PeriGen, Inc.

PeriCALM® CheckList™ User Guide

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Reader comments

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Trademarks

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

Intended Use

PeriCALM® CheckList™ 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 CheckList 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

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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® CheckList™ 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. PeriCALM® CheckList™ provides OB clinicians the capability to create configurable rule(s) based on combinations of detected FHR features.

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

2. This Guide

2.1. Versions

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

- As a hard copy,
- As a PDF (Portable Document Format) file available in the **PeriCALM CheckList** 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.
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; 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 CheckList User Guide* provides information that is related to the PeriCALM CheckList application. For additional information related to the PeriCALM suite of products, please refer to the following.

- *PeriCALM Tracings User Guide* – provides information about using the PeriCALM Tracings application.
- *PeriCALM Curve User Guide* – provides information about using the PeriCALM Curve application.

These do not apply when *PeriCALM CheckList* is used in conjunction with a non-PeriCALM Tracings surveillance system.

3. Overview

PeriCALM CheckList 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 CheckList** 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 CheckList** 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 CheckList** can calculate baseline, baseline variability, Montevideo units and contraction interval averages in a sliding window.

PeriCALM CheckList enhances **PeriCALM Patterns** fetal heart feature detection with color coding of user selected combinations of detected features.

PeriCALM CheckList provides OB clinicians the capability to create configurable rule(s) based on combinations of detected FHR features (Accelerations, Decelerations, Contractions, Baseline and Variability), so that when certain values are obtained a color code associated to the tracing will change to a defined color and this way be communicated to the user as part of the standard **PeriCALM CheckList** view or via a pop-up notification.

PeriCALM CheckList provides the following main components:

- **Central View** - Client software installed on a dedicated station at the Nursing Station(s).
- **Bedside View** - Bedside software installed on existing workstations and coexisting with other software on that station.

PeriCALM CheckList has the option to be used together with the PeriGen Computer Assisted Labor Monitoring (**PeriCALM Tracings**) system, or in parallel to 3rd party fetal surveillance systems. The user functions available directly from **PeriCALM CheckList** differ in these 2 separate configuration settings.

PeriCALM CheckList is intended for use as an adjunct to qualified clinical decision-making during antepartum or intrapartum obstetrical monitoring of singleton 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.
- Provides 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, for example a widely used oxytocin management protocol.

- Provides constant educational reinforcement to minimize the impact of inexperience.
- When PeriCALM CheckList is used together with PeriCALM Tracings it optionally 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 CheckList** annotations.

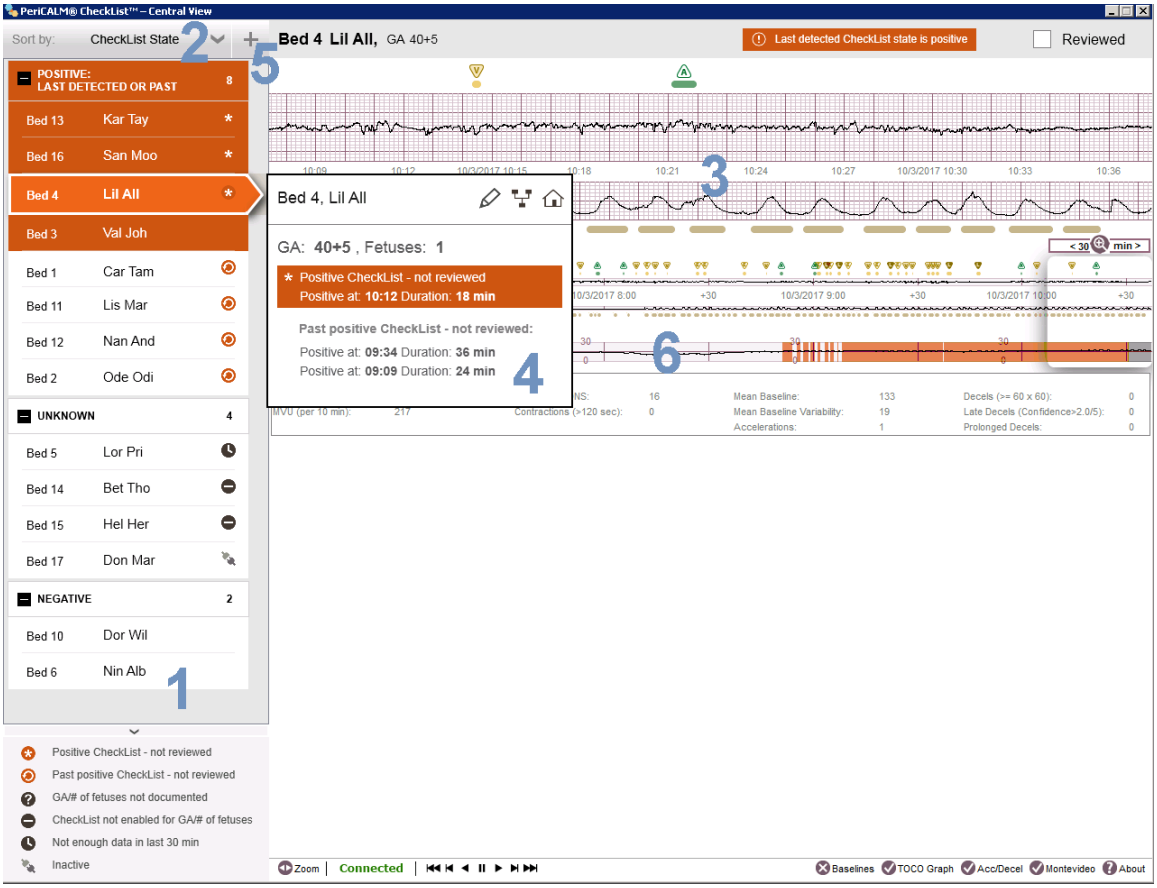
PeriCALM CheckList is intended to be used as an adjunct to a fetal surveillance system that provides standard alerts when fetal heart rates are out of bounds.

3.1. Central View

PeriCALM CheckList includes a **Central View** that is installed on a dedicated station at the Nursing Station(s).

The following shows the main components of the **PeriCALM CheckList – Central View**:

1. The **Patient List** listing all patients currently admitted to **PeriCALM CheckList** and presenting their CheckList state through the use of color code and icons (See 6. PeriCALM CheckList State)
2. Sorting options that include sorting by CheckList state (in which positive patients are listed at the top), or by alphabetical order of patient names or patient beds.
3. Patient-specific **Tracing View** displayed for each selected patient.
4. **Tooltip Window with Patient Details**, allowing easy access to change patient's data, merge patient charts or discharge patient.
5. Easy access to manually admit a patient.
6. The **PeriCALM CheckList Trend Panel**.



3.1.1. The Patient List

The **Patient List** allows nurses at a central nursing station to monitor the PeriCALM CheckList state of all the patients in their unit at a single glance. For each patient in the unit, the bed number, first 3 letters of the first name and first 3 letters of the last name, as well as a visual representation of the PeriCALM CheckList state (in background color and/or icon) are displayed.

A Legend at the bottom of the **Patient List** describes the different icons used, and can be closed or reopened as needed by clicking on the arrow above the Legend.

CheckList states are identified on the **Patient List** as follows:

State	Background Color	Icon
Positive CheckList, reviewed		No icon
Positive CheckList, not reviewed		
Past positive CheckList – not reviewed		
Not enough data in last 30 min		

CheckList not enabled for GA/# of fetuses		
GA/# of fetuses not documented		
Inactive		
Negative CheckList		No icon

Selecting a patient on the **Patient List** opens that patient's **Tracing View.**

Hovering over a patient on the **Patient List** opens that patient's **Tooltip Window with Patient Details**. Through this window the user can additionally edit the patient's data, merge the patient's manual chart with the same patient's ADT chart, or discharge the patient.

3.1.2. Sorting

The user can sort the **Patient List** by CheckList State, or by alphabetical order of patient names or patient beds. In order to sort the **Patient List** follow the steps below.

1. Click on the **Sorting** icon  to view the **Sorting** options.
2. Select the preferred **Sorting** option (by CheckList State, or by Names in ascending or descending order, or by Beds in ascending or descending order).
3. When Sorted by CheckList state, Positive state patients appear on the top followed by Unknown state and finally Negative state patients. Within each group, a secondary sorting is also applied, so that sub groups appear together as well. For Positive state patients this means that patients with a non-reviewed Positive state appear first, followed by patients with a reviewed Positive state, and these are then followed by patients with a non-reviewed Past Positive state.

3.1.3. PeriCALM CheckList Tracing View

The user can select a patient from the **Patient List** in order to open the patient's **Tracing View** (see 4. Fetal Tracing Display). The patient's information will be displayed in the patient banner (including the bed number, first 3 letters of the first name, first 3 letters of the last name, gestational age and CheckList state), and the tracing will be loaded on the screen.

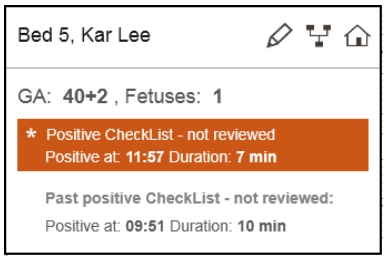
3.1.4. Tooltip Window with Patient Details

The user can hover over a patient on the **Patient List** in order to open a **Tooltip Window with Patient Details**. Within this window the bed number, first 3 letters of the first name, first 3 letters of the last name, gestational age (GA), # of Fetuses, as well as the CheckList state are displayed.

For patients whose CheckList state is Positive, the start time of the most recent Positive CheckList state evaluation is shown together with the duration (in minutes) since.

When multiple non-reviewed Positive CheckList state evaluations exist (in patients whose CheckList state is Positive or Past Positive) they are listed in the **Past Positive CheckList – not reviewed** section of the Tooltip Window, and for each of these events the start time and duration (in minutes) are shown.

The Tooltip Window additionally provides the user access to the **Change patient data** icon, **Merge charts** icon, and **Discharge patient** icon.



