PeriGen, Inc.

PeriCALM® Curve™ User Guide

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Copyright notice

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Reader comments

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

Trademarks

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

Intended Use

PeriCALM Curve is intended for use as a data analysis system to assess labor progress in singleton cephalic presentation pregnancies when the gestational age is ≥ 35 weeks.

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

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® Patterns™ provides an instant view of the mother's and baby's current status and trends over time to prevent errors, increasing patient safety and reducing risk for clinicians and hospitals.

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

2. This Guide

2.1. Versions

The ***PeriCALM Curve*** *User Guide* is provided to the user:

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

2.2. Conventions

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

Bold	Used to identify view menus, options, and screen titles.
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 Curve User Guide* provides information that is related to the PeriCALM Curve application. For additional information related to the PeriCALM suite of products, please refer to the following.

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

3. Overview

The labor of childbirth is defined as the process by which regular uterine contractions cause the fetus to move through the birth canal. In order to evaluate how labor is progressing, clinicians periodically measure cervical dilation and station (fetal descent). The rate of labor progress is affected by several factors, such as the mother's parity, the frequency of uterine contractions and the resilience of the cervix. These parameters are interrelated and may change throughout labor. Therefore, it may be difficult to determine if slow progress in dilation is abnormal, indicating a misfit between the size of the baby and the birth canal, or if it is a normal response to that mother's particular combination of factors that influence cervical dilation.

The **PeriCALM Curve** uses statistical formulas to show how cervical dilation generally changes during labor, based on data from a reference group of mothers who delivered vaginally.

PeriCALM Curve is intended to use in labor with a cephalic presenting singleton where the gestational age is ≥ 35 weeks and dilation has reached 3 cm. Calculations are confined to the first stage of labor.

The **PeriCALM Curve** considers these conditions that affect how the cervix dilates:

- Parity;
- Cervical dilation;
- Effacement;
- Station;
- Uterine contraction frequency;
- Presence of epidural anesthesia;
- First vaginal delivery or attempted VBAC.

Each time pelvic exam results are entered, **PeriCALM Curve** reexamines these factors and updates its calculations.

PeriCALM Curve calculations produce a graph which shows the *average expected* cervical dilation. It also shows a *range* of values that would be expected, because not all women who deliver vaginally respond in exactly the same way.

Clinicians can now compare the observed dilation of a specific mother under their care to the dilation pattern from women with similar labor related conditions from the reference group. The comparison can be viewed in a graph or via percentile rankings.

The following sections explain the different components of the **PeriCALM Curve** screen, in addition to the conditions and data elements required for the calculations.

