GE Healthcare

Technical Publication

Centricity Perinatal Analytics

Version 2.00

User Guide

PeriGen
Specialists in OB Risk Reduction

Centricity Perinatal does not replace clinical observation and evaluation of the patient at regular intervals, by a qualified care provider, who will make diagnoses and decide on treatments or interventions. Features of the Centricity Perinatal system are intended to support clinical decision making and should be used in combination with other clinical inputs, such as real time patient observation and information contained within other systems or recording tools. Not intended to be used as a primary monitoring device.

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Centricity Perinatal – Analytics is a private label version of PeriGen Inc.'s **PeriCALM® Patterns** product.

Centricity Perinatal – Analytics 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.

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

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

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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GE Healthcare, a leader in perinatal solutions, and PeriGen, Inc. have united to build upon the decision support and monitoring capabilities of GE's top rated Centricity Perinatal suite. PeriGen PeriCALM® Patterns is embedded in Centricity Perinatal, a solution for clinicians seeking to help improve the quality of care delivered.

About GE Healthcare

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care.

Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our "healthymagination" vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access and improving quality around the world. Headquartered in the United Kingdom, GE Healthcare is a unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employees are committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our website at www.gehealthcare.com.

About PeriGen, Inc.

PeriGen, Inc. is a technology enabled professional services company specializing in risk reduction and clinical quality improvement in Obstetrics and is the only OB-specific risk reduction company to provide solutions which generate quantifiable clinical value. Singularly focused on reducing risk and improving financial performance, PeriGen's advanced clinical decision support and fetal monitoring solutions are installed in hospitals across North America.

A pioneer in advanced clinical support, PeriGen provides innovative solutions and a full suite of complementary professional and consulting services that reduce risk and improve clinical outcomes. For more information about PeriGen, Inc., visit our website at www.perigen.com.

2.1. Versions

The Centricity Perinatal – Analytics User Guide is provided

- as a hard copy,
- as a PDF (Portable Document Format) file available in the Centricity Perinatal – Analytics server installation folder, and
- as an online help system available from within Centricity Perinatal.

2.2. Conventions

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

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

2.3. Additional Documentation

The Centricity Perinatal – Analytics User Guide provides information that is related to the Analytics application of Centricity Perinatal. For additional information related to other GE Healthcare products, please visit www.gehealthcare.com.

3. Overview

The Analytics module of Centricity Perinatal 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, the Analytics module detects and analyzes fetal heart rate accelerations, late, early, variable and prolonged decelerations, as well as uterine contractions, and displays these as colored markings. The analytics module 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, Analytics module can calculate baseline, baseline variability, Montevideo units and contraction interval averages in a sliding window, as well as warn against persistence in uterine tachysystole, as defined by the institution.

The Analytics module of Centricity Perinatal 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

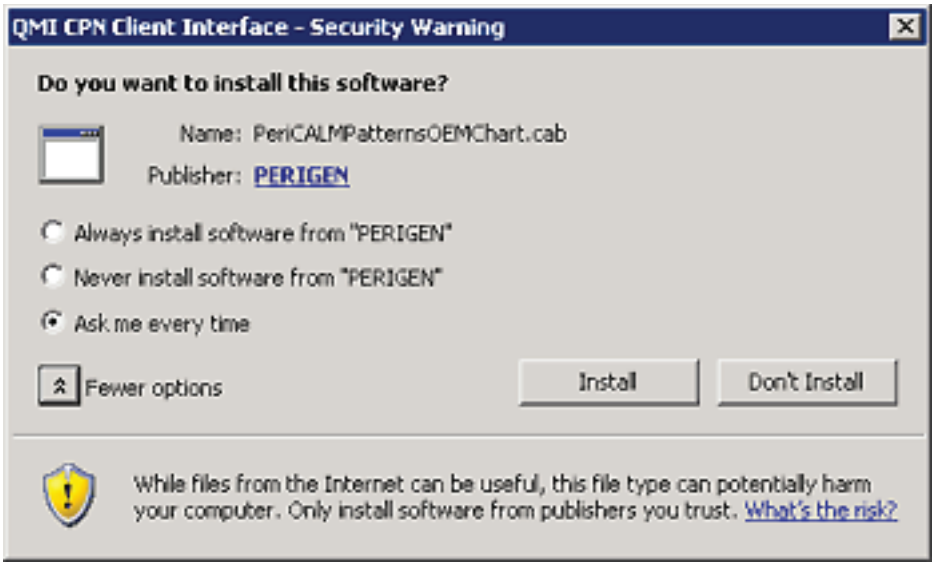
- Represents fetal heart rate events and uterine contractions in a visually intuitive manner.
- Calculates several important clinical metrics in real-time.
- Displays 17-minute, 2-hour and 12-hour views of tracings.
- Brings standard definitions such as NICHD guidelines to the bedside.
- Displays the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

WARNING: Evaluation of FHR during labor and patient management decisions should not be based solely on the Analytics module of Centricity Perinatal annotations.

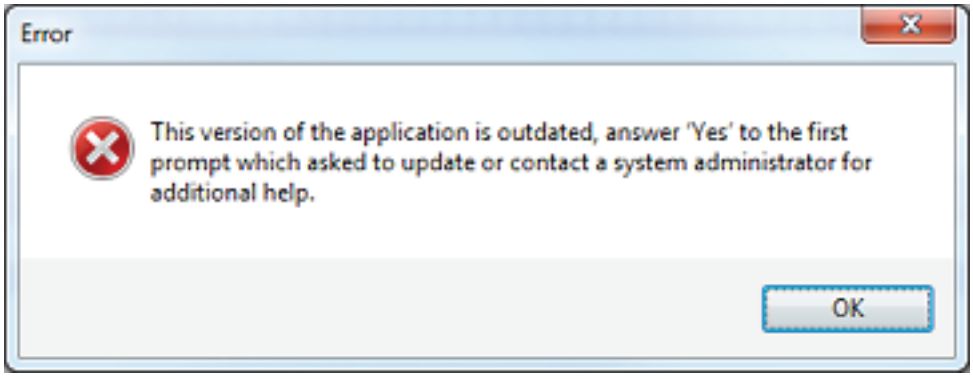
The Analytics module of Centricity Perinatal is intended to be used as an adjunct to a fetal surveillance system that provides standard alerts when fetal heart rates are out of bounds.

3.1. Initial Installation and Updates

Attempting to use the Analytics module of Centricity Perinatal for the first time or attempting to use an outdated version of the Analytics module will yield a prompt asking to manually install the client software.



Refusal of the update prompt will yield the following message and the Analytics module of Centricity Perinatal will not be available.