3.1.5. PeriCALM CheckList Trend Panel

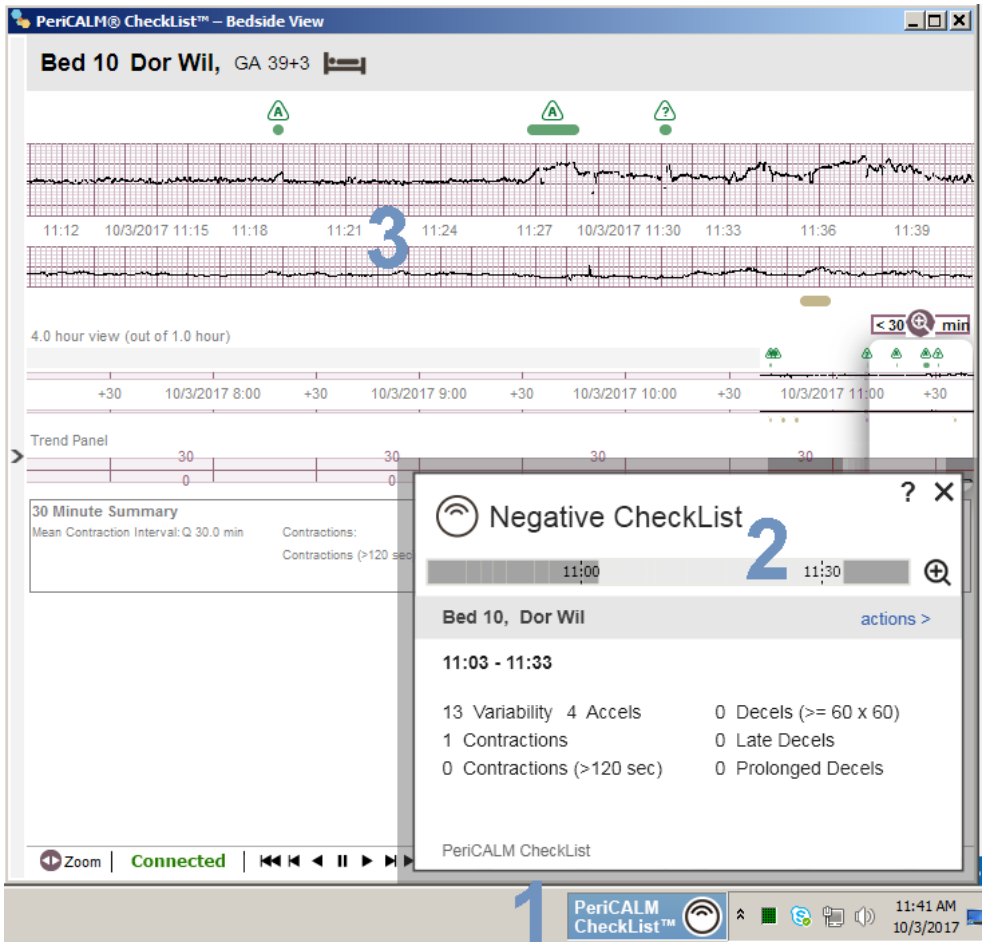
The **PeriCALM CheckList Trend Panel** is a 4 hour (or up to 12 hours) graph that plots contractility over time and displays a site-defined color coded system to indicate the PeriCALM CheckList level based on the presence or absence of 6 specific EFM features over a 30 minute period. For a detailed description see 5.4 PeriCALM CheckList Trend Panel.

3.2. Bedside View

PeriCALM CheckList includes a **Bedside View** client installed on each workstation associated with a bed.

The following shows the main components of the **PeriCALM CheckList – Bedside View**:

1. The **PeriCALM CheckList State Toolbar Icon** shows the CheckList state for the patient in the bed associated with the workstation at all times.
2. The **Notification Dialog,** when open, shows the CheckList state of the patient in the bed associated with the workstation, a 1 hour view of the PeriCALM CheckList Trend Panel, and a detailed content section that is dependent on the patient's Checklist state. The **Notification Dialog** automatically pops up when the CheckList state is identified by the system as Positive, displaying a summary of the detected FHR and Contractions features at the time of the positive CheckList state identification. The **Notification Dialog** can also be manually opened by the user from the **Toolbar Icon**. Additionally, it allows easy access to manually admit a patient, change existing patient's data, merge patient charts or discharge patients.
3. Patient-specific **Tracing View** from which (configuration-permitting) users may also open the **Patient List** to view other patients or navigate to their **Tracing View**.



3.2.1. PeriCALM CheckList State Toolbar Icon

The **Toolbar Icon** shows the CheckList state of the patient in the bed associated with the workstation at all times. The icon is docked to the right side of the toolbar.

CheckList states are identified on the **Toolbar Icon** as follows:

- Positive CheckList – 

- Past positive CheckList – not reviewed – 

- Not enough data in last 30 min – 

- CheckList not enabled for GA/# of fetuses – 

- GA/# of fetuses not documented – 

- Inactive – 

- Negative CheckList – 

When the user clicks on the **Toolbar Icon** the **Notification Dialog** opens.

3.2.2. Notification Dialog

The **Notification Dialog** displays a short summary of the patient's PeriCALM CheckList state. The content of this screen is dependent on the CheckList state (See 6. PeriCALM CheckList State). It also provides the user access to an **actions** menu from which the user can open the patient's **Tracing View**, close the **PeriCALM CheckList** application, or perform (when applicable) manual admission, modification of patient data, merging of patient charts, or patient discharge.

The **Notification Dialog** displays the bed number, first 3 letters of the first name and first 3 letters of the last name, as well as the PeriCALM CheckList state. For patients whose CheckList state is Positive, the start time of the most recent Positive CheckList state evaluation is shown together with the duration (in minutes) since. A dynamic PeriCALM CheckList Trend panel presents the color coded CheckList level based on the presence or absence of 6 specific EFM features over the most recent 60 minute period. Clicking on the PeriCALM CheckList Trend panel or on the icon next to it opens the **Tracing View**.

The **Notification Dialog** automatically pops up when a Positive CheckList state is calculated by the system. Additionally, it can be opened by the user by clicking on the **Toolbar Icon**. The **Notification Dialog** remains visible and in the foreground until the user clicks the X to interactively close the **Notification Dialog**, or opens the **Tracing View**. During the time the **Notification Dialog** remains open, the CheckList state may change and this too will affect the content of the screen, as described below.

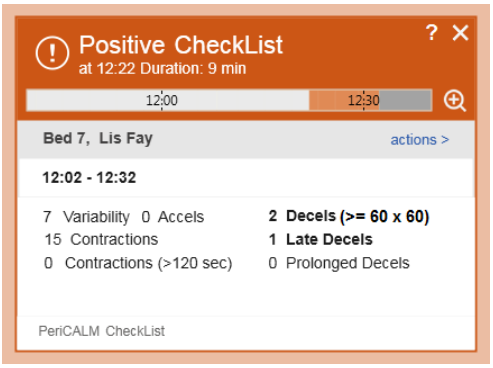
Note: After the **Notification Dialog** automatically pops up by the system, clicking the X to close it can optionally automatically open the **Tracing View**.

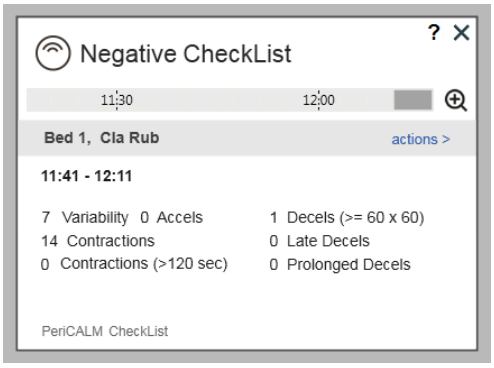
Once the user interactively closes the **Notification Dialog** by clicking the X, or opens the **Tracing View** through alternative means (such as clicking on the **PeriCALM CheckList Trend** panel, or on the icon next to it, or through the

Actions menu) the positive CheckList state is considered as having been reviewed.

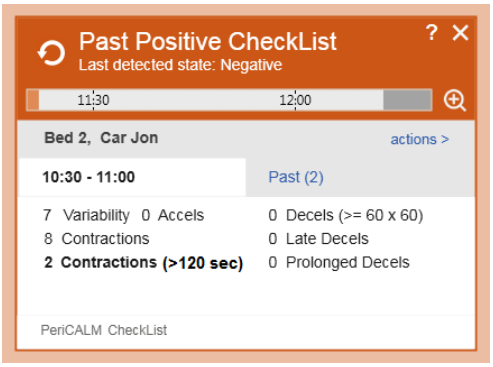
An optional function that may not be available depending on site configuration, enables users to manually mark a positive or past positive CheckList state as having been reviewed directly from the patient's **Tracing View** when the patient is selected from the **Central View's Patient List**.

For Positive CheckList and Negative CheckList patients the **Notification Dialog** presents a static 30 minute summary of the detected FHR and Contractions features at the time of the opening of the **Notification Dialog**. When values exceed the CheckList criteria for an FHR feature, its name is displayed in bold letters.

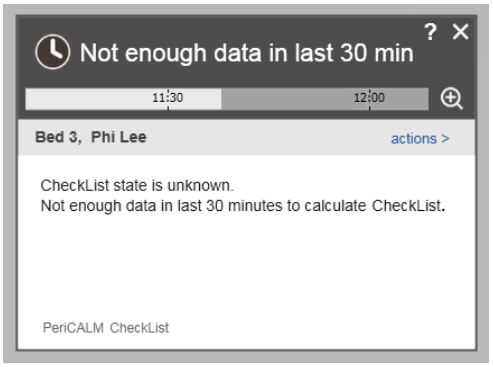


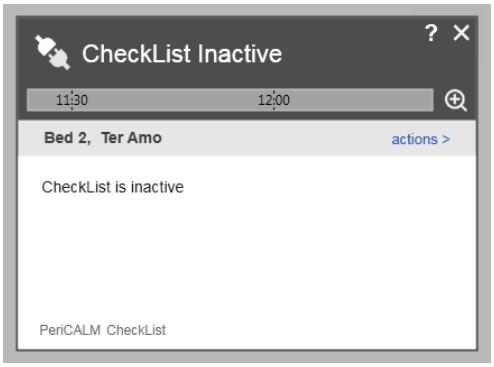


A second tab entitled **Past** appears when multiple non-reviewed Positive CheckList state evaluations exist (in patients whose CheckList state is Positive or Past Positive). These past events are listed on the **Past** tab detailing for each event the start time and duration (in minutes). Once the user interactively closes the **Notification Dialog**, or opens the **Tracing View** the list of non-reviewed Positive CheckList state evaluations is cleared.



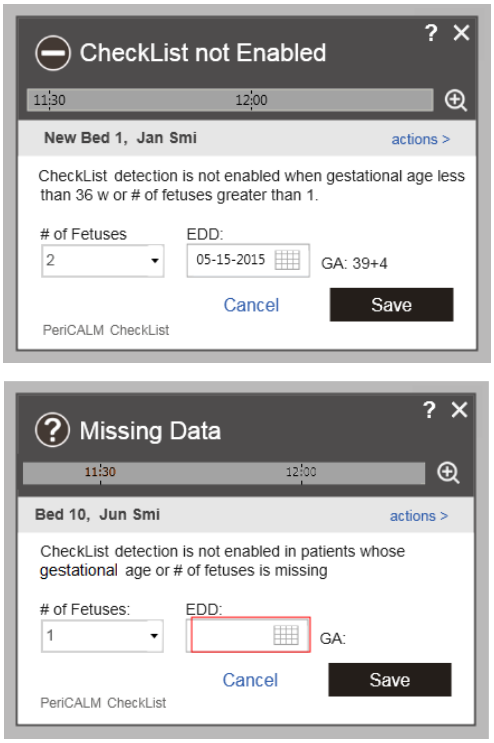
For patients whose CheckList state is unknown due to not enough data in last 30 minutes, or due to Inactive state, the **Notification Dialog** presents a text indicating that the CheckList state is unknown due to not enough data in last 30 minutes to calculate the PeriCALM CheckList, or that PeriCALM CheckList is inactive, respectively.