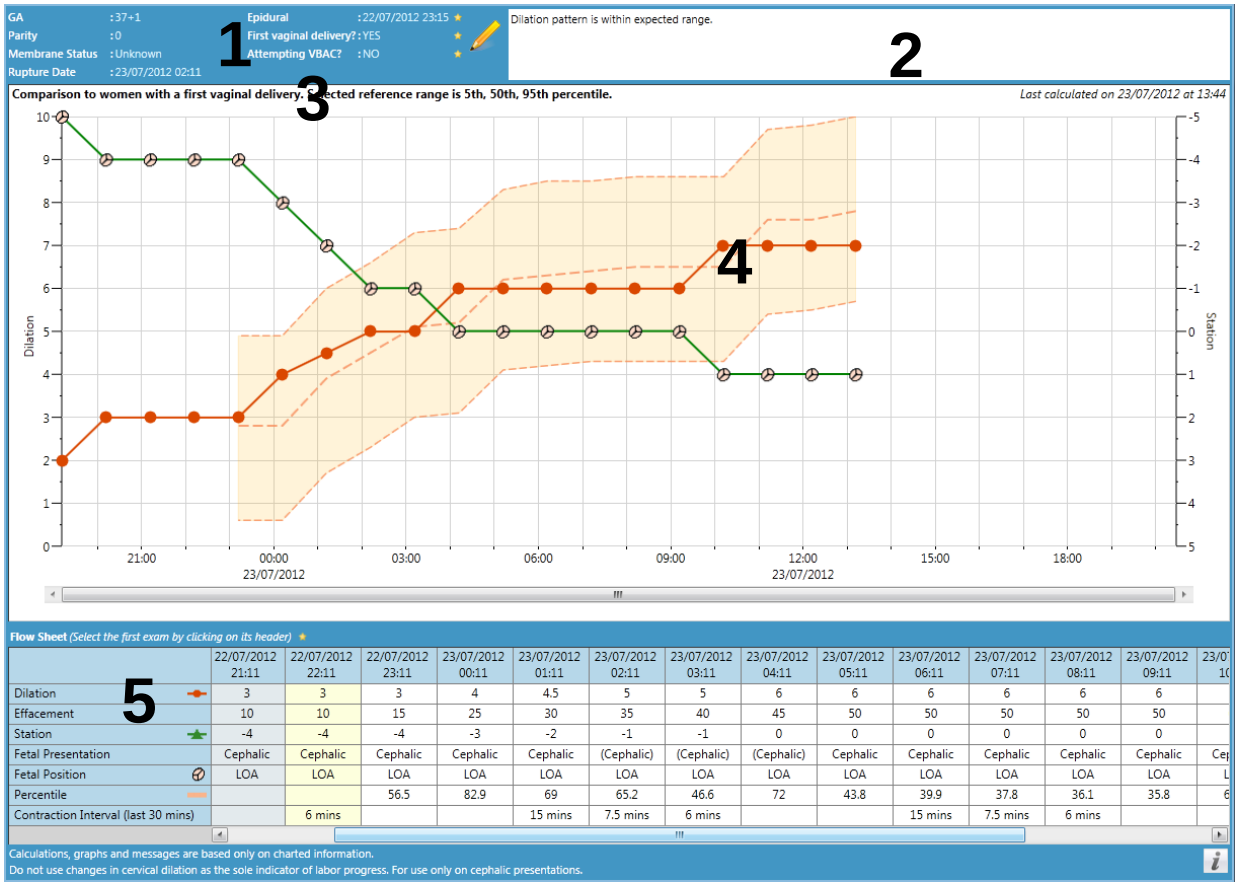
PeriCALM Curve is a web based component embeddable into a hosting system. Charted patient data is provided through the medical record in that hosting system.

3.1. The PeriCALM Curve Screen

The PeriCALM Curve screen is divided into sections including a graphical representation of the labor progress and areas that allow the user to quickly monitor the patient's labor progress.

The following shows the main components of the **PeriCALM Curve** screen.

1. The **Patient Information Banner** displays clinical information about the selected patient.
2. The **Labor Progress Message** provides descriptions about the labor progress of this patient or additional information required for further calculation.
3. The **Labor Comparison Profile** shows what reference population has been selected as a comparison for this patient as well as the upper and lower percentiles selected by your site to outline the reference range limits.
4. The **Labor Progress Graph** displays this patient's dilation and station at each examination and the computerized reference range calculated for her.
5. The **Vaginal Exams** flow sheet displays the vaginal exams for this patient.



	22/07/2012 21:11	22/07/2012 22:11	22/07/2012 23:11	23/07/2012 00:11	23/07/2012 01:11	23/07/2012 02:11	23/07/2012 03:11	23/07/2012 04:11	23/07/2012 05:11	23/07/2012 06:11	23/07/2012 07:11	23/07/2012 08:11	23/07/2012 09:11	23/07/2012 10
Dilation	3	3	3	4	4.5	5	5	6	6	6	6	6	6	
Effacement	10	10	15	25	30	35	40	45	50	50	50	50	50	
Station	-4	-4	-4	-3	-2	-1	-1	0	0	0	0	0	0	
Fetal Presentation	Cephalic	Cephalic	Cephalic	Cephalic	Cephalic	(Cephalic)	(Cephalic)	(Cephalic)	Cephalic	Cephalic	Cephalic	Cephalic	Cephalic	Cep
Fetal Position	LOA	LOA	LOA	LOA	LOA	LOA	LOA	LOA	LOA	LOA	LOA	LOA	LOA	L
Percentile			56.5	82.9	69	65.2	46.6	72	43.8	39.9	37.8	36.1	35.8	6
Contraction Interval (last 30 mins)		6 mins			15 mins	7.5 mins	6 mins			15 mins	7.5 mins	6 mins		

4. Patient Information Banner

4.1. The Patient Data Fields

Patient information is displayed in the Patient Information Banner.