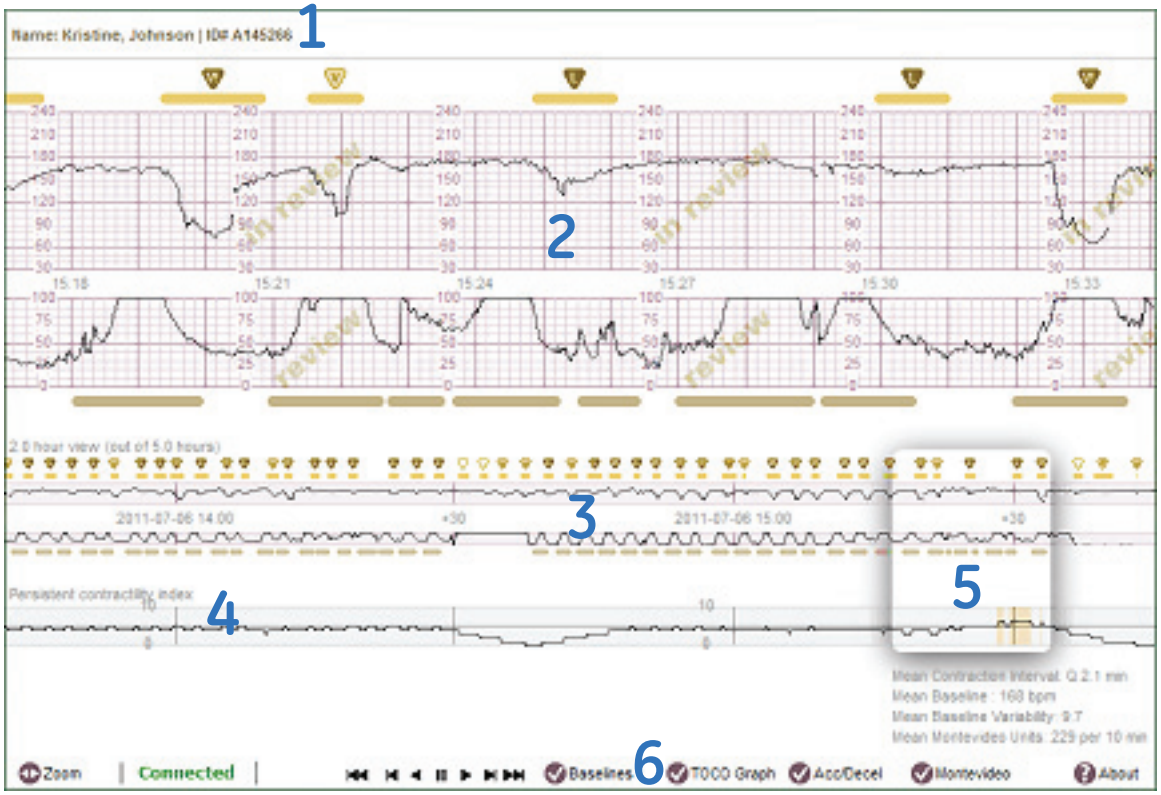
A subsequent attempt to view a patient in the Analytics module of Centricity Perinatal will yield the message asking to upgrade again.

3.2. The Analytics Module Interface

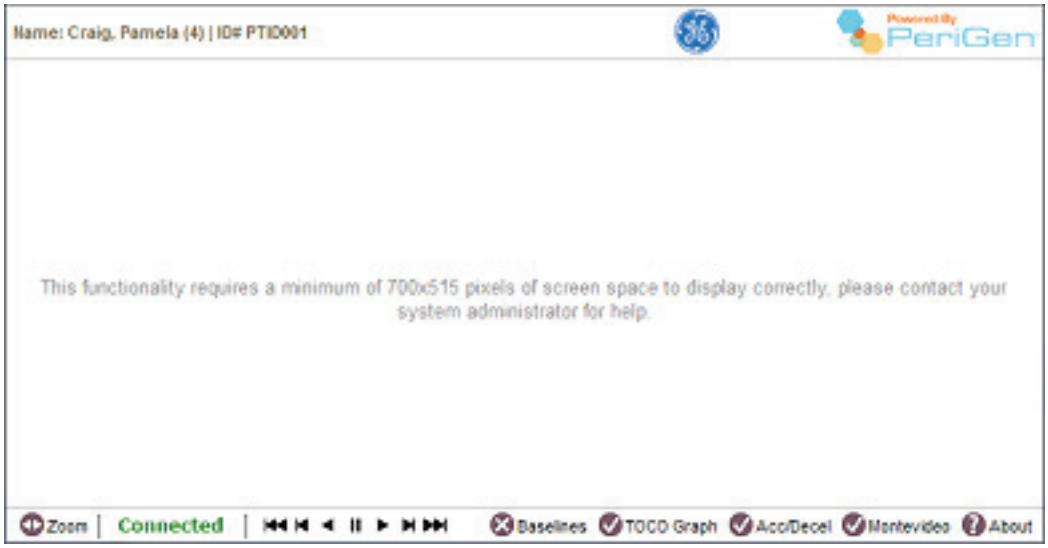
The following shows the main components of the Analytics module interface.

1. The **Patient Banner** displays information on the currently selected patient.
2. The **Expanded Tracing View** shows 17-minutes worth of fetal tracings including events and contractions.
3. The **Compressed Tracing View** shows 2 or up to 12-hours of compressed fetal tracings including events and contractions.
4. The **Persistent Contractility Index** indicates the patient's level of contractility, and indicates when it exceeds user-defined limits..
5. The **Slider Window** allows a specific 17-minute section of tracing to be viewed in the Expanded Tracing View.
6. The **Toolbar** is used to access many features of the Analytics module of Centricity Perinatal and display any messages about the status of the application.

The screen contents may vary according to the installation setup and configuration at a particular facility.

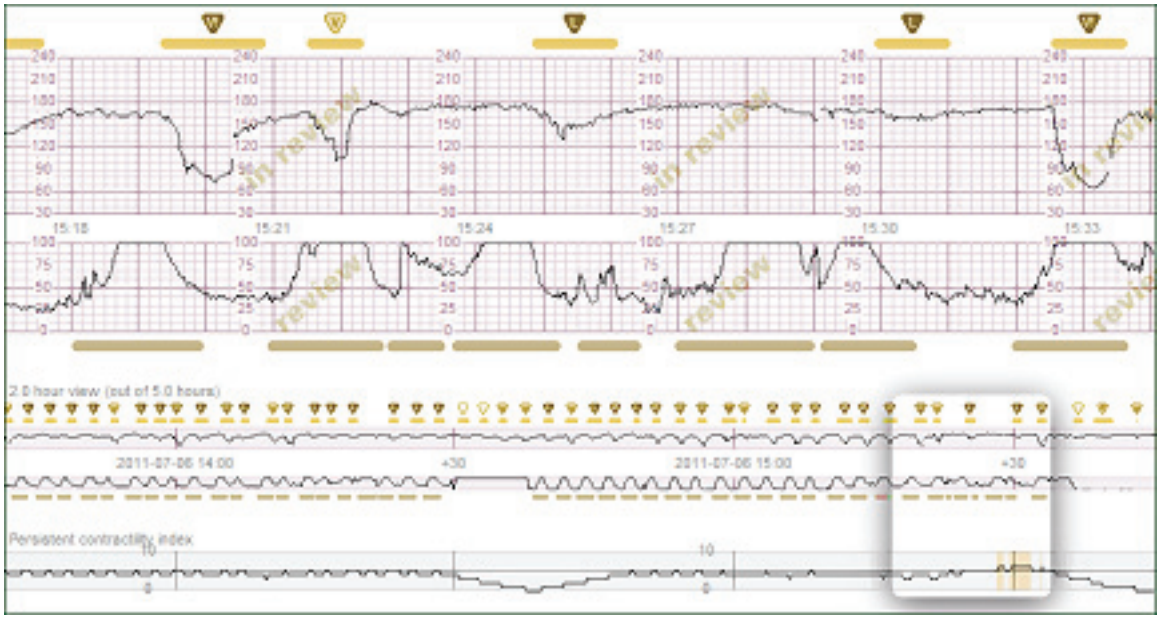


The Analytics module of Centricity Perinatal requires at least 700x515 of screen space in order to display tracings and events properly and not have any of its data truncated. Should the Analytics module of Centricity Perinatal detect that the screen space that it has available is inadequate; the following screen will be displayed.



4.1. The Expanded and Compressed Tracing Views

The Analytics module of Centricity Perinatal displays the equivalent of a paper fetal strip on the computer monitor. The application shows this strip in two levels of detail: an **Expanded View**, which shows 17-minutes of tracing, and a **Compressed View**, which shows 2-hours of tracing. Both the 17-minute **Expanded View** and 2-hour **Compressed View** are displayed in the same aspect ratio as seen on a typical paper strip.



To ensure that the aspect ratio of the tracings on the computer monitor corresponds to the aspect ratio of an actual paper strip, please ensure that your computer monitor is set to its native resolution.