For patients whose PeriCALM CheckList state is unknown due to missing GA or # of Fetuses data, or due to the GA or # of Fetuses values documented (not enabling PeriCALM CheckList calculation), the **Notification Dialog** presents the EDD and Fetuses fields when opening the **Notification Dialog**, with a text indicating the reason PeriCALM CheckList is not enabled. Users can edit these values directly from the **Notification Dialog** if needed, then click **Save.** The data is saved.

When **PeriCALM CheckList** is used together with **PeriCALM Tracings** a user name and password will be required upon changing patient data.

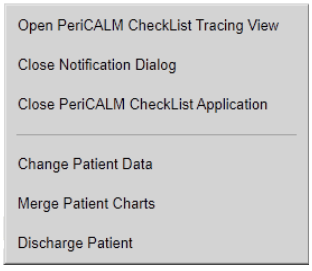


CheckList state changes that occur while the **Notification Dialog** is already open will affect the content of the screen as follows:

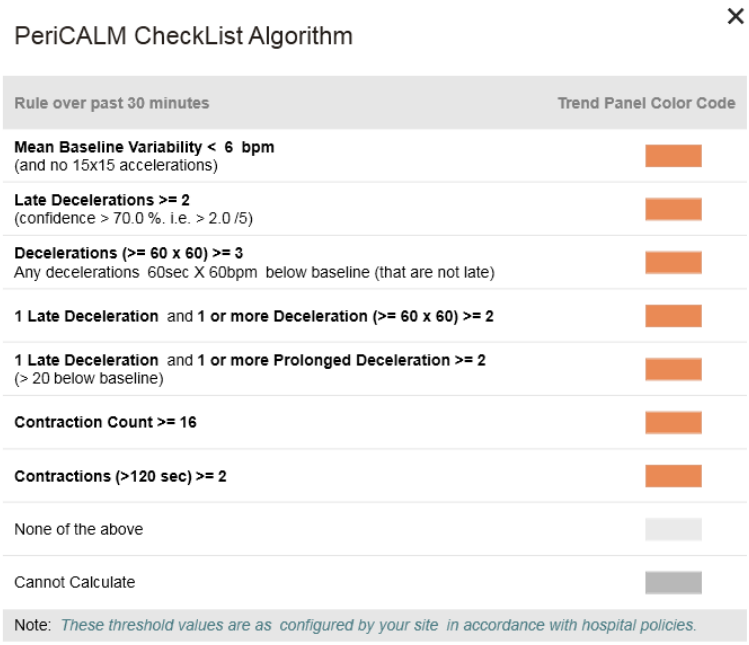
If while an automatically opened **Notification Dialog** remains open (indicating that it was not yet reviewed by a user) the last detected PeriCALM CheckList algorithm calculation is negative, the CheckList state displayed on the screen will change from Positive CheckList to Past Positive CheckList. The static 30 minute summary of the detected FHR and Contractions features at the time of the opening of the **Notification Dialog** will remain on the screen, and only be replaced with a more recent 30 minute summary if the CheckList state once again is evaluated as positive.

If while a manually opened **Notification Dialog** remains open a change occurs to the CheckList state, the CheckList state displayed on the screen will change to show the new state, and the content displayed will change as if the screen was reopened.

The **actions** menu opening from the **Notification Dialog** looks as follows. The availability of some of the actions on it (such as Merge Patient Charts, Discharge Patient) is dependent on site configuration:



For reference purposes, the **PeriCALM CheckList Algorithm** rules calculating the color coded **PeriCALM CheckList Trend Panel** are accessible from the **Notification Dialog** through the **?** icon. Click on the **?** icon 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.



PeriCALM CheckList Algorithm

Rule over past 30 minutes	Trend Panel Color Code
Mean Baseline Variability < 6 bpm (and no 15x15 accelerations)	
Late Decelerations >= 2 (confidence > 70.0 %. i.e. > 2.0 /5)	
Decelerations (>= 60 x 60) >= 3 Any decelerations 60sec X 60bpm below baseline (that are not late)	
1 Late Deceleration and **1 or more Deceleration (>= 60 x 60) >= 2**	
1 Late Deceleration and **1 or more Prolonged Deceleration >= 2** (> 20 below baseline)	
Contraction Count >= 16	
Contractions (>120 sec) >= 2	
None of the above	
Cannot Calculate	

Note: *These threshold values are as configured by your site in accordance with hospital policies.*

3.2.3. PeriCALM CheckList Tracing View

In order to open the patient's **Tracing View** (see 4. Fetal Tracing Display) click on the **Toolbar Icon** to open the **Notification Dialog** and then follow one of the following steps:

1. Click on the **PeriCALM CheckList Trend Panel.**
2. Select the **Open PeriCALM CheckList Tracing View** option from the **actions** menu.

Note: After the **Notification Dialog** automatically pops up by the system, clicking the X to close it automatically opens the **Tracing View** as well.

Closing the **Tracing View** using the X will be considered in this scenario as having reviewed all positive CheckList events not previously reviewed.

Opening the patient's **Tracing View** automatically closes the **Notification Dialog**.

By default, the **Tracing View** displayed is of the patient in the bed associated with the current workstation, as indicated by the bed icon  that appears in the patient banner.

3.2.4. Navigation to Other Patients

Showing the **Patient List** from the **Bedside View's Tracing View** in order to navigate to other patients is an optional function and may not be available depending on site configuration.

In bedside view the **Tracing View** opens without the **Patient List** open by default. In order to navigate to other patients, follow the steps below.

1. Open the patient's **Tracing View** (as described in 3.2.3 PeriCALM CheckList Tracing View).
2. Click on the **Patient List** icon > on the left hand side of the **Tracing View**. The patient list opens and displays the currently admitted patients. The patient in the bed associated with the current workstation is identified by a bed icon.
3. Select a patient from the **Patient List** in order to open that patient's **Tracing View.**

Note: When a patient from another bed is displayed on the **Tracing View**, a blue attention box appears above the patient banner with a message highlighting this mismatch.

A link intended to enable a quick return to the current bed's patient is available as well. This link is highlighted with an orange background when a **Notification Dialog** (of the current patient) pops up on the screen.

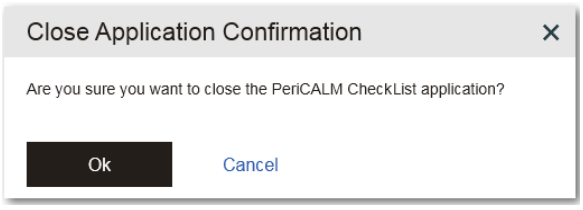
When the **Tracing View** displays a patient from another bed it will automatically close after a configurable period of inactivity.

The user can also hover over a patient on the **Patient List** in order to open a **Tooltip Window with Patient Details**.

3.2.5. Closing the PeriCALM CheckList Application

To close the **PeriCALM CheckList** application from the **Bedside View**, follow the steps below.

1. Click on the **Toolbar Icon** to open the **Notification Dialog**.
2. Click on the **actions** menu and select the **Close PeriCALM CheckList application** option.
3. A **Close Application Confirmation** dialog opens asking the user to confirm closing the application (see below).
4. Click **OK**. The application is closed.



3.3. Admission, Discharge, Merge, Change Data

Manual Admission, Patient Discharge, Merge Patient Charts and Change Patient Data actions can be performed either from the **Central View** of from the **Bedside View**.

The **Manual Admission, Patient Discharge**, and **Merge Patient Charts** functionalities are not available when **PeriCALM CheckList** is used together with **PeriCALM Tracings**. In this configuration, these actions should be done using **PeriCALM Tracings**.

Additionally, some fields may be disabled on the **Change Patient Data** dialog when **PeriCALM CheckList** is used together with **PeriCALM Tracings**.

Per site configuration, a user name and password may be required upon selecting the **Merge Patient Charts** function or accessing the **Change Patient Data** dialog.

3.3.1. Manual Admission

Normally, admission is done automatically through ADT. There are circumstances, though, in which a user would like to perform a manual admission to the PeriCALM CheckList application (emergency admission; ADT system is down). To do so, follow the steps below.

1. **Central View**: Click the **Admit a patient** icon  on the **Patient List.**

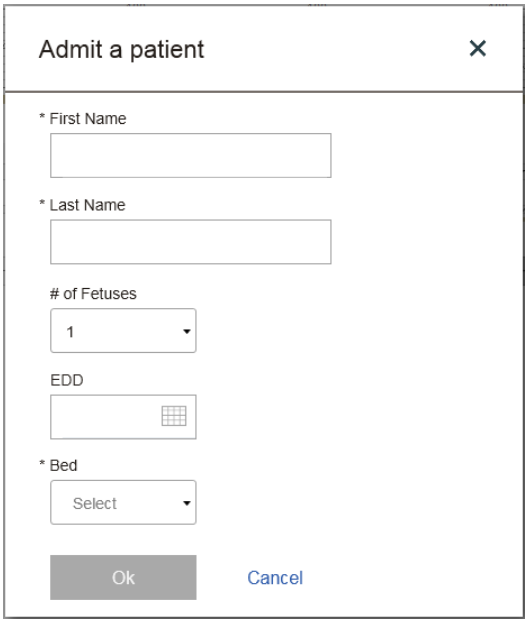
   Bedside View: If a patient is not admitted to the bed associated with the current workstation click on the **Toolbar Icon** to open the **Notification Dialog**, and then click on the **actions** menu and select the **Admit a patient** option.

   The **Admit a patient** dialog opens (see below).
2. Enter information into the required fields: First Name, Last Name, and Bed. These fields are identified by an asterisk. Afterwards the OK button is enabled.
3. To additionally enable calculation of the CheckList enter information into the optional fields as well: # of Fetuses, EDD.

Note: By default, the # of Fetuses is set to 1.

When used with systems other than PeriCALM Tracings, patient IDs like MRNs are managed internally by the application.

4. Click the OK button. A message shows up on the screen to indicate whether the patient was admitted successfully or not.



3.3.2. Change Patient Data

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

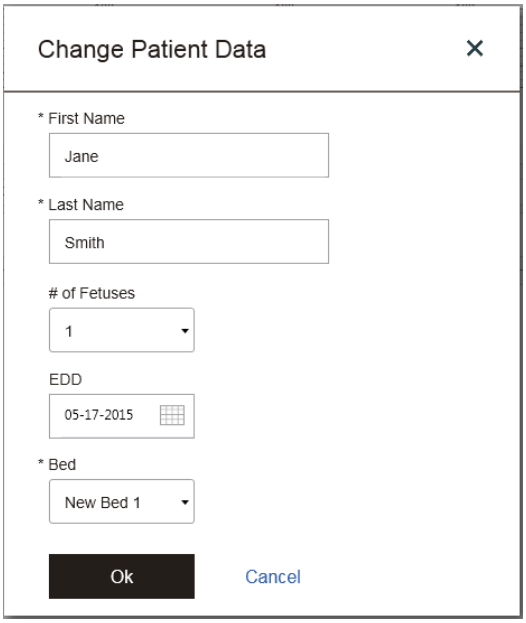
1. **Central View**: Hover over the patient of interest in the **Patient List**. A tooltip window with patient details opens. Click the icon from the tooltip window.

   Bedside View: Click on the **Toolbar Icon** to open the **Notification Dialog**, and then click on the **actions** menu and select the **Change patient data** option.