GA

This field indicates the patient's Gestational Age.

This field is read-only because the information comes from the medical record.

Parity

This field indicates the patient's Parity.

This field is read-only because the information comes from the medical record.

Membrane Status

This field indicates the current status of the patient's membranes.

This field is read-only because the information comes from the medical record.

Rupture Date

This field indicates the date and time of the patient's membranes rupture.

This field is read-only because the information comes from the medical record.

Epidural

This field indicates the date and time the Epidural administration was started.

This field can be configured as modifiable and if so can be edited by selecting the **Edit** icon on the right.

First Vaginal Delivery

This field indicates if this is the patient's first vaginal delivery.

This field can be configured as modifiable and if so can be edited by selecting the **Edit** icon on the right. Based upon the value of this field, the message above the labor graph will change.

Attempting VBAC

This field indicates if this is a vaginal delivery after a cesarean.

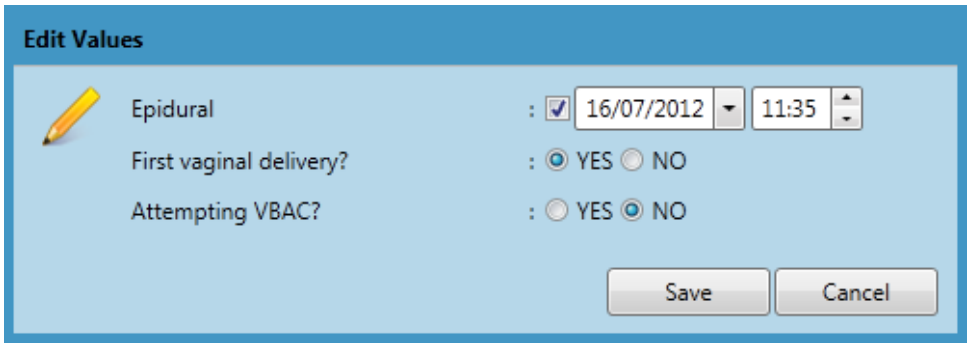
This field can be configured as modifiable and if so can be edited by selecting the **Edit** icon on the right. Based upon the value of this field, the message above the labor graph will change.

4.2. Editing the Labor Curve Comparison Profile

If the current user has read-only access to **PeriCALM Curve**, the Edit icon will be unavailable.

To edit the **Labor Curve Comparison Profile** in **PeriCALM Curve** follow these steps:

1. Select the **Edit** icon on the right of the patient information banner to open the Edit dialog.



2. Select the appropriate date and time values for **Epidural**.
3. Select the appropriate value for **First Vaginal Delivery**.
4. Select the appropriate value for **Attempting VBAC**.
5. Save the values by selecting the **Save** button or cancel them with the **Cancel** button.

If some of these values are not configured as editable through the **PeriCALM Curve** screen, they will be displayed as disabled and will be read only in the edit dialog.

If all of these values are not configured as editable through **PeriCALM Curve**, the Edit icon will be unavailable.

4.3. Viewing Audit Information

For each modifiable field of the **Labor Progress Profile**, information is recorded with the date and time its value was last created or modified and the identity of the person carrying out that action. A star icon is displayed next to the created or modified value and audit information for each field can be displayed in a tool tip by hovering the mouse over that icon.

4.4. The Labor Comparison Profile Message

The reference population selected for comparison and the site-selected **PeriCALM Curve** reference range (see Reference Range) are specified above the **Labor Progress** graph.

- If the value of **First Vaginal Delivery** is set to “YES”, the following comparison message is displayed: *Comparisons to women with a first vaginal delivery*.
- If the value of **First vaginal delivery** is set to “NO”, the following comparison message is displayed: *Comparisons to women with previous vaginal deliveries*.

