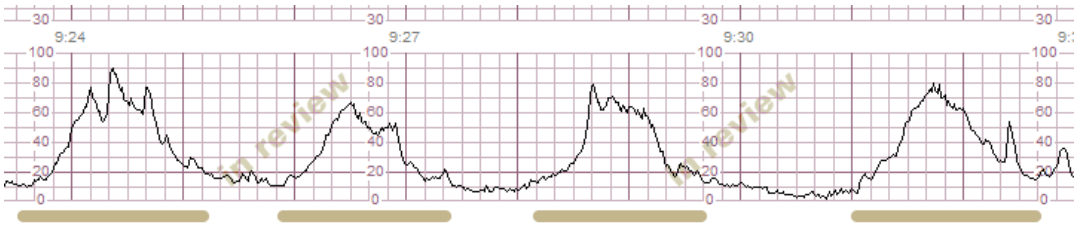



1. Select the Non-Interpretable Event of interest.
2. Click on the checkmark icon located in the highlighted area. A message is displayed, asking the clinician whether they are sure they want to confirm the non-interpretable event.
3. Click **OK**. The “?” event icon is replaced by one of the specific decelerations types possible (see Signal Quality for additional information).

# 6.3. Contractions

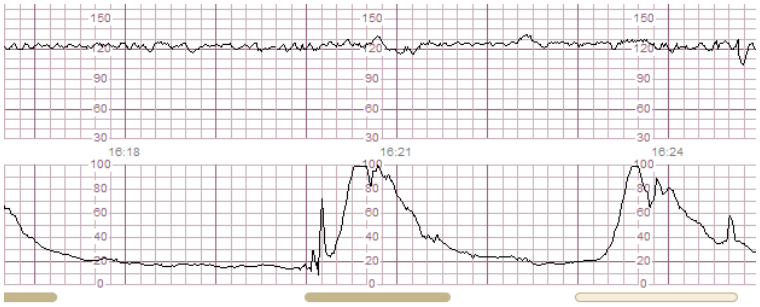
## 6.3.1. Contraction Markers

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.




## 6.3.2. Non-final Contractions

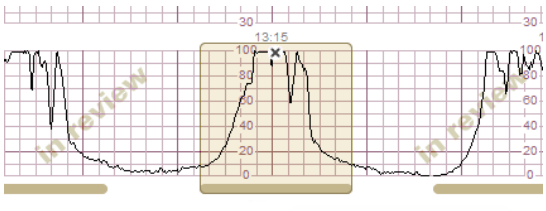
PeriCALM Patterns identifies new contractions for live tracings in real-time. When contractions are first detected, they appear in a lighter shade of beige (see below), indicating that the contraction is “non-final”. Once PeriCALM Patterns has finished its analysis of the contraction and is confident of having detected an actual contraction, the contraction marker turns to the darker beige.



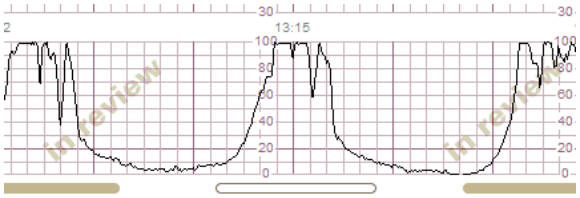

## 6.3.3. Striking Out a Detected Contraction

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 the desired contraction marker. The contraction becomes selected as shown below.



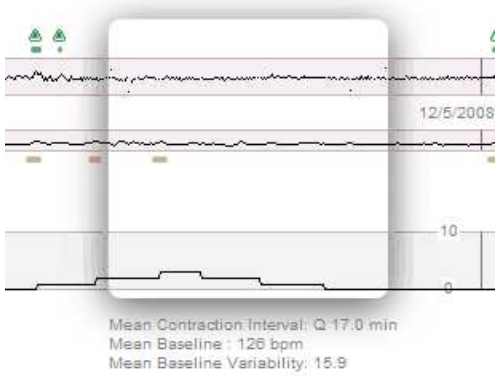
2. Click on the "**X**" button located at the top of the highlighted area. A message appears, warning that a contraction is about to be struck-out.
3. Click OK. The contraction marker turns from beige to white, indicating that the contraction has been struck out (see below).