   The **Change patient data** dialog opens (see below).

2. Modify the information as desired. **First Name**, **Last Name**, **and Bed** are required fields.

3. Click **OK**. The data is saved.



3.3.3. Merge Patient Charts

It is possible to merge information from a manually admitted patient chart and an ADT chart. For example, a patient has been manually admitted as an emergency and is transmitting fetal tracings. The patient is then actually admitted with the proper demographic information at the admissions' office (ADT). This information must then be merged to the chart that is transmitting tracings to the application since the user cannot overwrite an ID number. The merge functionality completes this task and creates a new visit with the appropriate information and all the tracings intact. The merge function facilitates the administrative work of those involved in the maternity unit admissions.

To merge patient charts, follow the steps below.

1. **Central View**: Hover over the patient of interest in the **Patient List**. A tooltip window with patient details opens. Click the icon from the tooltip window.

   Bedside View: Click on the **Toolbar Icon** to open the **Notification Dialog**, and then click on the **actions** menu and select the **Merge patient charts** option.

   The **Merge patient charts** dialog opens (see below).

Note: The chart from which the dialog is opened appears on the left hand side of the dialog. If this chart is a manually admitted chart, only ADT charts will appear on the right hand side box for the user to choose from. If the chart on the left hand side is an ADT chart, only manually admitted charts will appear on the right hand side box for the user to choose from.

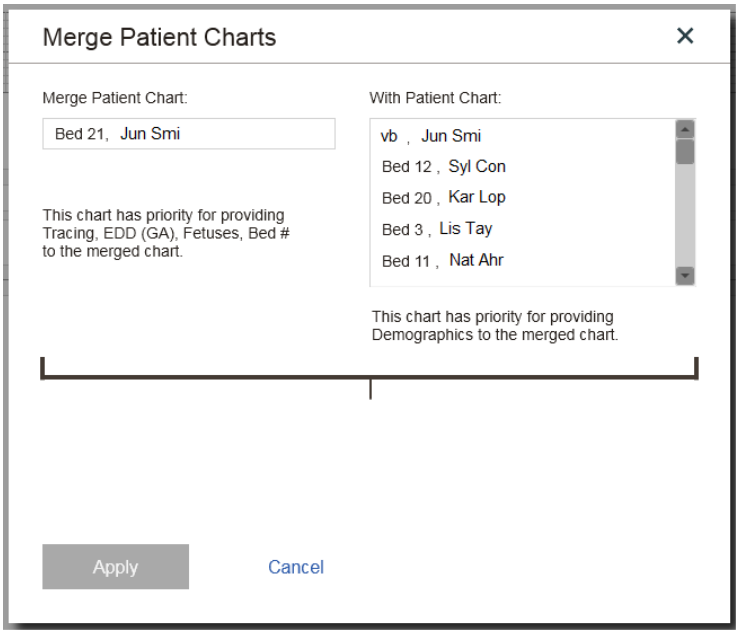
2. Select the chart that is to be merged with the current chart. Beneath each chart that is to be merged are listed the data elements that are to be provided by each of the charts to the merged chart.

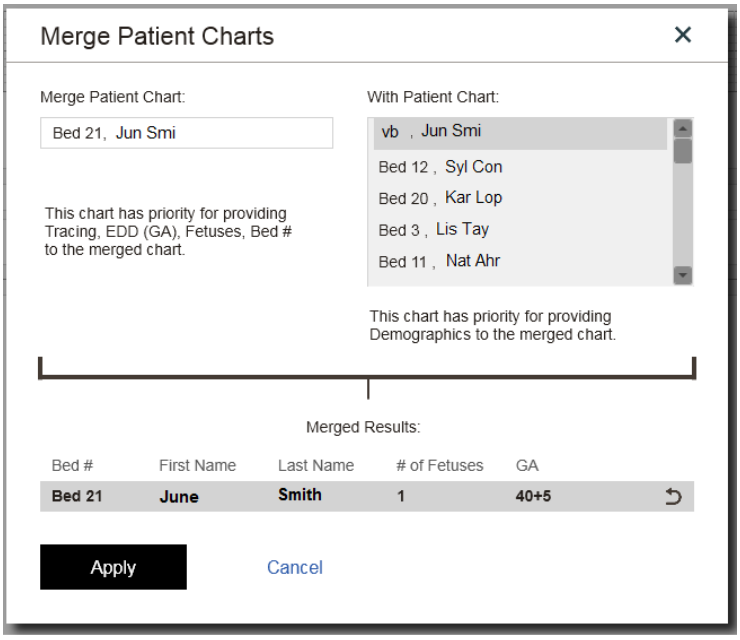
Note: The left hand side chart has priority in providing Tracing, EDD (GA), Fetuses, Bed # data to the merged chart. The ADT chart (regardless which side it is listed on)

has priority in providing Demographics data to the merged chart. In the event that the 2 charts have overlapping data or tracing segments, the chart that has priority provides the information to the merged chart.

3. Once a chart is selected the expected result of the merge action is displayed on the bottom of the dialog. If a different chart is to be selected instead, click the undo icon ⮌ and then repeat step #2.
4. If the expected result displayed is acceptable, click **Apply**. The application closes the dialog box and the patient data is merged into the new chart.

The charts that have been merged will be automatically discharged and deleted.





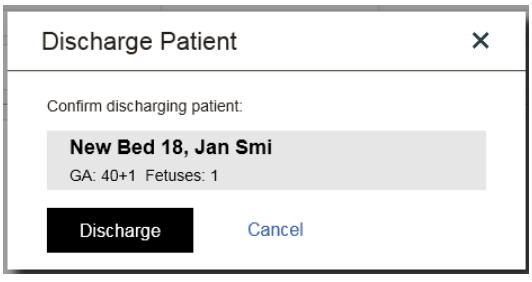
3.3.4. Patient Discharge

To discharge a patient, follow the steps below.

1. **Central View**: Hover over the patient of interest in the **Patient List**. A tooltip window with patient details opens. Click the icon from the tooltip window.
2. **Bedside View**: Click on the **Toolbar Icon** to open the **Notification Dialog**, and then click on the **actions** menu and select the **Discharge patient** option.

   The **Discharge patient** dialog opens (see below).

3. PeriCALM CheckList will ask you to confirm that you indeed want to discharge the given patient.
4. Click **Discharge**.



5. If the fetal monitor is still active and collecting data, a **Discharge Patient Confirmation** dialog box will open informing the user of this fact and asking the user to confirm the discharge action.
6. Patient is discharged.

4. Fetal Tracing Display

4.1. The PeriCALM CheckList Tracing View

PeriCALM CheckList displays the equivalent of a paper fetal strip on the computer monitor. The application shows this strip in two levels of detail – expanded and compressed.

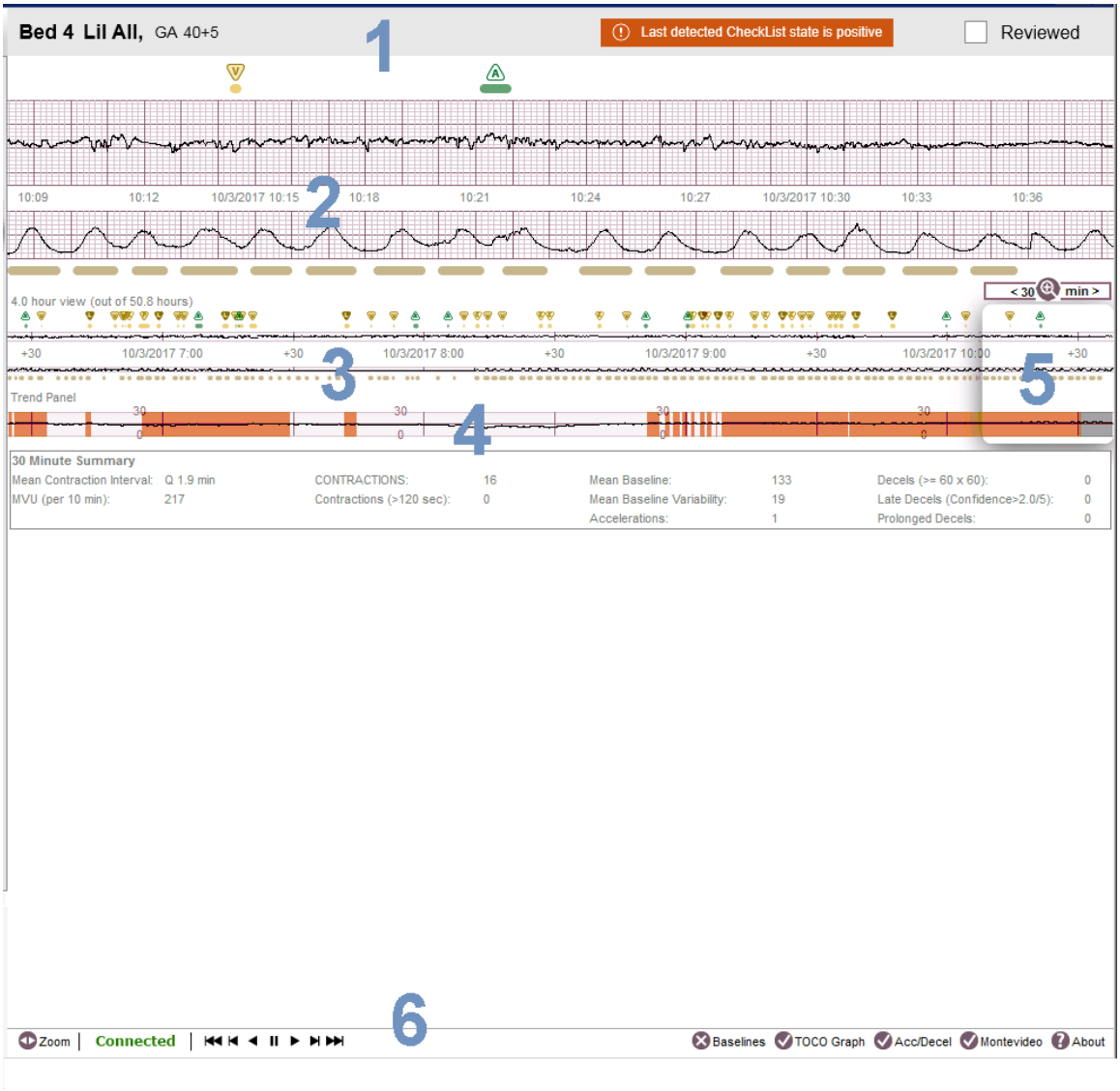
The following shows the main components of the **Tracing View**:

1. A **Patient Banner** displays information on the currently selected patient (including the bed number, first 3 letters of the first name, first 3 letters of the last name, gestational age and CheckList state).

Note: An optional function that may not be available depending on site configuration, includes a **Reviewed** checkbox on the **Patient Banner**, shown when a non-reviewed positive or past positive CheckList state exists. It enables users to manually mark a positive or past positive CheckList state as having been reviewed from the **PeriCALM CheckList – Central View** without the need to actively close the **Notification Dialog** at the patient's workstation.