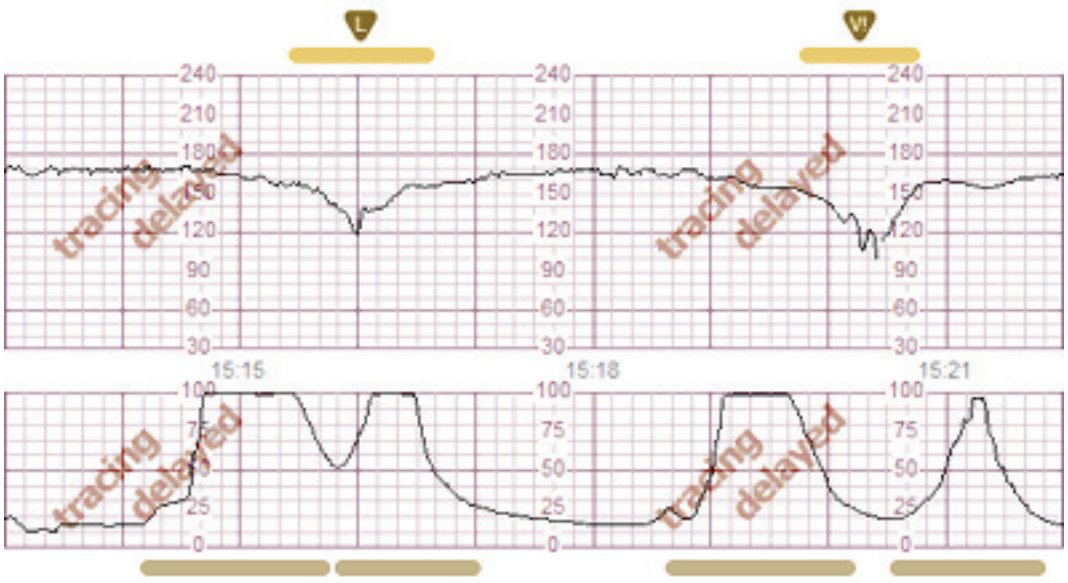
The Analytics module of Centricity Perinatal also requires a minimum amount of space in order to display tracings. Should the application not have the space it requires, an informational message will appear and no tracings will be visible. Should this occur, contact a system administrator.

When a patient is selected, the most recent tracing for that patient is loaded on the screen. If less than 17-minutes of tracing exists for the selected patient, a portion of blank tracings will be visible on the left hand section of the **Expanded View**. Likewise, if less than 2-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 17-minutes will be shown. Additionally, the text "**in review**" will appear as a watermark behind the tracings. If the fetal monitor is turned back on for this patient, both the unplugged icon and the watermark will disappear and live tracings will be shown.

When the Analytics module of Centricity Perinatal detects a 10-second or more discrepancy between the timestamp on the tracing received and the Centricity Perinatal – Analytics server, it will display a **Tracing Delayed** watermark on the tracing.



The presence of this watermark does not cripple any of the functionality of the Analytics module of Centricity Perinatal; 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 typically temporary and occurs when the system is under load.

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

4.2. Navigating Through the Tracings Views

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

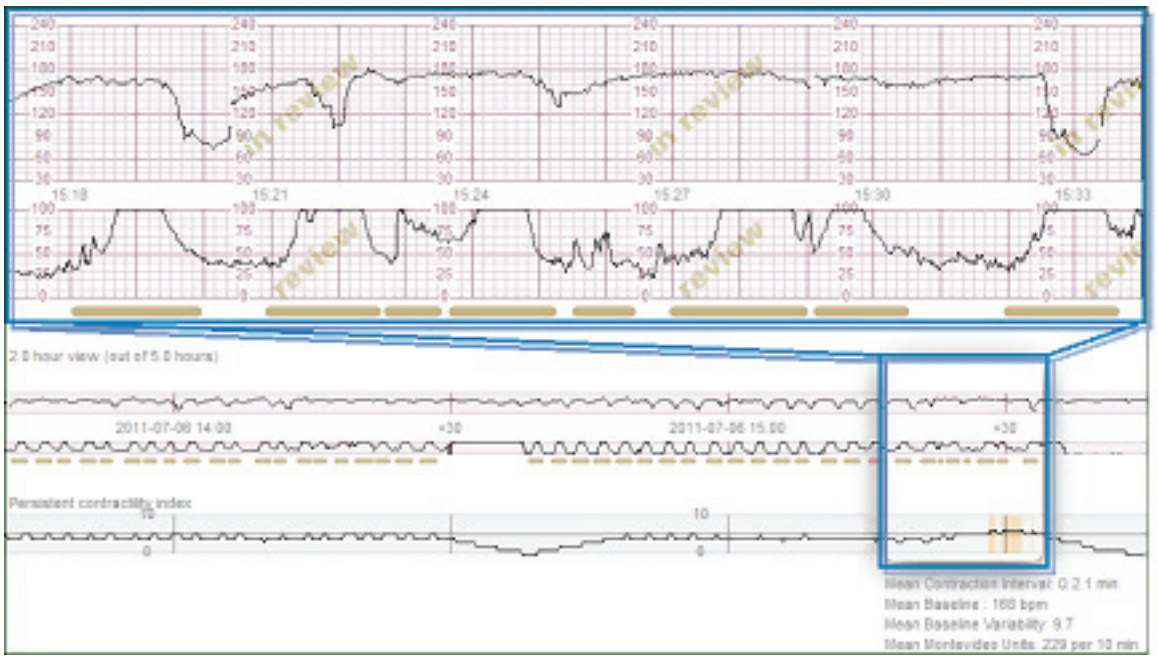
The tracing views can also be moved via the **Slider Window** (see The Slider Window) and the **Navigation Buttons** (see The Navigation Buttons).

Each time the Analytics module of Centricity Perinatal 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 17-minute overlap between the **Expanded View** and the 2-hour **Compressed View**.

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



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 17-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 views will also stop the auto-scrolling.
	Auto-scroll the **Slider Window** towards the past. Note: clicking the button more times increases the auto-scrolling speed.
	Skip backward to the previous 17-minute window of tracings.
	Jump to the beginning of the tracing.

4.3. Zooming the Compressed Tracing View

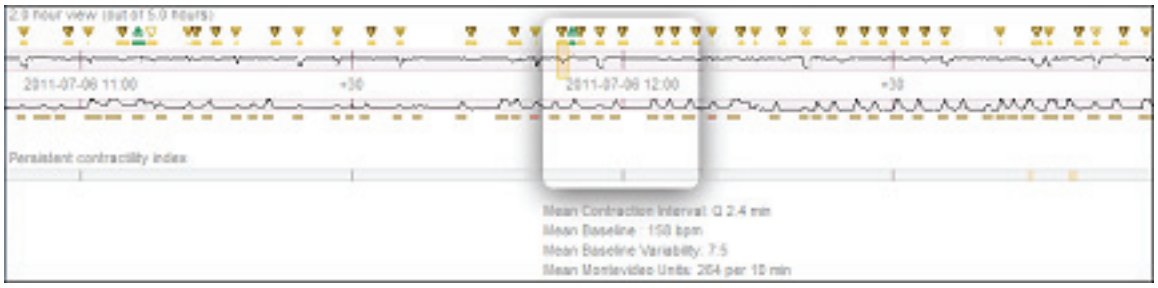
The 2-hour **Compressed View** can be zoomed out to display a maximum of 12-hours of tracing by clicking on the **Zoom**  icon .

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.

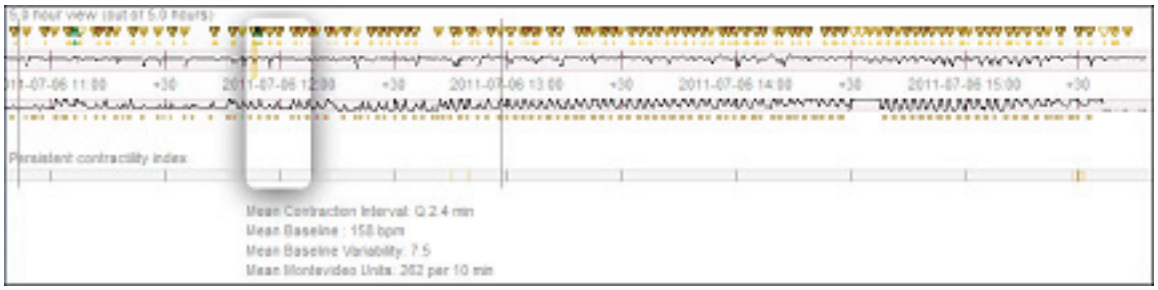
In the 12-hour view, tracings are compressed horizontally and are no longer in an aspect ratio that is equivalent to a paper strip. The horizontal compression is roughly 6-fold.