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

## 6.4. Mean Contraction Interval

Using the contractions detected, PeriCALM Patterns calculates the average time between contractions within a 17 minute window. Similarly to Mean Baseline and Mean Baseline Variability, these values are displayed dynamically beneath the 17 minute Slider Window.

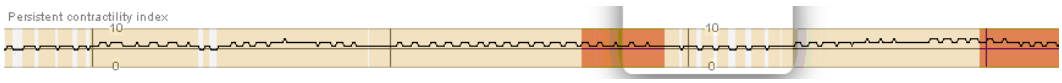



## 6.5. Contractility

In addition to the two fetal strip tracing views, PeriCALM Patterns displays a "**Persistent Contractility Index**", which is a 2 hour (or up to 12 hour) graph that plots contractility over time. By pressing Ctrl-H on the keyboard, this graph can be displayed in either a Simple or Multifaceted version.

Simple View:


Multifaceted View:



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

- White – contractility below the threshold level set by the site (for example, 5 or fewer contractions per 10 minutes)
- Beige – contractility at or above the threshold level set by the site, but for a period of time less than that determined by the site for persistency (for example, 5 or more contractions per 10 minutes, for a duration of less than 20 minutes)
- Orange – contractility at or above the threshold level set by the site for an uninterrupted period greater than that determined by the site for persistency (for example, 5 or more contractions per 10 minutes, for a duration of 20 minutes or longer, uninterrupted)

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 as well.

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

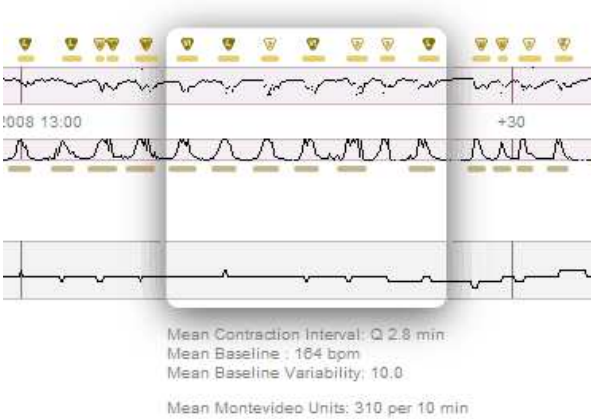
- The number of minutes over which contractions are being evaluated (e.g. 10 minutes)
- The threshold to distinguish normal uterine contraction levels from tachysystole (e.g. greater than 5 contractions in 10 minutes)
- The time frame for evaluating persistency of uterine tachysystole (e.g. 20 minutes)

## 6.6. Montevideo Units

PeriCALM Patterns can also calculate Montevideo Units. This calculation is optional and must be turned on manually by clicking the Montevideo icon 

in the toolbar. This turns the “X” in the icon into a checkmark 

and Montevideo units appear beneath the Slider Window (shown below).



While Montevideo Units are calculated over the 17 minute span of the Slider Window, the value is normalized over 10 minutes. In the above figure, for example, an average of 310 Montevideo Units is calculated for 10 minutes while the 17 minutes of the Slider Window would actually correspond to a total of 527 Montevideo units.

A contraction is considered within the 17 minute window if its peak is within the 17 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.

# 7. ADT

Patients can be manually admitted, transferred and discharged within the PeriCALM Patterns application via the **ADT** buttons located in the toolbar. The four icons below are described respectively in the next 4 sections.

This chapter applies only when the application is used in standalone mode, i.e. when not launched from a central monitoring system.