2. An **Expanded Tracing View** shows 15 or 30 minutes worth of fetal tracings including events and contractions.
3. A **Compressed Tracing View** shows 4 or up to 12 hours of compressed fetal tracings including events and contractions.
4. 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.
5. 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.
6. The **Toolbar** is used to access many PeriCALM CheckList features.

Note: An optional function that may not be available depending on site configuration, includes an **Export Panel** above the **Toolbar**. It enables 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.



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.

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 CheckList also requires a minimum amount of space in order to display tracings in the correct aspect ratio, 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.

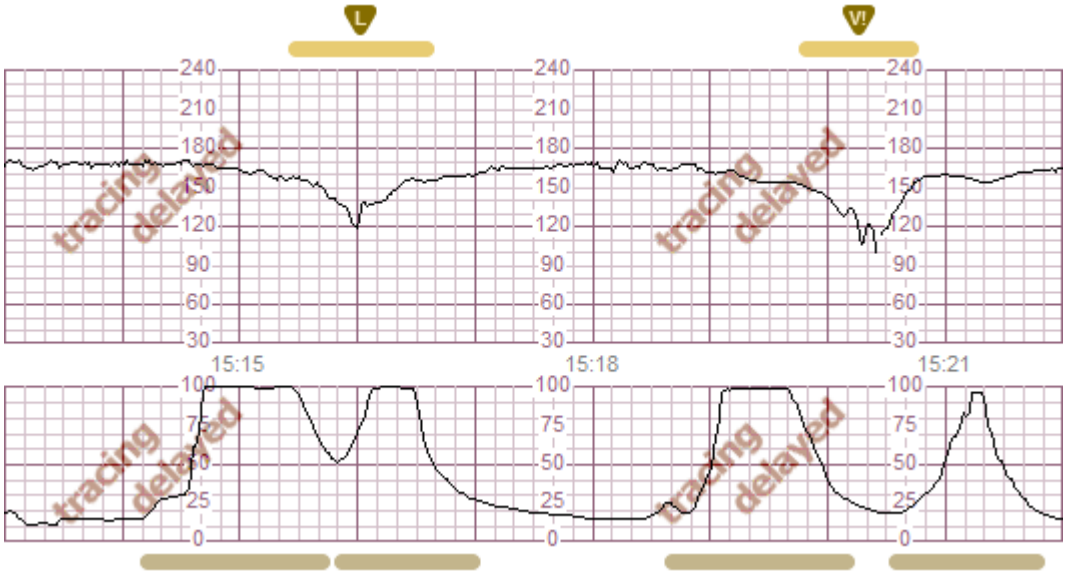
When a patient is selected, the most recent tracing for that patient is loaded on the screen. If less than 15 or 30 minutes of tracing exists for the selected patient (depending on Expanded view configuration), a portion of blank tracings will be visible on the left hand section of the Expanded View. 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 15 or 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 CheckList** detects a discrepancy of 10 seconds or more between the timestamp on the tracing received and the time according to the **PeriCALM CheckList 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 CheckList**; 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

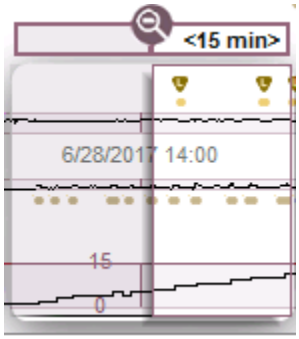
both tracings to the left or right. The scrolling will stop once the strip has been dragged all the way to either the beginning or the end of the tracing.

The tracing views can also be moved via the **Slider Window** (see 4.2.1 The Slider Window) and the **Navigation Buttons** (see 4.2.2 The Navigation Buttons).

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

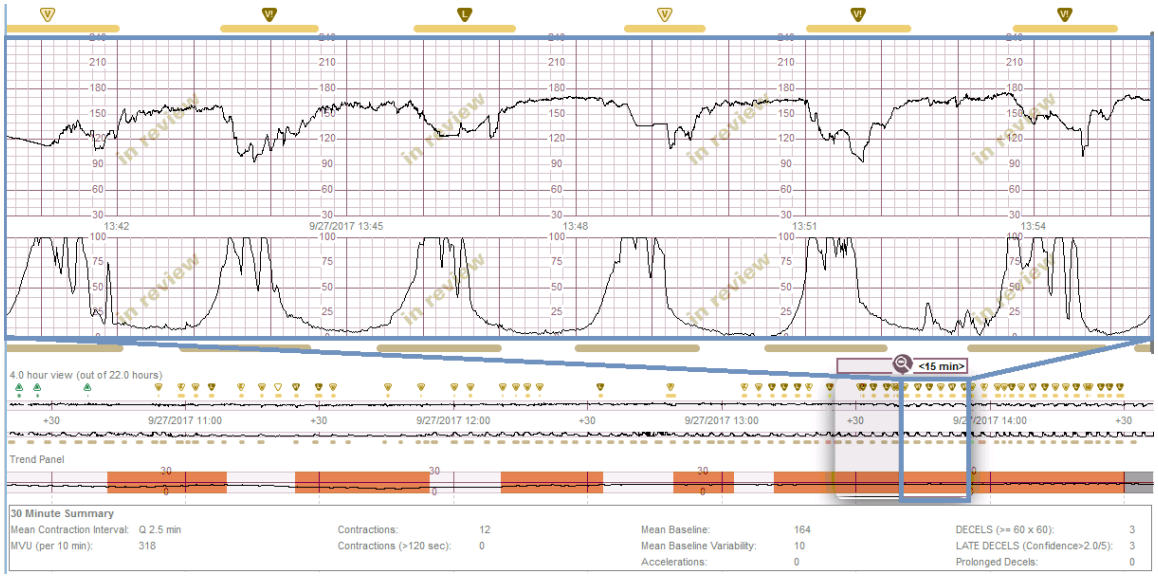
4.2.1. The Slider Window

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.

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



When set to show 15 minutes, the Expanded view adapts to display the matching 15 minutes 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 **Tracings** view and then reopening it changes the **Expanded View** display back to its default 15 minute setting.

4.2.2. 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 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** 

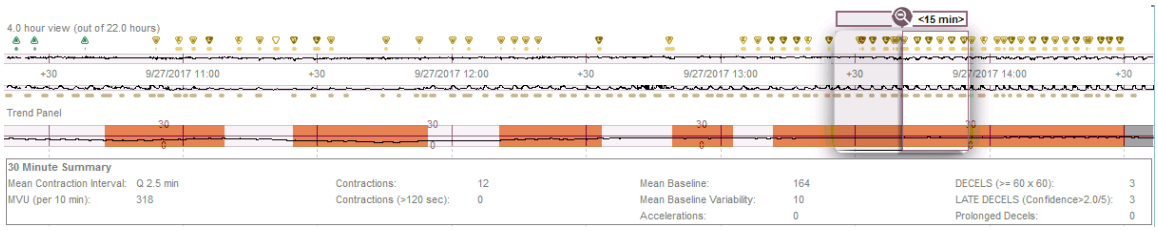
icon.

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.

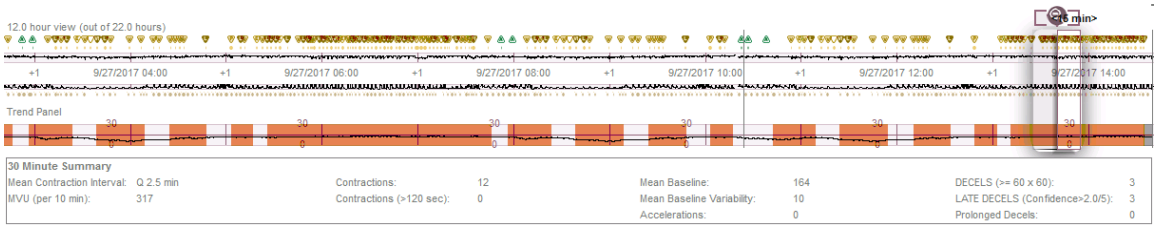
In the 12 hour view, tracings are compressed horizontally and are no longer in an aspect ratio that is equivalent to a paper strip.

The **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



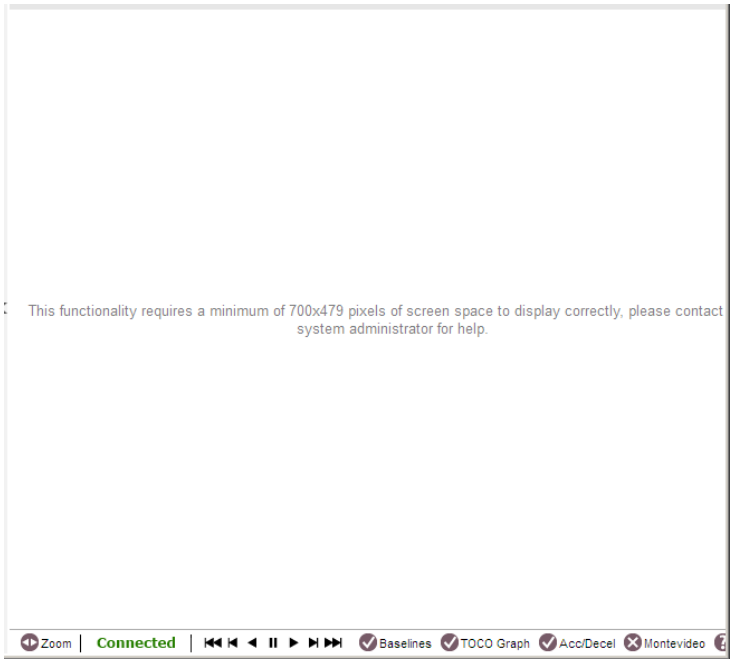
12 hour view



When less than 12 hours of tracings are available, the 12 hour view compresses all available tracings into the view as per the above example.

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

PeriCALM CheckList requires at least 700x479 of screen space in order to display tracings and events properly and not have any of its data truncated. Should **PeriCALM CheckList** detect that the available screen space is inadequate, the following screen will be displayed.

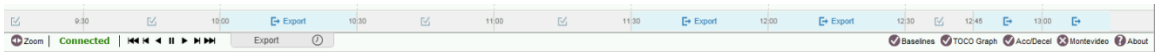


4.4. Export Panel

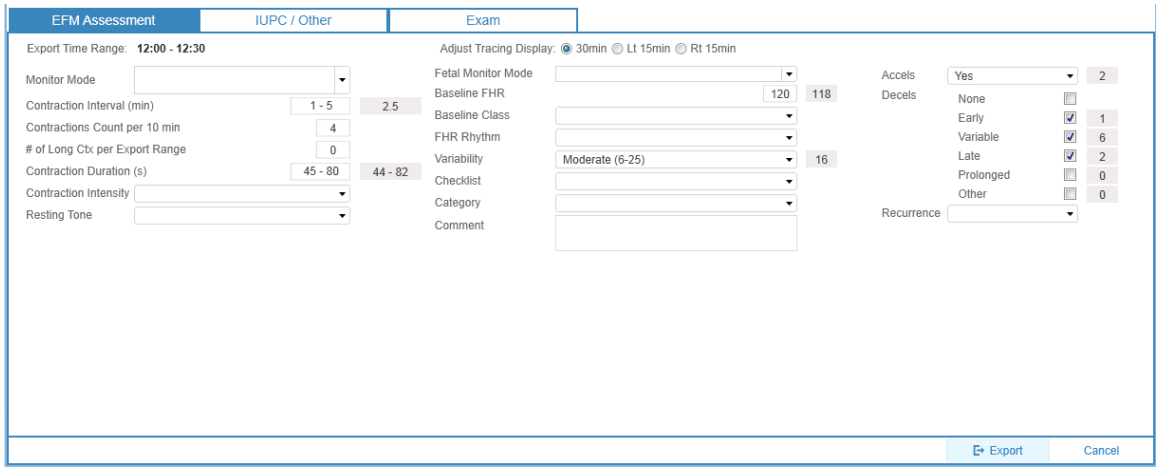
The **Export Panel** is an optional function that allows users to export 30 minute or 15 minute summaries of the Tracing View into the PeriGen Computer Assisted Labor Monitoring (PeriCALM Tracings) system, or to 3rd party Electronic Health Records. When activated, the Export Panel appears directly above the Toolbar and is shown if the Compressed Tracing View displays a 4 hour view.