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

2-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 2-hours when the **Slider Window** is dragged and then released.

The Analytics module of Centricity Perinatal is powered by PeriGen Inc., using the PeriCALM Patterns pattern detection engine. This uses advanced mathematical models to analyze a tracing's fetal heart rate and uterine pressure values, in order to identify and calculate:

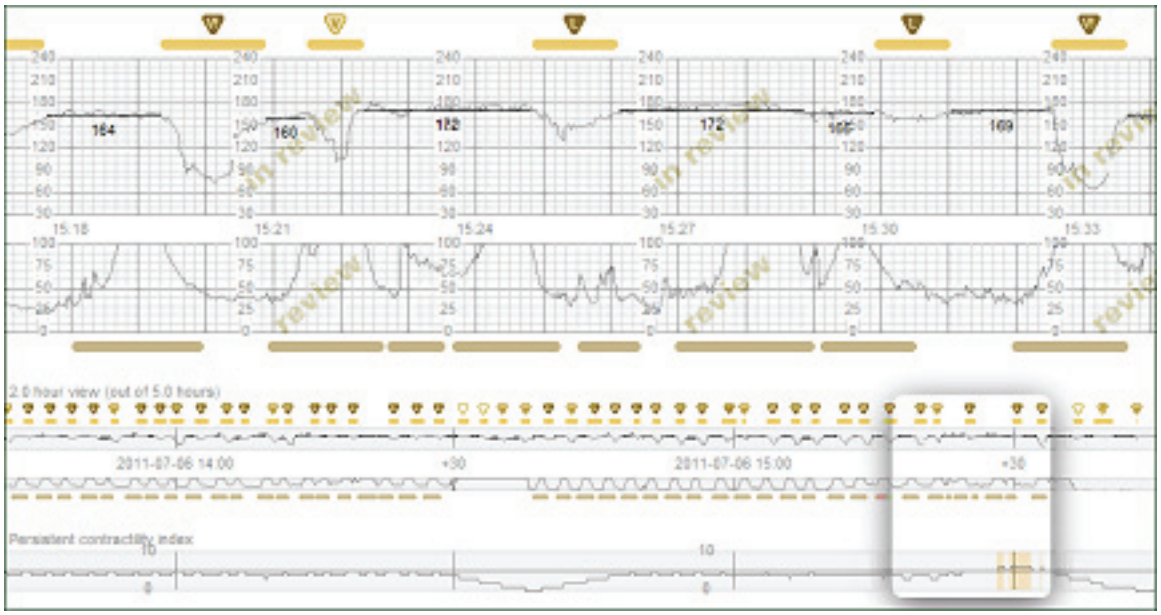
- Baseline and variability
- Fetal heart rate features
- Uterine contractions
- Mean contraction interval
- Montevideo units

5.1. Baselines and Variability

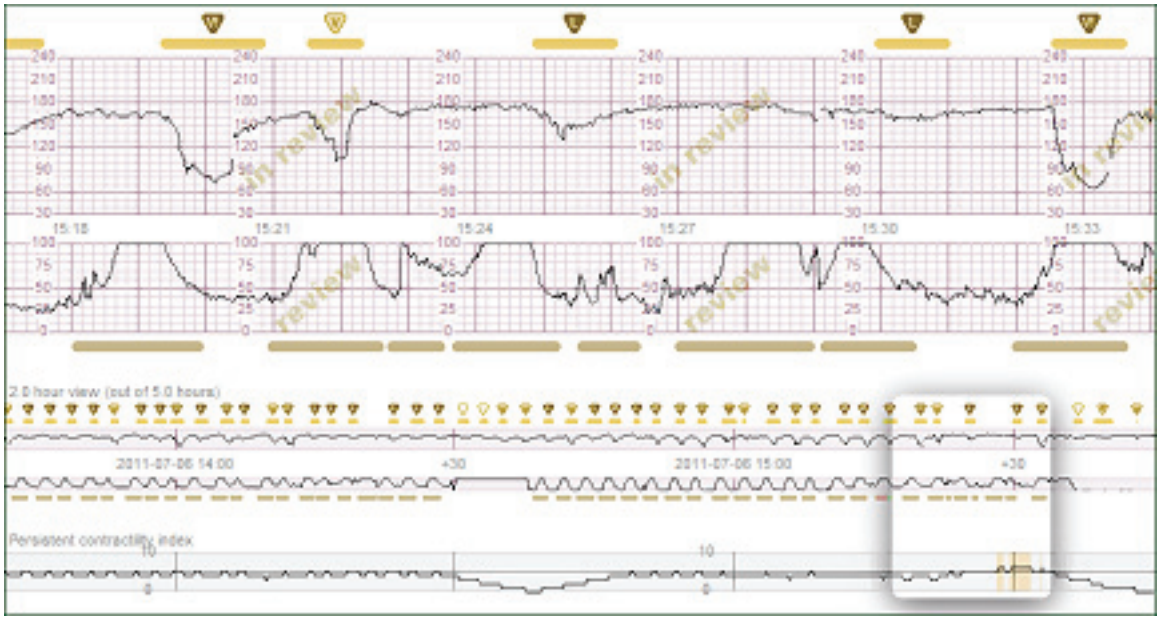
5.1.1. Baselines

The Analytics module of Centricity Perinatal identifies baselines within the FHR tracing—the approximate mean fetal heart rate in relatively flat segments of the fetal tracing—and excludes accelerations, decelerations, periods of marked fetal heart rate variation and artifacts.

The baselines are used as a source for several other calculations (see next sections). Baselines are not displayed by default. By clicking the **Baselines** icon Baselines, horizontal lines will appear over the FHR tracing, indicating the different areas where baselines are identified. A number corresponding to the baseline fetal heart rate value (in beat per minute) will be displayed below the horizontal lines. The Analytics module of Centricity Perinatal does not label baselines as abnormally high (tachycardia) or low (bradycardia).

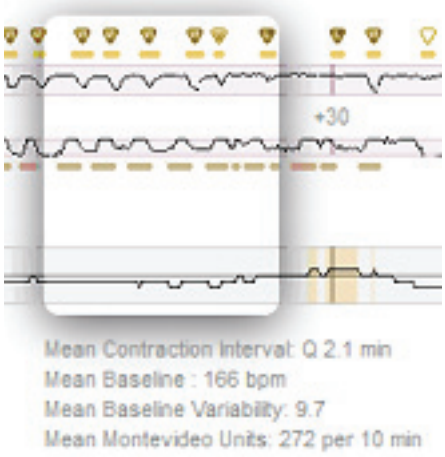


By clicking the **Baselines** icon Baselines a second time the baselines can be hidden.



5.1.2. Variability

Variability refers to a measurement of the variation in fetal heart rate values in a baseline segment. The Analytics module of Centricity Perinatal 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.



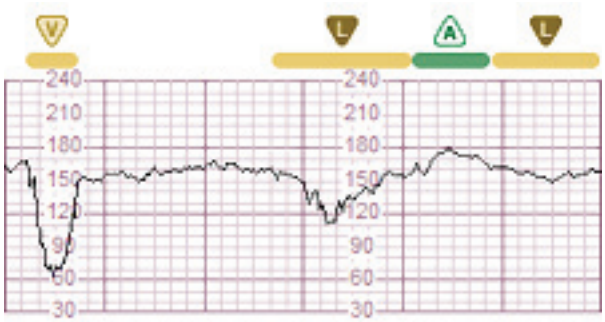
Mean Baseline and Mean Baseline Variability

Using the baselines detected, The Analytics module of Centricity Perinatal calculates **Mean Baseline** and **Mean Baseline Variability** over a 17-minute window. These values are displayed beneath the 17-minute **Slider Window** (shown above). **Mean Baseline** and **Mean Baseline Variability** are calculated in real-time as new tracing becomes available. Additionally, the **Slider Window** can be moved over existing sections of tracing and these two calculations will be updated dynamically.

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 the Analytics module of Centricity Perinatal are labeled according to standard nomenclature.[1]

When the Analytics module of Centricity Perinatal 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 when the gestational age is below 36 weeks or for patients who have more than one fetus.