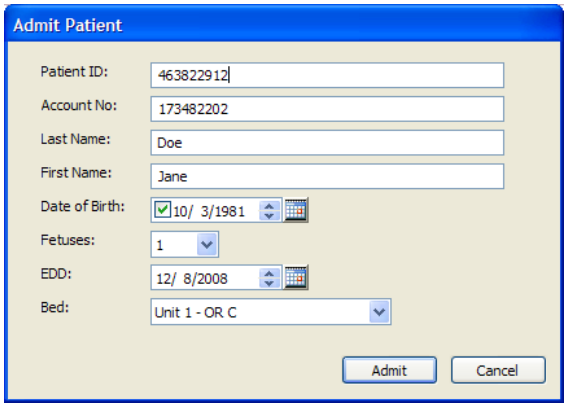
## 7.1. Admit

To admit a patient in PeriCALM Patterns, follow the steps below.

1. Log in to PeriCALM Patterns.
2. Click the  icon in the toolbar. PeriCALM Patterns opens the **Admit Patient** screen (shown below).
3. Enter information into the required fields: **Patient ID**, **Last Name**, **Fetuses**, **EDD** and **Bed**.

**Patient ID** is a unique field and therefore, two patients with the same ID cannot be admitted at the same time.

4. Enter information into the optional fields as needed: **Account Number**, **First Name** and **Date of Birth**.
5. Click the **Admit** button. The patient is admitted and the bed that was selected is displayed on the screen.



## 7.2. Discharge

To discharge a patient, follow the steps below.

1. Log in to PeriCALM Patterns.
2. Select the Patient/Bed of interest.
3. Click the D icon from the toolbar. PeriCALM Patterns will ask you to confirm that you indeed want to discharge the given patient.
4. Click **OK**. The patient is discharged and you remain on the current bed, which is now unoccupied.

If the patient is currently acquiring fetal tracings, a discharge will result in fetal tracings no longer be collected by PeriCALM Patterns for this patient.

## 7.3. Transfer

To transfer a patient, follow the steps below.

1. Log in to PeriCALM Patterns.
2. Select the Patient/Bed of interest.
3. Click the T icon from the toolbar. PeriCALM Patterns opens the **Transfer Patient** window (shown below).
4. Select the bed you wish to transfer the patient to.
5. Click the **Transfer** button. The patient is transferred and PeriCALM Patterns displays the new bed that was selected.


If the patient is currently acquiring fetal tracings, a transfer will result in fetal tracings no longer be collected by PeriCALM Patterns for this patient.

## 7.4. Modification

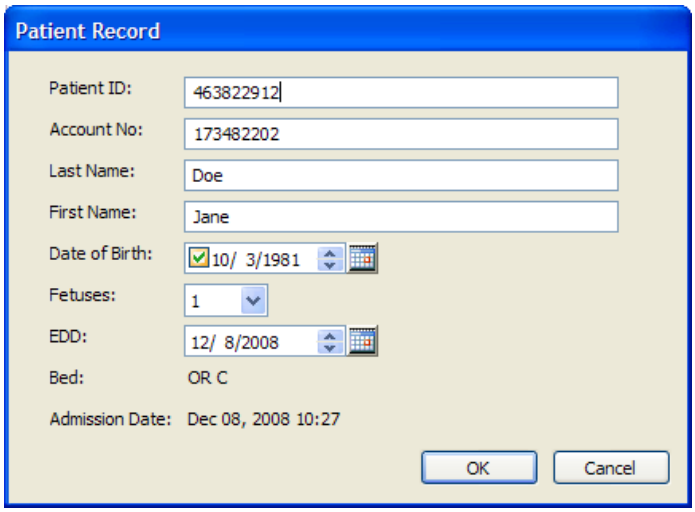
While a patient is admitted, it is possible to modify the information that was entered at the time of admission. To modify the patient record, follow the steps below.

1. Log in to PeriCALM Patterns.
2. Select the Patient/Bed of interest.
3. Click the icon from the toolbar. PeriCALM Patterns opens the **Patient Record** window (shown below).