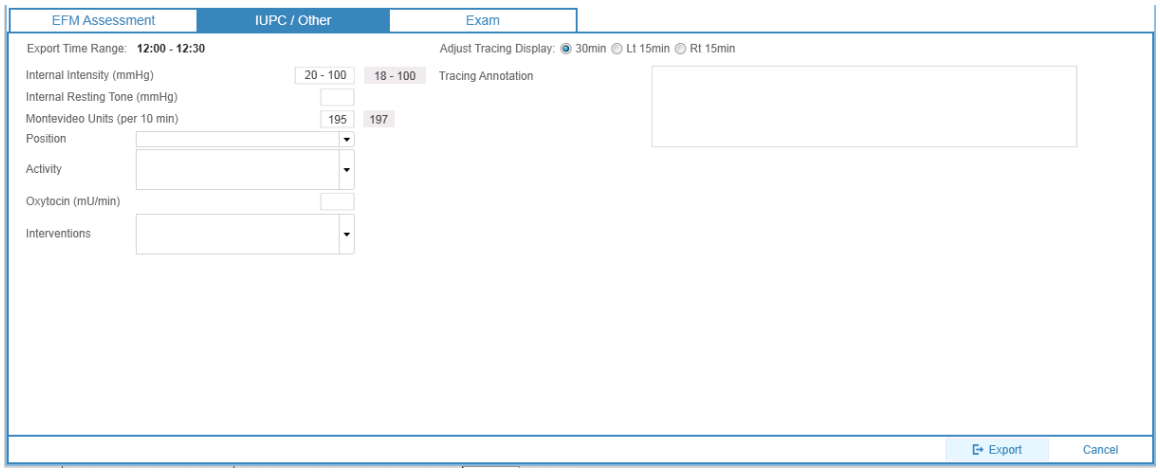
The **Export Panel** functionality is not available when **PeriCALM CheckList** is not used together with **PeriCALM Tracings**.

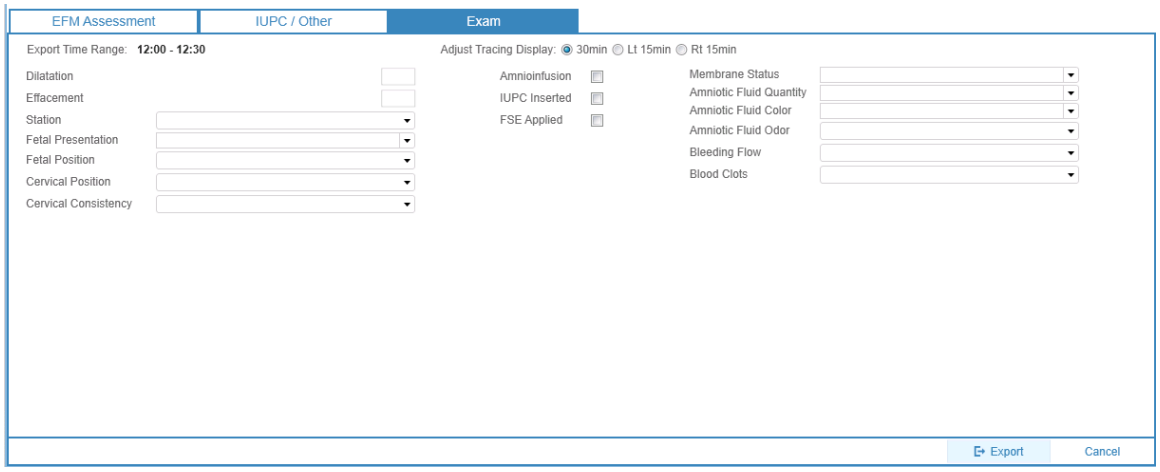
The Export Panel easily displays to the user which Tracing View sections were already exported and which sections were not yet exported by displaying different Export icons.



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 CheckList,** 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 in the Toolbar.

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

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

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

Some of the calculated read-only fields have editable values associated with them that are rounded to the nearest 0 or 5, and these editable values are those that are exported. 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.

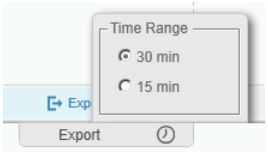
When the peak of an acceleration is located at the boundary of the 30 minute interval there may be a difference of 1 between the number of calculated Accelerations displayed on the Export dialog and the number of calculated Accelerations displayed in the Summary beneath the slider window.

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.

Note: A user name and password will be required in order to use the Export function.

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 CheckList™ Engine

PeriCALM CheckList is powered using the **PeriCALM CheckList** 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:

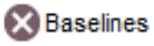
- Baseline and baseline variability
- Fetal heart rate features
- Uterine contractions
- Mean contraction interval
- Montevideo units

5.1. Baselines and Variability

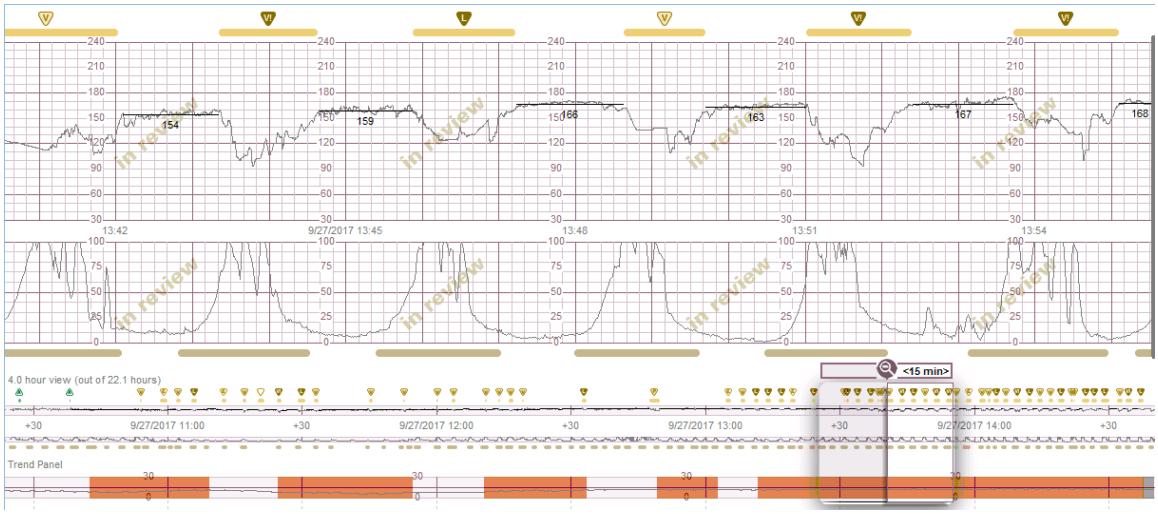
5.1.1. Baselines

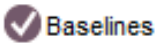
PeriCALM CheckList identifies baselines within the FHR tracing – the approximate mean fetal heart rate in relatively flat segments of the fetal tracing – and excludes accelerations, decelerations, periods of marked fetal heart rate variation and artifacts.

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

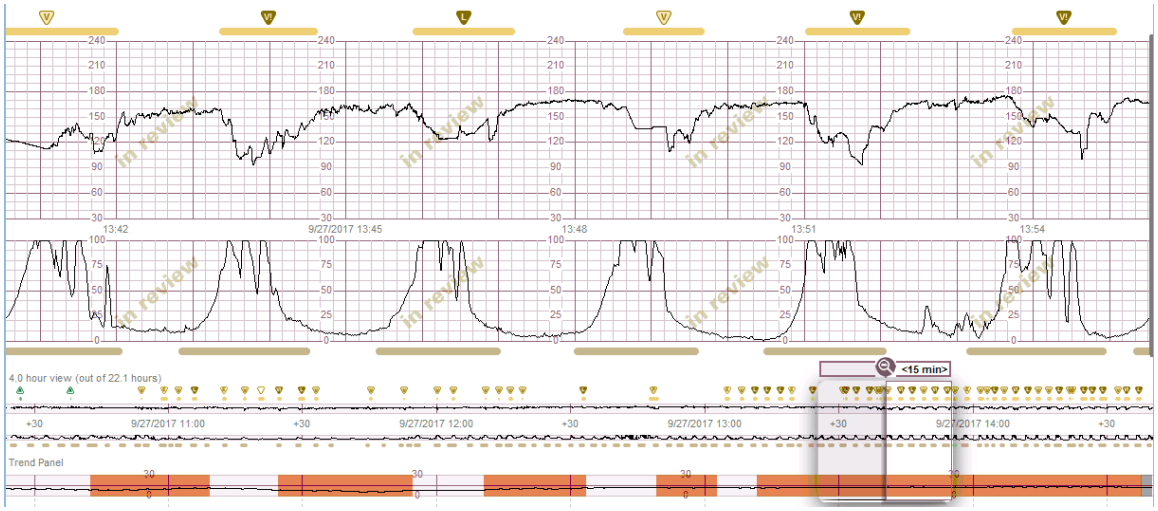
Baselines are not displayed by default. By clicking the **Baselines** icon 

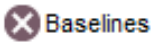
horizontal lines appear over the FHR tracing, indicating the different areas where baselines are identified. A number corresponding to the baseline fetal heart rate value (in beats per minute) will be displayed below the horizontal lines. **PeriCALM CheckList** does not label baselines as abnormally high (tachycardia) or low (bradycardia).



Clicking the **Baselines** icon 

a second time hides the baselines.

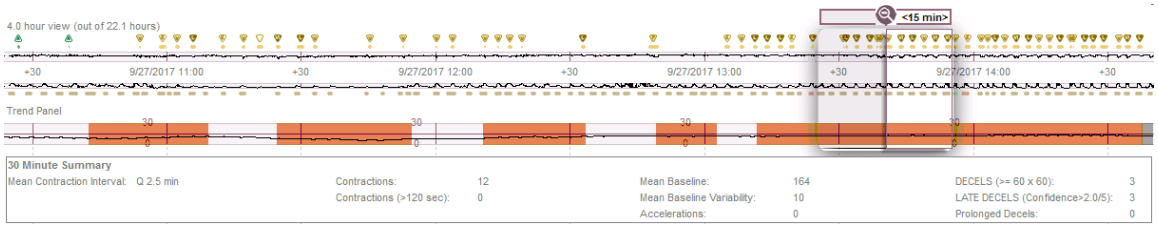


Clicking the **Baselines** icon 

a second time displays the baselines once again.