5.2.1. Signal Quality

To properly interpret events, the Analytics module of Centricity Perinatal 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 the Analytics module of Centricity Perinatal to suspect an acceleration or a deceleration. When this occurs the event markers will have a question mark within the triangle and the event will be labeled Non-Interpretable. A Non-Interpretable event can be confirmed or struck out by the user. See Confirming a Non-Interpretable Event and Striking Out an Event.

5.2.2. Accelerations

Accelerations refer to episodic increases in the fetal heart rate that are at least 15 beats above the baseline and last for at least 15-seconds. The Analytics module of Centricity Perinatal does not sub-classify accelerations according to length.

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
The Analytics module of Centricity Perinatal recognizes that an event with the shape of acceleration has occurred, but portions of the tracing are missing. The Analytics module of Centricity Perinatal will not give a definitive label unless the event is confirmed by a user.

5.2.3. Decelerations

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

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

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

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

The following illustrations show the pictograms that appear in the Analytics module of Centricity Perinatal, as well as the basic definitions. Because of the ambiguities in the NICHD definitions as described above, the Analytics module of Centricity Perinatal 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 the Analytics module of Centricity Perinatal, 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
The Analytics module of Centricity Perinatal recognizes that an event with the shape of a deceleration has occurred, but portions of the tracing are missing, therefore Centricity Perinatal – Analytics will not give a definitive label unless the event is confirmed by a user.

Non-Associated Deceleration
The Analytics module of Centricity Perinatal recognizes that a deceleration with gradual onset has occurred, but there is no contraction to associate the deceleration with; therefore the Analytics module of Centricity Perinatal 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.

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 , in press 2011

5.2.4. Displaying Events

The Analytics module of Centricity Perinatal can display or hide events. In either case, this can be changed at any time by clicking the **Acc/Decel** button located in the toolbar.

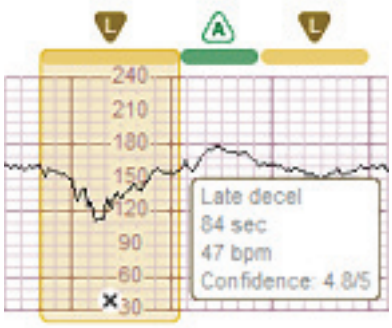
When the button displays a checkmark ✓ Acc/Decel, events are currently displayed and clicking the button will hide events.

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

While the Analytics module of Centricity Perinatal detects events in real-time, several minutes of tracing may be required to confidently identify and display an event or a baseline.

5.2.5. Selecting Event Markers

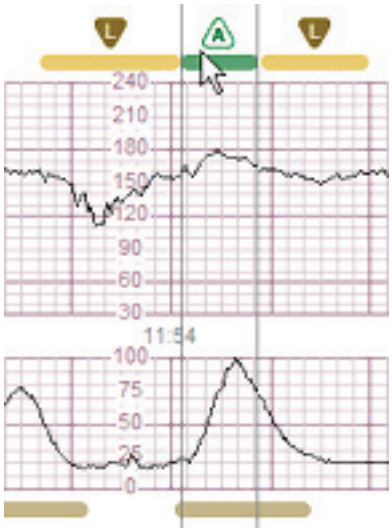
An event can be selected by clicking on the event marker or pictogram.



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

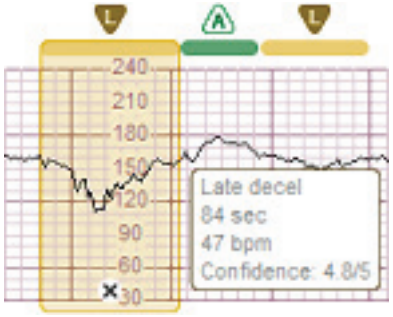
In addition to being able to select an event, a clinician can also hover the mouse over an event without clicking. In this case, vertical lines representing the start and end points of an event will traverse the tracing to assist in determining pattern association and timing with uterine contractions.



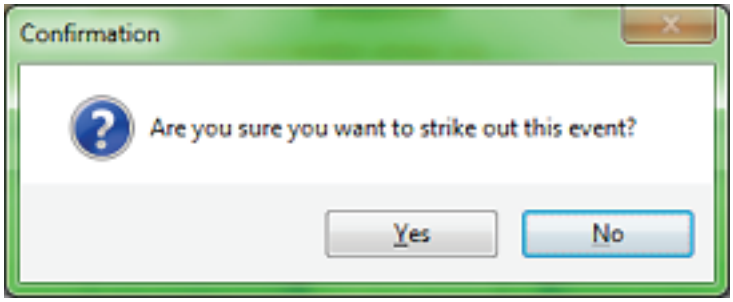
5.2.6. Striking Out an Event

In some cases, a clinician may not agree with an event that the Analytics module of Centricity Perinatal detected. In such an instance, it is possible for the clinician to strike out a detected event.

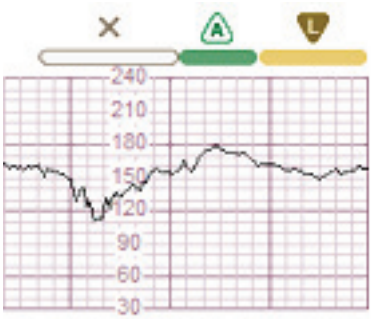
1. Click on the event marker in question.



2. Click on the "**X**" icon located at the bottom of the highlighted area. A message is displayed, warning that an event will be struck out.



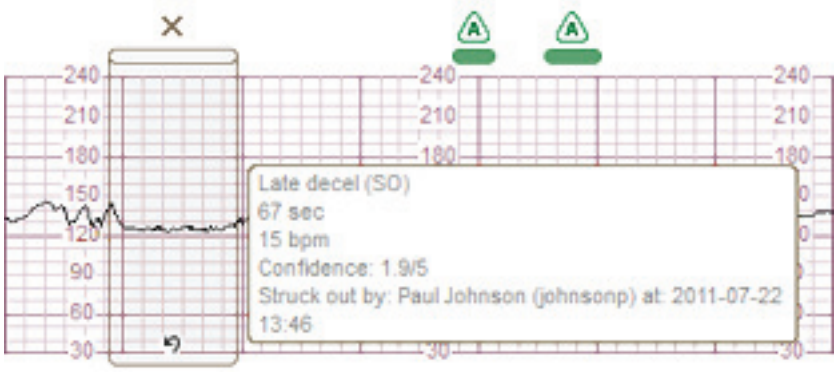
3. Click **Yes**. The event marker turns white with an "**X**" above it, indicating that the event has been struck out (see below).



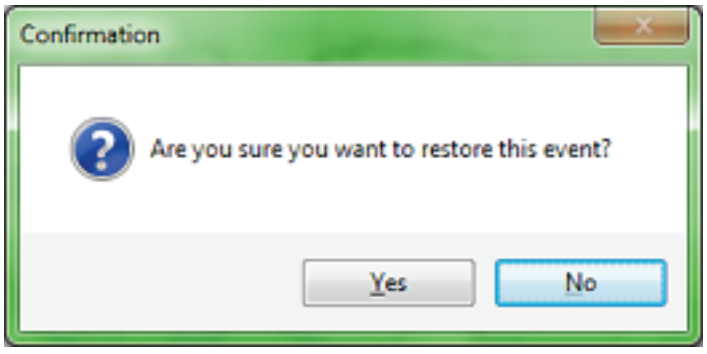
5.2.7. Restoring an Event

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

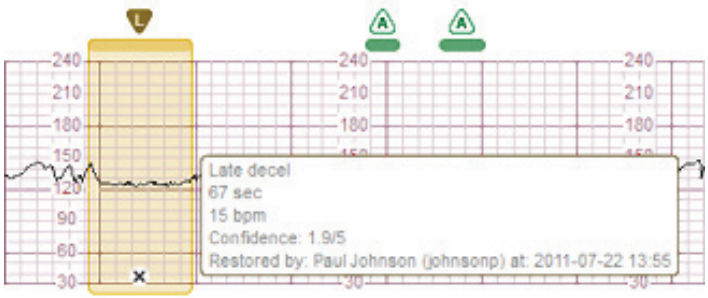
1. Click on the event marker in question.