4. Modify the information as desired. **Patient ID**, **Last Name**, **Fetuses**, **EDD** are required fields.

**Patient ID** is a unique field and therefore, two patients with the same ID cannot be admitted at the same time.

5. Click **OK**. The patient record is saved and you remain on the current bed.



# 8. Discharged Visits

PeriCALM Patterns is intended for viewing currently admitted patients only. Discharged visits can be viewed by using a variant of PeriCALM Patterns, called the **PeriCALM Patterns Viewer**. This application can view discharged visits, provided that the visit has been saved to a file via the **PeriCALM Patterns Archive Manager** application. This chapter describes both how to save discharged visits (see Saving Discharged Visits) and how to view these visits (see Viewing Discharged Visits).

## 8.1. Saving Discharged Visits

Once a visit is discharged from PeriCALM Patterns, it is ready for saving. Saving can be done manually or on a scheduled basis. For the latter, please contact PeriGen support for help in configuration. To manually save discharged visits, follow the steps below.

1. Open the PeriCALM Patterns Archive Manager.

By default, this application (PeriCALMPatternsArchiveManager.exe) is located in the "Bin" folder where PeriCALM Patterns was installed (typically "C:\PeriCALM\Bin"). However, this application can be run from any workstation that has access to the Patterns Server. Please contact PeriGen support for help in setting up archiving.

2. If you would like Patient ID, Account Number and Patient Name to not be saved in the archive files, please make sure that **Remove Patient Identifiers** under the **Options** menu is checked.

In addition to the option to not have patient identifiers saved, the saved files themselves are encrypted. Only the PeriCALM Patterns Viewer application is able to decrypt and view information contained in a saved visit.

3. From the menu, click on **Tools** and then **Run an Archive Session**. PeriCALM Patterns checks for newly discharged visits and saves them.
4. Close the application.

## 8.2. Viewing Discharged Visits

Once a visit has been saved, it can be opened via the PeriCALM Patterns Viewer application.

1. Open the PeriCALM Patterns Archive Manager.
2. From the list of archived visits, select the row corresponding to the visit of interest.

For patient confidentiality, Patient ID, Account Number and Patient Name are not displayed in the list of archived visits, even if the option to save these values was selected.

3. Open the visit either by right-clicking and selecting **View Archived Visit in Patterns** or by selecting **File** from the menu and then **View Archived Visit in Patterns**. PeriCALM Patterns Viewer is launched and the selected visit is displayed.

PeriCALM Patterns Viewer displays visits exactly as they appeared in PeriCALM Patterns at the moment of discharge. As such, any events or contractions that were struck out in PeriCALM Patterns by a clinician while the visit was admitted will also be displayed as stuck-out in PeriCALM Patterns Viewer. When viewing archived visits, the following functionalities described in previous sections of this user guide are not available

- Switching between beds/patients
- Performing ADT actions
- Striking out events or contractions
- Confirming non-interpretable events

If the option **Remove Patient Identifiers** was chosen at the time of saving (see Saving Discharged Visits), **Name**, **Patient ID** and **Account Number** in the patient banner will all display “n/a” as their value.

# 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 1.

**Table 1 - 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

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 in 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 PeriCALM Patterns
- **Missed** is the number of features in Clinical Panel Standard that were not detected by PeriCALM Patterns
- **False positives** are the number of features that were identified by the software but were not identified by the panel majority hence in Clinical Panel Standard. A false positive may have been identified by none, one, or two of the 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 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[5,6,7,8,9]. A single report of the performance of another commercially available software for EFM pattern recognition showed proportions of agreements of 55% for accelerations and 46% for decelerations[10].

**Table 2 - 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 |

When a deceleration was detected, it was further classified as to type. The performance regarding detection for each deceleration type is summarized in Table 3 and Table 4.

**Table 3 - 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 |

[5] 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

[6] 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

[7] 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

[8] 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

[9] 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

[10] 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

**Table 4 - 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, Patterns detected 92% of decelerations and 72% of accelerations. Because not all features present on a tracing are identified by Patterns, it is essential that a qualified clinician review the tracings.