5.1.2. Variability

Variability refers to a measurement of the variation in fetal heart rate values in a baseline segment. **PeriCALM CheckList** 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.

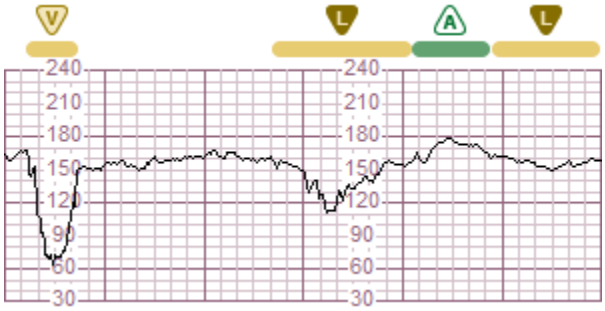


Using the baselines detected, **PeriCALM CheckList** calculates **Mean Baseline** and **Mean Baseline Variability** over a 30-minute window. These values are displayed in the **30 Minute Summary** box beneath the **Slider Window** (shown above). **Mean Baseline** and **Mean Baseline Variability** are calculated in real-time as new tracing becomes available. Additionally, moving the **Slider Window** over existing sections of tracing updates these two calculations dynamically. When values exceed the **PeriCALM CheckList** 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 CheckList** are labeled according to standard nomenclature[1].

When **PeriCALM CheckList** 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 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 CheckList** 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 CheckList** 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 5.2.7 Confirming a Non-Interpretable Event 5.2.7and 5.2.6 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 CheckList** does not sub-classify accelerations according to length.

Using the accelerations detected, **PeriCALM CheckList** 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** criteria for an FHR feature, its name is displayed in all capital letters.

[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).

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

5.2.3. Decelerations

In **PeriCALM CheckList**, 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 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 CheckList** 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**.

Using the decelerations detected, **PeriCALM CheckList** 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** 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 CheckList**, as well as the basic definitions. Because of the ambiguities in the NICHD definitions as described above, **PeriCALM CheckList** 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 CheckList**, 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 CheckList recognizes that an event with the shape of a deceleration has occurred, but portions of the tracing are missing, therefore **PeriCALM CheckList** will not give a definitive label unless the event is confirmed by a user.

Non-Associated Deceleration

PeriCALM CheckList recognizes that a deceleration with gradual onset has occurred, but there is no associated contraction; therefore **PeriCALM CheckList** 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]

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:

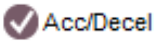
- **Loss of Variability** within the deceleration. Note this does not refer to baseline variability.
- Rule of **60's** (passes 2 of 3 following criteria: 60 seconds in duration, down 60 beats from the baseline; and/or nadir of deceleration is 60 beats/min)[2,3,4,5]

Struck-out Event

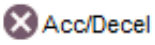
This symbol will be displayed for both acceleration and deceleration events that have been struck out manually.

5.2.4. Displaying Events

PeriCALM CheckList 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 

, events are currently displayed and clicking the button will hide events.

When the button displays an "**X**" 

, events are currently hidden and clicking the button will show events.

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

[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

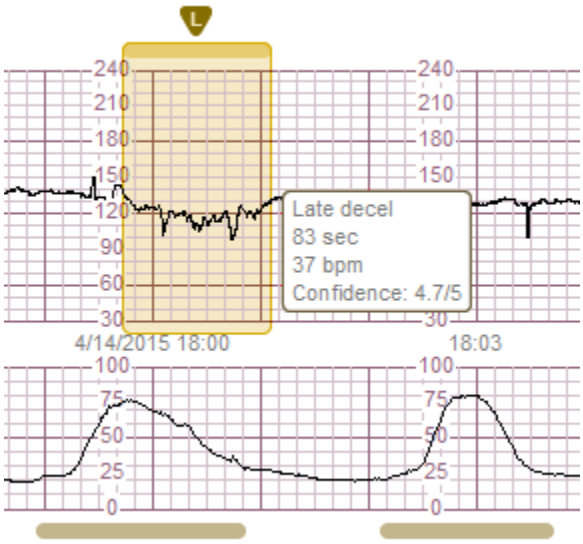
[3] Practice bulletin no. 116: Management of intrapartum fetal heart rate tracings. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2010 Nov;116(5):1232-40

[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

[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

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:

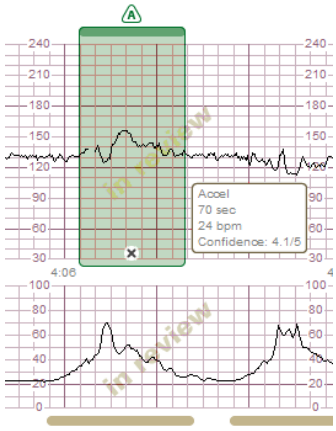
- **The type of event and any specified features** (see 5.2.2 Accelerations, 5.2.3 Decelerations).
- **The duration of the event**: The time (in seconds) from the beginning to the end of the event.
- **The depth or height of the event**: The increase or decrease of the heart rate (in bpm) during the event.
- **The confidence of detection**: The degree to which the **PeriCALM CheckList** detection engine is confident that the event detected is indeed an actual event. This value is expressed as a score out of 5 points, where 0 indicates that **PeriCALM CheckList** is only “somewhat confident” and 5 indicates that it is “very confident”.

5.2.6. Striking Out an Event

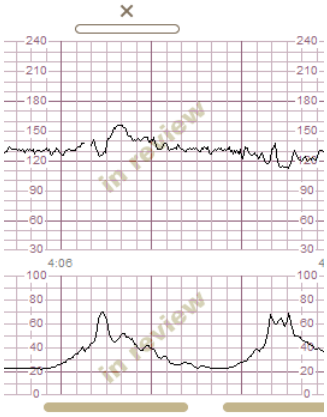
In some cases, a clinician may not agree with an event that **PeriCALM CheckList** detected. In such an instance, it is possible for the clinician to strikeout a detected event.

A user name and password will be required upon selecting to strike out an event.

1. Click on or hover over 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).



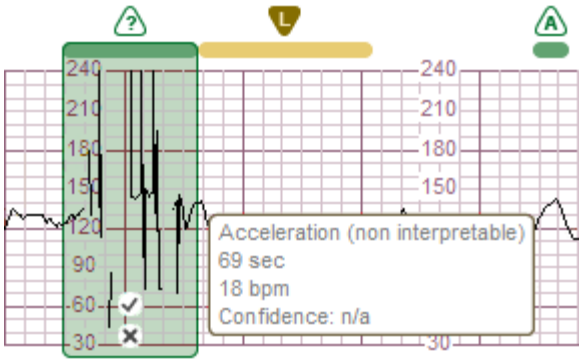
5.2.7. Confirming a Non-Interpretable Event

When **PeriCALM CheckList** identifies a potential event, but portions of the tracing are missing, the event is classified as non-interpretable and a **Non-interpretable Deceleration** or a **Non-interpretable Acceleration** pictograph is displayed, as applicable (see 5.2.1 Signal Quality for additional information on non-interpretable events).

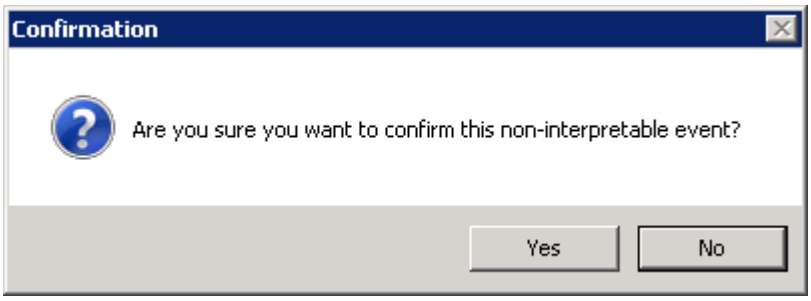
If the clinician is confident that an event has indeed occurred over the given area of tracing, the non-interpretable event can be confirmed.

A user name and password will be required upon selecting to confirm an event.

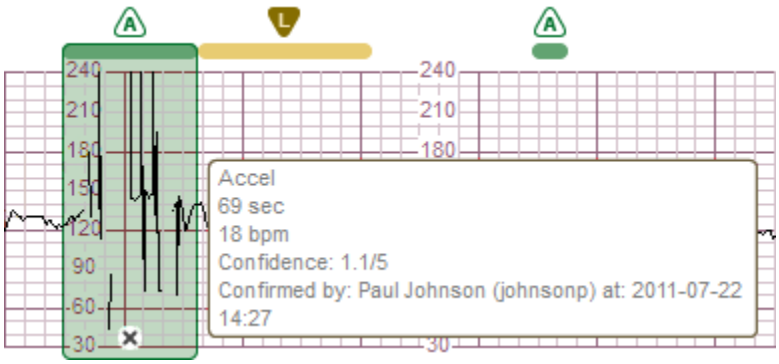
1. Select the Non-Interpretable event of interest by clicking on it or hovering over it.



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.



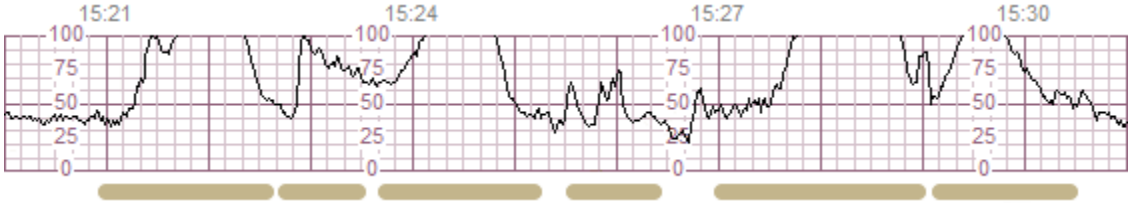
2. Click **OK**. The "?" event pictograph is replaced by the applicable event type pictograph.



5.3. Contractions

5.3.1. Contraction Markers

PeriCALM CheckList 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.



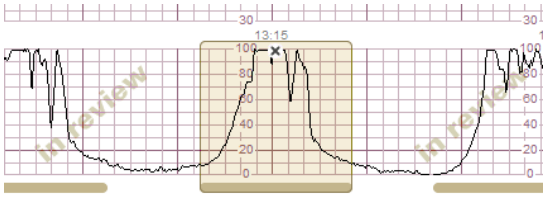
Using the contractions detected, **PeriCALM CheckList** dynamically displays beneath the 30 minute **Slider Window** the total number of contractions counted over a 30-minute window and the number of contractions whose duration >120 sec counted over the same period of time. When values exceed the PeriCALM CheckList criteria for an FHR feature, its name is displayed in all capital letters.