2. Click on the arrow icon located at the bottom of the highlighted area. A message is displayed, indicating that an event will be restored.



3. Click **Yes**. The event marker returns to its original, pre-strike out marked and interpreted state.

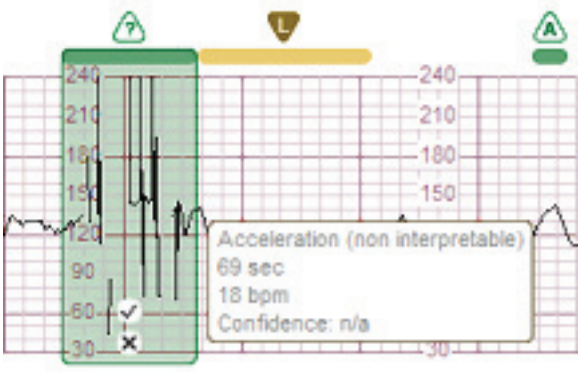


5.2.8. Confirming a Non-Interpretable Event

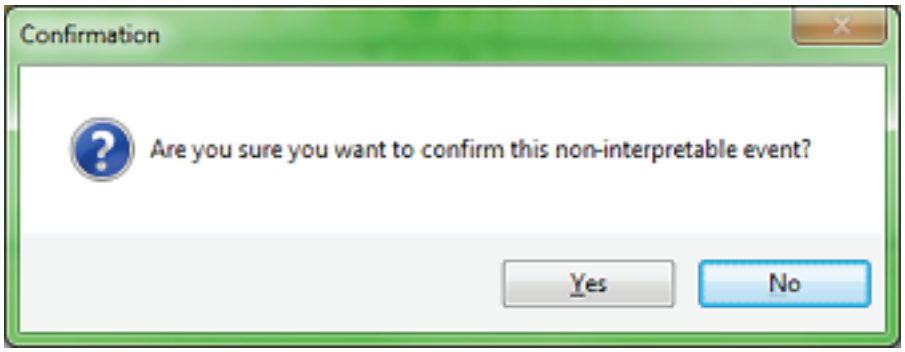
When the Analytics module of Centricity Perinatal identifies a potential event, but portions of the tracing are missing, the event is classified as non-interpretable and a **Non-interpretable Deceleration** or a **Non-interpretable Acceleration** pictograph is displayed, as applicable (see Signal Quality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

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

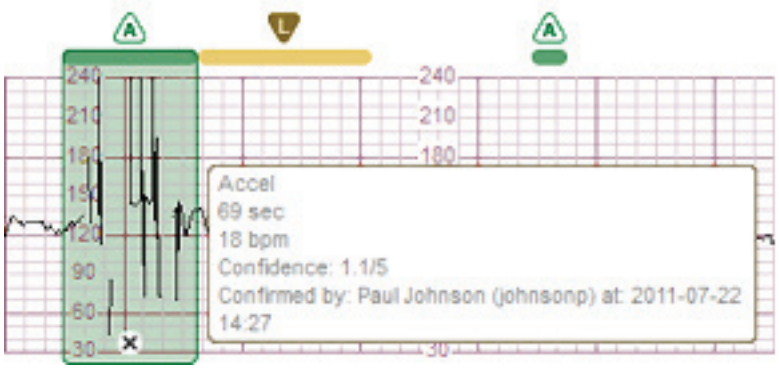
1. Select the Non-Interpretable event of interest.



2. Click on the checkmark icon located at the bottom of the highlighted area. A message is displayed, asking the clinician whether they are sure they want to confirm the non-interpretable event.



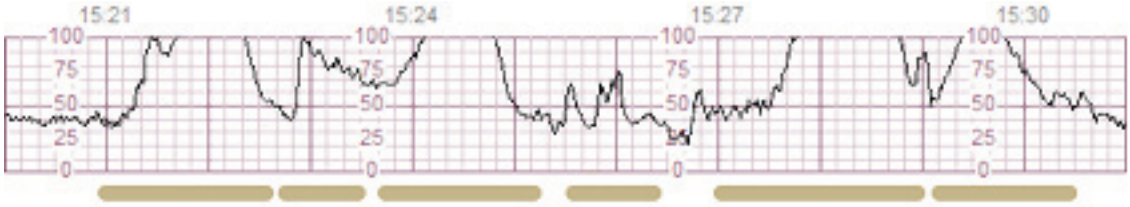
3. Click **OK**. The "?" event pictograph is replaced the applicable event type pictograph.



5.3. Contractions

5.3.1. Contraction Markers

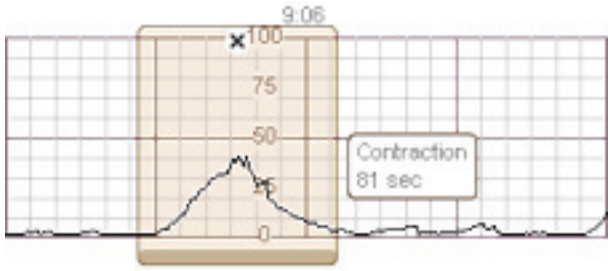
The Analytics module of Centricity Perinatal identifies contractions by analyzing the uterine pressure tracing. Detected contractions are displayed by Contraction Markers. These are beige lines displayed beneath the uterine pressure grid (see below). The left and right parts of the lines respectively indicate the beginning and end of each contraction.



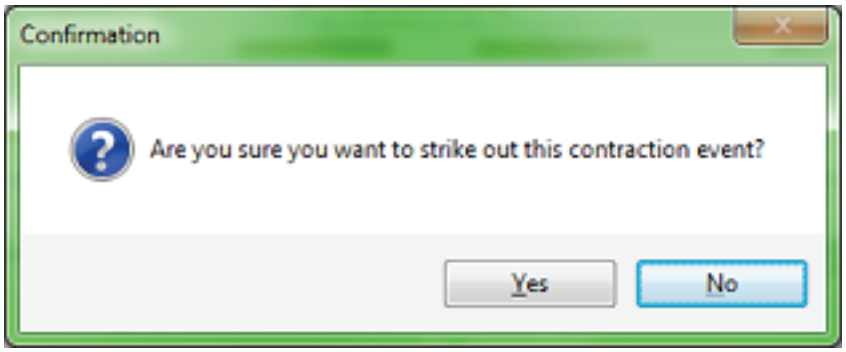
5.3.2. Striking Out a Detected Contraction

In some cases, a clinician may not agree with a contraction that the Analytics module of Centricity Perinatal detected. In such an instance, it is possible for the clinician to strike out a detected contraction.

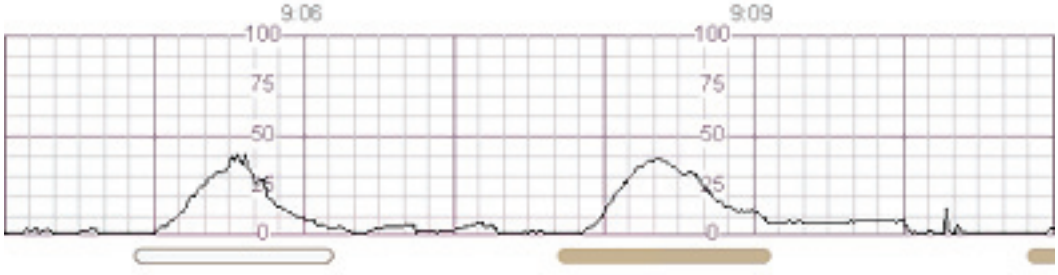
1. Click on the desired contraction marker. The contraction becomes selected as shown below.



2. Click on the "**X**" icon located at the top of the highlighted area. A message appears, warning that a contraction is about to be struck out.



3. Click **Yes**. The contraction marker turns from beige to white, indicating that the contraction has been struck out (see below).