5.3.2. Striking Out a Detected Contraction

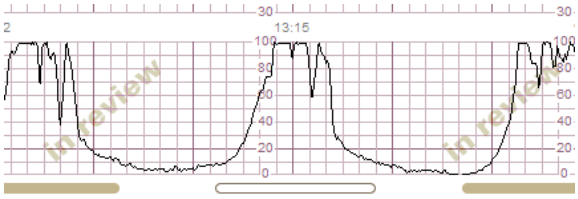
In some cases, a clinician may not agree with a contraction that **PeriCALM CheckList** detected. In such an instance, it is possible for the clinician to strike-out a detected contraction.

A user name and password will be required upon selecting to strike out a contraction.

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



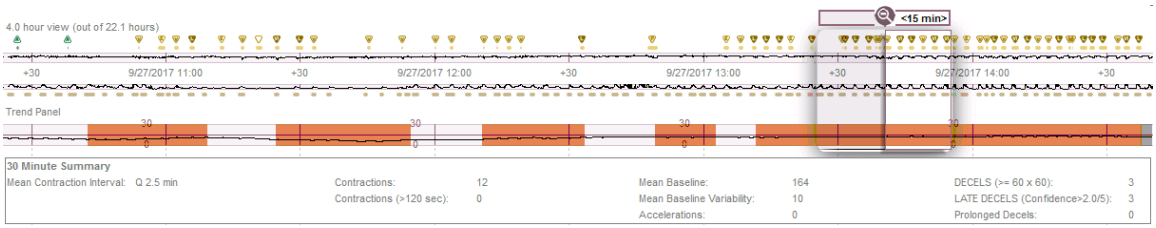
2. Click on the "**X**" button located at the top of the highlighted area. A message appears, warning that a contraction is about to be struck-out.
3. Click OK. The contraction marker turns from beige to white, indicating that the contraction has been struck out (see below).



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

5.3.3. Mean Contraction Interval

Using the contractions detected, **PeriCALM CheckList** 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**.



5.4. PeriCALM CheckList Trend Panel

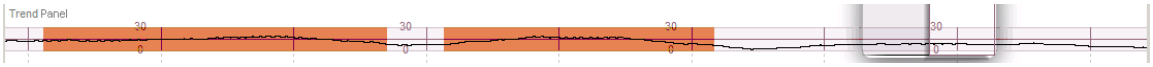
In addition to the two fetal strip tracing views, **PeriCALM CheckList** displays a **PeriCALM CheckList Trend Panel**, which is a 4 hour (or up to 12 hours) graph that plots the CheckList algorithm results over time. By clicking the **TOCO Graph** button TOCO Graph , this graph can be displayed in either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

In the **Simple** view, a site-defined color coded system is employed to indicate the 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 Pattern 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

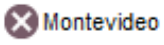
Default Parameters		
Rule over past 30 minutes	**Threshold***	**Color Code**
Mean Baseline Variability (and no 15X15 accelerations)	< 6 bpm	
Late Decelerations (greater than a minimal confidence factor)	>=2 (confidence >70%, i.e. >2/5)	
Any Decelerations (that are not late) 60secX60bpm below baseline (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		

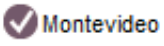
* These threshold values are provided as an example of a typical or commonly accepted configuration. The actual threshold values to be used will be configured by your site in accordance with hospital policies.

During initial 30 minutes, once Decelerations or Contractions criteria have been exceeded, the PeriCALM CheckList 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 **PeriCALM CheckList Trend Panel** are accessible from the **Notification Dialog** through the **?** icon. Click on the **?** icon 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.

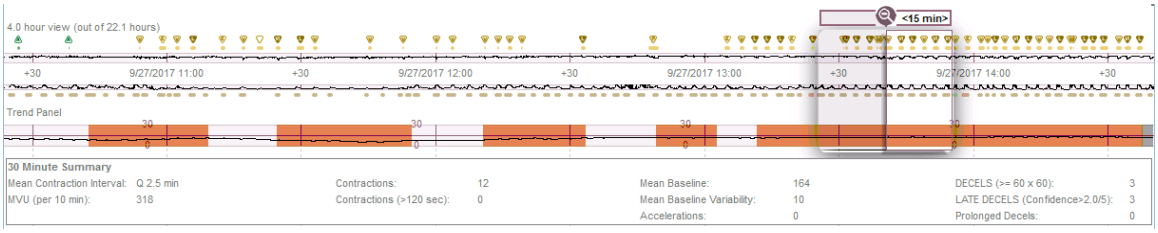
5.5. Montevideo Units

PeriCALM CheckList also calculates **Montevideo Units**. They can be displayed by clicking the icon 

in the toolbar. This turns the "**X**" in the icon into a checkmark 

and **Montevideo Units** appear in the **30 Minute Summary** box beneath the **Slider Window**. Additionally, for users 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 CheckList Tracing screen is subsequently opened, until a user unchecks it. Such changes will not be reflected, though, on other workstations in which the PeriCALM CheckList Tracing 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 CheckList 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. PeriCALM CheckList State

The PeriCALM CheckList State, that is presented to the users through color coding and the use of icons, as well as through the use of pop up notification, enables the system to easily communicate to clinicians that one or more EFM features persistently exceed specified numeric criteria without directly viewing the **PeriCALM CheckList Tracing View**.

Clients can configure both the EFM features' numeric criteria (see 5.4 PeriCALM CheckList Trend Panel) and the predefined periods of time defining persistence for positive, negative, or unknown PeriCALM CheckList states.

6.1. Possible PeriCALM CheckList States

6.1.1. Positive CheckList

The PeriCALM CheckList State is calculated as Positive when the value measured over a 30 minute window for one or more EFM features persistently exceeds the PeriCALM CheckList Trend panel criteria beyond a predefined period of time called positive persistence.

Clients can configure the length of the predefined period of positive persistence time, as well as the percentage of that period in which values should exceed the PeriCALM CheckList Trend panel criteria in order to generate a CheckList state change.

When the CheckList State changes to Positive, the **Notification Dialog** automatically pops up on the **Bedside View**, and a  icon appears for the patient on the **Patient List**. Once the patient's **Tracing View** is reviewed at bedside and then closed, the Positive CheckList event is considered reviewed.

6.1.2. Negative CheckList

The PeriCALM CheckList State is calculated as Negative when none of the values measured over a 30 minute window for all EFM features exceed the institutional criteria persistently beyond a predefined period of time called negative persistence, and there is no non-reviewed Positive CheckList event.

Clients can configure the length of the predefined period of negative persistence time, as well as the percentage of that period in which values should not exceed the PeriCALM CheckList Trend panel criteria in order to generate a CheckList state change.

6.1.3. Past Positive CheckList

The PeriCALM CheckList State is calculated as Past Positive when while an automatically opened **Notification Dialog** remains open (indicating that it was not yet reviewed by a user) none of the values measured over a 30 minute window for all EFM features exceed the institutional criteria persistently beyond a predefined period of time called negative persistence.

When the CheckList state changes to Past Positive, the **Notification Dialog** continues to show the original 30 minute summary of the positive CheckList state, and a  icon appears for the patient on the Patient List.

6.1.4. Not Enough Data in Last 30 min

The PeriCALM CheckList State is calculated as 'Unknown – Not enough data in last 30 min' when the collected tracing data available for calculation is less than a predefined percentage (default set at 75%) of a 30 minute window, and none of the values for Decelerations or Contractions that are measured persistently exceed the PeriCALM CheckList Trend panel criteria beyond the predefined period of positive persistence time. Reasons for such circumstances can either be that tracing was just recently initiated, or as a result of loss of signal during subsequent tracing.

Clients can configure the minimal percentage of available signal required within a 30 minute window in order to define a tracing legible for PeriCALM CheckList calculation.

6.1.5. GA/# of Fetuses not documented

The PeriCALM CheckList State is calculated as 'Unknown – GA/# of Fetuses not documented' when patient's Gestational Age or **#** of Fetuses are not known.

6.1.6. CheckList not enabled for GA/# of fetuses

The PeriCALM CheckList State is calculated as 'Unknown – CheckList not enabled for GA/# of fetuses' when patient's Gestational Age is less than 36 weeks or # of Fetuses is greater than 1.

6.1.7. Inactive

The PeriCALM CheckList State is calculated as Inactive when the monitor is turned off or when there are connection problems.

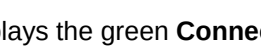
7. System Connection Status

On the left hand side of the toolbar, to the right of the **Zoom** icon, **PeriCALM CheckList** displays its current connection 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 connection 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.

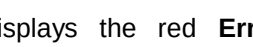
7.1. Possible System Connection States

7.1.1. Connected State

PeriCALM CheckList displays the green **Connected** state 

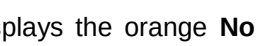
when the application has no issues to report.

7.1.2. Error State

PeriCALM CheckList displays the red **Error** state 

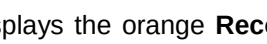
when the application has connection issues to report. When this state occurs, the **PeriCALM CheckList** screen is blank and patient data is not available. Clicking on the icon will display an informational message detailing the cause of this state.

7.1.3. No Data State

PeriCALM CheckList displays the orange **No Data** state 

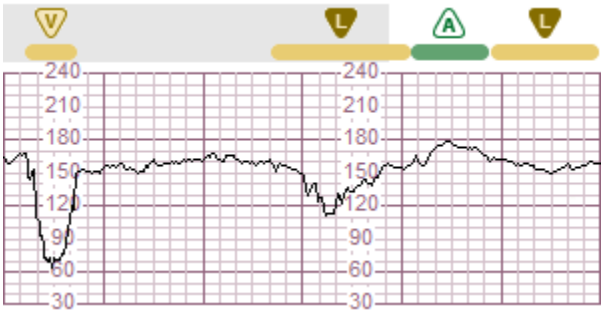
when the application cannot access the patient's episode of tracing. When this state occurs, the **PeriCALM CheckList** screen is blank and patient data is not available. Clicking on the icon will display an informational message detailing the cause of this state.

7.1.4. Recovery State

PeriCALM CheckList displays the orange **Recovery** state 

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 CheckList** down time. Clicking on the icon will display an informational message detailing the cause of this state. Once **PeriCALM CheckList** 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 CheckList** 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.

Upon recovery following down time that exceeds a configurable time period (default set at 15 minutes) the system will automatically assign all non-reviewed positive events that started earlier than the configurable time period as system reviewed. These events will no longer affect the CheckList state of the patient and will no longer be listed on the notification dialog or tooltip window. They will also be considered differently than events reviewed by a user in the statistical reports summarizing user response to the PeriCALM CheckList.

8. Using PeriCALM CheckList

8.1. Important Notes

- None of the information generated within **PeriCALM CheckList** will update the patient record in the hosting clinical system. **PeriCALM CheckList** only reads information from the hosting system.
- By selecting the hosting system's configured link or menu item, **PeriCALM CheckList** will be launched for the currently selected patient and will use the currently logged-in user credentials to track changes.
- **PeriCALM CheckList** 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 CheckList**.

- 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.
- This version of **PeriCALM CheckList** 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 CheckList** data, i.e., no events or contractions will be struck out or confirmed.

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

Appendix: Development and Testing

Developing the CheckList 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 CheckList** 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 CheckList** is evaluated to verify that good correlation is maintained between measured Baseline and visual estimates.

Baseline Variability

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

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[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