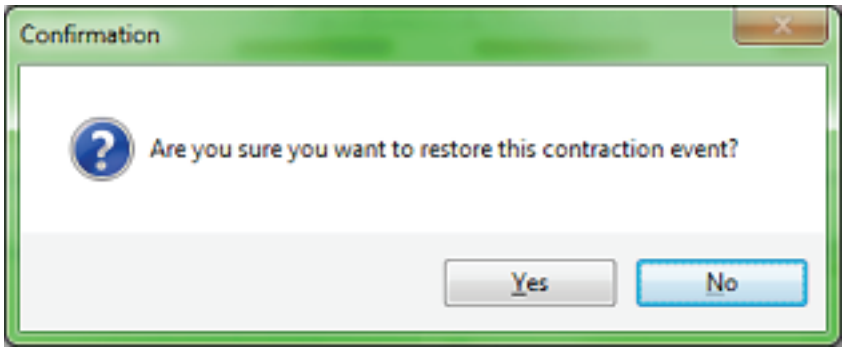
Striking out a contraction will result in the Mean Contraction Interval, Montevideo Units and Contractility being recalculated. Striking out a contraction will not affect the detection of Fetal Heart Rate Events.

5.3.3. Restoring a Struck Out Contraction

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

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

2. Click on the arrow icon located at the top of the highlighted area. A message appears, warning that a contraction is about to be restored.

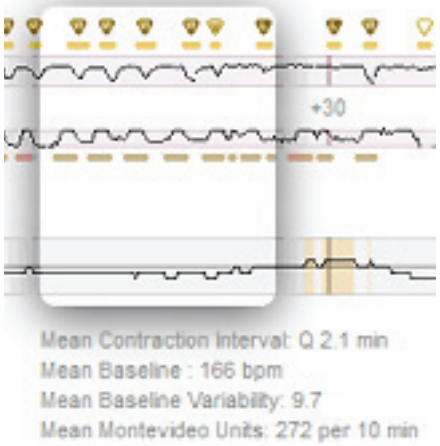


3. Click **Yes**. The contraction marker turns from white to beige, indicating that the contraction has been restored (see below).

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

5.4. Mean Contraction Interval

Using the contractions detected, the Analytics module of Centricity Perinatal calculates the average time between contractions within a 17-minute window. Similarly to **Mean Baseline** and **Mean Baseline Variability**, these values are calculated and displayed dynamically beneath the 17-minute **Slider Window**.



5.5. Contractility

In addition to the two fetal strip tracing views, the Analytics module of Centricity Perinatal displays a **Persistent Contractility Index**, which is a 2-hour (or up to 12-hour) graph that plots contractility 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 3-color system is employed to indicate the level of contractility.

- **White** – contractility below the threshold level set by the site (for example, 5 or fewer contractions per 10-minutes).
- **Beige** – contractility at or above the threshold level set by the site, but for a period of time less than that determined by the site for persistency (for example, more than 5 contractions per 10-minutes, for a duration of less than 30-minutes).

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

- **Orange** – contractility at or above the threshold level set by the site for an uninterrupted period greater than that determined by the site for persistency (for example, more than 5 contractions per 10-minutes, for a duration of 30-minutes or longer, uninterrupted).

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

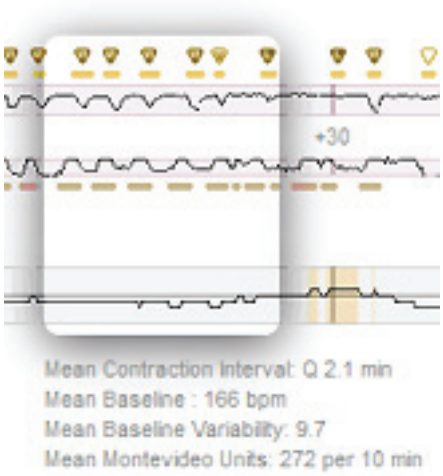
In the **Multifaceted** view, in addition to the 3-color system, the actual number of contractions in the site-defined persistency timeframe is plotted. The maximum value of the y-axis (e.g. 10 contractions per 10-minutes) and the value of an intermediate line (e.g. 5 contractions per 10-minutes) are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

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

- The number of minutes over which contractions are being evaluated (e.g. 10-minutes)
- The threshold to distinguish normal uterine contraction levels from tachysystole (e.g. greater than 5 contractions in 10-minutes)
- The time frame for evaluating persistency of uterine tachysystole (e.g. 30-minutes)

5.6. Montevideo Units

The Analytics module of Centricity Perinatal also calculates **Montevideo Units**. They can be displayed by clicking the **Montevideo** icon ✕ Montevideo in the toolbar. This turns the "**X**" in the icon into a checkmark ✓ Montevideo and **Montevideo Units** appear beneath the **Slider Window**.

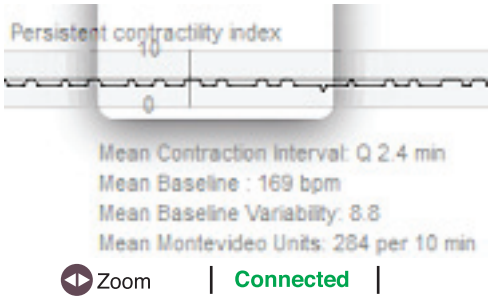


While **Montevideo Units** are calculated over the 17-minute span of the **Slider Window**, the value is averaged and expressed as a number per 10-minutes. In the above figure, for example, an average of 272 **Montevideo Units** is calculated for 10-minutes while the 17-minutes of the **Slider Window** would actually correspond to a higher total of **Montevideo Units**.

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

The Analytics module of Centricity Perinatal 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.

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



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

6.1. Possible System States

6.1.1. Connected State

The Analytics module of Centricity Perinatal displays the green **Connected** state | Connected | when the application has no issues to report.

6.1.2. Error State

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

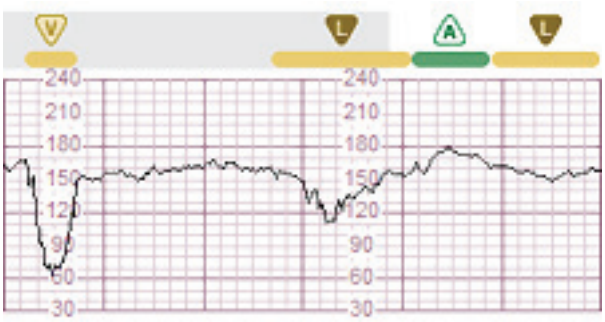
6.1.3. No Data State

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

6.1.4. Recovery State

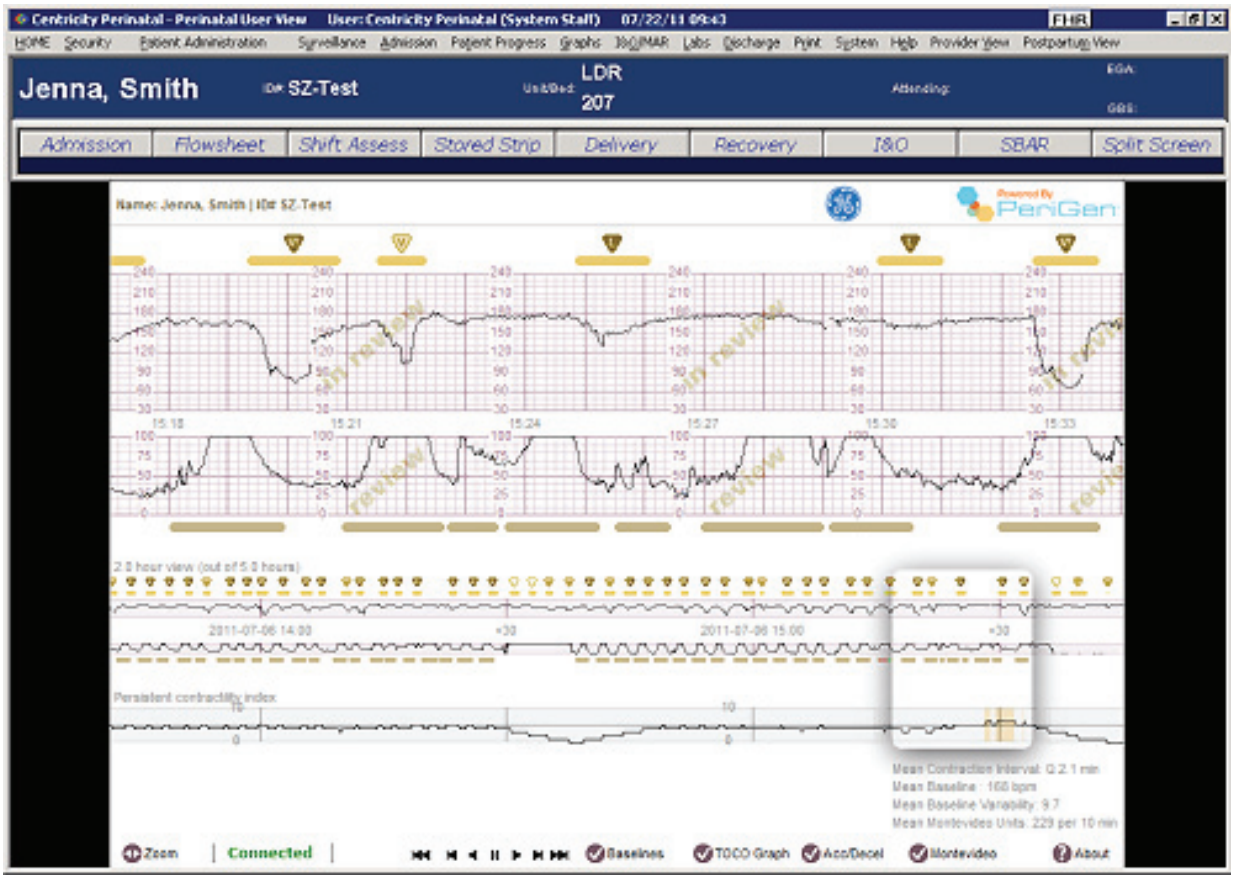
The Analytics module of Centricity Perinatal displays the orange **Recovery** state | Recovery | when the application needs to calculate and display events for large amounts of historical data instead of the usual punctual display and calculations; typically this occurs after a period of down time of the Analytics module of Centricity Perinatal. Clicking on the icon will display an informational message detailing the cause of this state. Once the Analytics module of Centricity Perinatal 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 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.

The Analytics module of Centricity Perinatal is provided as an embedded component into the Centricity Perinatal application. The Centricity Perinatal system delivers this functionality via the existing, and configurable, capability of hosting generic, web browser content on patient specific screens.



7.1. Important Notes

- None of the information generated within the Analytics module of Centricity Perinatal will update the patient record in Centricity Perinatal. The Analytics module of Centricity Perinatal only reads information from the Centricity Perinatal system.
- By selecting the Centricity Perinatal configured link or menu item, the Analytics module of Centricity Perinatal will be launched for the currently selected patient and will use the currently logged-in user credentials to track changes.
- The Analytics module of Centricity Perinatal requires that the following fields be charted in the Centricity Perinatal system in order to calculate and display events: the **Estimated Date of Confinement** (EDC) and **Babies in the Womb**.

A modification to a patient's **Estimated Date of Confinement**, **Babies in the Womb**, **Patient Name** or **Patient ID** in Centricity Perinatal will require up to 60-seconds to be reflected in the Analytics module of Centricity Perinatal.

- Episodes of tracing have a maximum length of 7 days. Should this maximum be reached, the episode of tracing will be closed and a new episode will automatically be created. Only the last 12-hours of tracing data and events will appear as historical data, however live tracing will continue to be gathered and marked.
- The Analytics module of Centricity Perinatal is meant to display fetal heart patterns during active labor. This means that only Actively Monitored patients in Centricity Perinatal can be viewed in the **Analytics** module.
- The Analytics module of Centricity Perinatal provides no print or archiving capability in this version of the software.

The Analytics module of Centricity Perinatal does not provide a way to view past episodes in this version of the software as episodes of tracing are permanently deleted after their closure.

- While a patient file in Centricity Perinatal is being merged, it cannot be accessed by the Analytics module of Centricity Perinatal. Upon completion of the merging process, the last 12-hours of tracing data and events will appear as historical data and live tracing will continue to be gathered and marked.
- If the Analytics module of Centricity Perinatal experiences an interface issue with Centricity Perinatal or detects conflicting patient identification, the affected patients will no longer be available in the Analytics module of Centricity Perinatal and an error message will indicate the actions to take in order to resolve the issue, i.e. transfer the affected patients to different beds and then back.

Confirmation message boxes and the **About** window will disappear automatically after 60-seconds in order not to cause conflict with the Centricity Perinatal auto-log off feature. When this occurs, no changes will be made to the Analytics module of Centricity Perinatal data, i.e. no events or contractions will be struck out or confirmed.

7.2. Example Workflow Scenarios and Results

7.2.1. Scenario 1

Updating a patient's ID while she is not being actively monitored will reset any currently opened episode of tracing. Upon return to an actively monitored bed, the Analytics module of Centricity Perinatal will recalculate and display the last 12-hours of tracings and events; any previously gathered tracings and events will *not* be available.

7.2.2. Scenario 2

If the patient remains in an actively monitored bed but the monitor is turned off, or the probes are unplugged, or the patient is transferred to a non-actively monitored bed for *more than 4 and less than 12-hours*, then that patient will no longer be available in the Analytics module of Centricity Perinatal.

Turning the monitor back on, re-plugging the probes or transferring that patient back to an actively monitored bed will re-enable pattern detection and display; previously gathered tracing and events will also be available.

If the patient is transferred more than 8 times during the period of time while the patient is not being actively monitored, the Analytics module of Centricity Perinatal will reset the episode of tracing for that patient. Upon return to an actively monitored bed, the Analytics module of Centricity Perinatal will recalculate and display the last 12-hours of tracings and events; any previously gathered tracings and events will not be available.

7.2.3. Scenario 3

If the patient remains in an actively monitored bed but the monitor is turned off, or the probes are unplugged, or the patient is transferred to a non-actively monitored bed for *more than 12-hours*, then that patient will no longer be available in the Analytics module of Centricity Perinatal.

Turning the monitor back on, re-plugging the probes or transferring that patient back to an actively monitored bed will re-enable pattern detection and display; any previously gathered tracing and events will *not* be available.

7.2.4. Scenario 4

If the patient remains in an actively monitored bed but the monitor is turned off, or the probes are unplugged, or the patient is transferred to a non-actively monitored bed for *less than 4-hours*, then tracing and events will remain available but the Analytics module of Centricity Perinatal will display the unplugged icon and no new tracing or events will be added.

7.2.5. Scenario 5

Multiple sequential transfers of a patient (3 or more) done within one minute may cause the Analytics module of Centricity Perinatal to reset any currently opened episode of tracing for that patient. The Analytics module of Centricity Perinatal will then recalculate and display the last 12-hours of tracings and events for that patient; any previously gathered tracings and events will *not* be available.

Developing the Pattern Detection Algorithms

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

Tracings were collected from a sample of patients with outcomes ranging from normal to abnormal so that examples of all types of features were available. The clinical aspects of the patients from whom these tracings were collected are summarized in Table 1.

Table 1

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

The Clinician Panel comprised five 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 Analytics module of Centricity Perinatal 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 the Analytics module of Centricity Perinatal is evaluated to verify that good correlation is maintained between measured Baseline and visual estimates.

Baseline Variability

The Analytics module of Centricity Perinatal defines FHR variability as two standard deviations of FHR values in baseline segments. Each version of the Analytics module of Centricity Perinatal is evaluated to verify that good correlation is maintained between measured Baseline Variability and visual estimates.

Accelerations and Decelerations

Performance testing 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 Analytics module of Centricity Perinatal
- **Missed** is the number of features in Clinical Panel Standard that were not detected by the Analytics module of Centricity Perinatal
- **False positives** are the number of features that were identified by the software but were not identified by the panel majority in Clinical Panel Standard. A false positive may have been identified by none, one, or two of the clinicians.
- **Sensitivity** is the percentage of Clinical Panel Standard features that the software detected. Mathematically it is defined as the ratio of (detected) / (number in test).
- **Proportion of Agreement** refers to the percentage of all the **Analytics** module of **Centricity Perinatal** 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 .

Table 2

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

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 3 and Table 4.

Table 3

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

Table 4

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

Limitations

The following limitations are present in the application:

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

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

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

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

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

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

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

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