5. Labor Progress Assessment Module

5.1. The Labor Progress Message

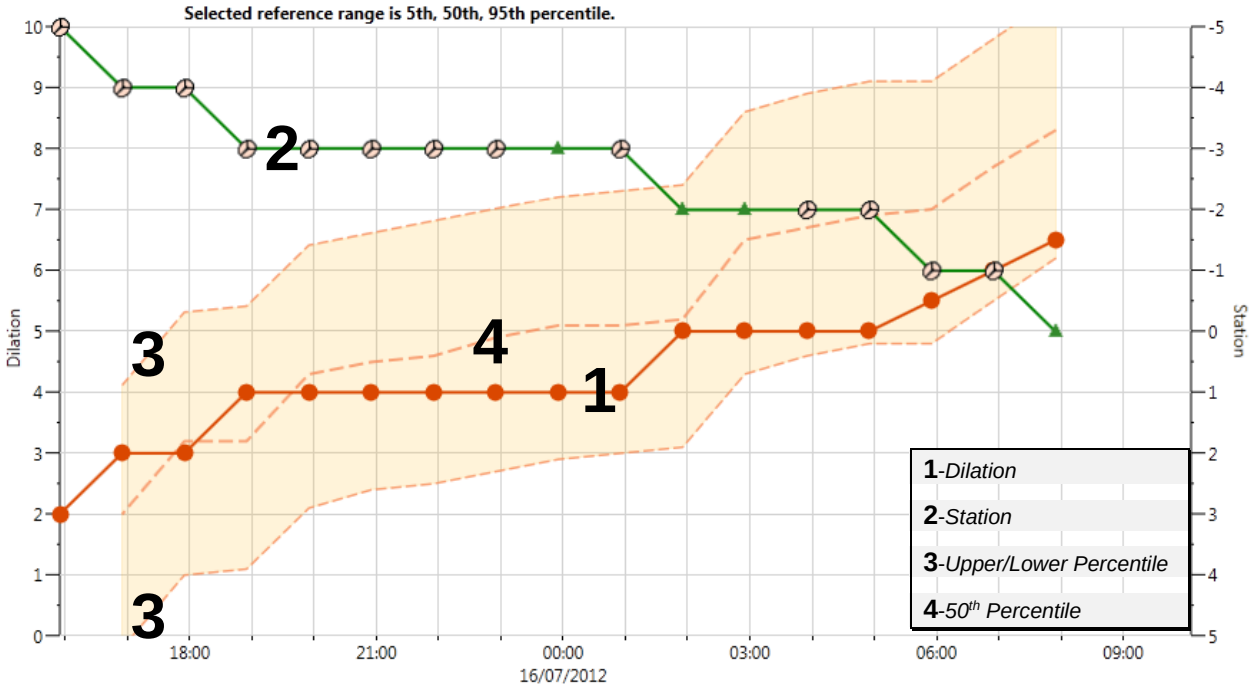
The **Labor Progress Message** provides advisory messages about the status or errors associated with the **PeriCALM Curve** definitions. See Prerequisite Conditions chapter for details.

5.2. The Labor Progress Graph

The labor progress graph displays a patient's first-stage labor progress in terms of three variables:

- **Dilation**: Numerically represented in centimeters on the left Y-axis, from 0 cm to 10 cm;
- **Station**: Numerically represented on the right Y-axis, from +5 to -5;
- **Time**: The time of the examinations in 1 hour increments represented on the bottom X-axis.

5.3. Graphical Elements on the Labor Progress Graph



5.3.1. Dilation Curve

The Dilation curve plots a patient's dilation values recorded in the **Dilation** row on the patient's exams flow sheet. The Dilation curve is displayed in a dark orange color and each dilation value is identified with a dark orange circle mark.

5.3.2. Station Graph

The Station graph plots a patient's station values as they are recorded in the **Station** row on the patient's exams flow sheet. The Station graph is displayed in a green color and each station value is identified with a green triangle mark.

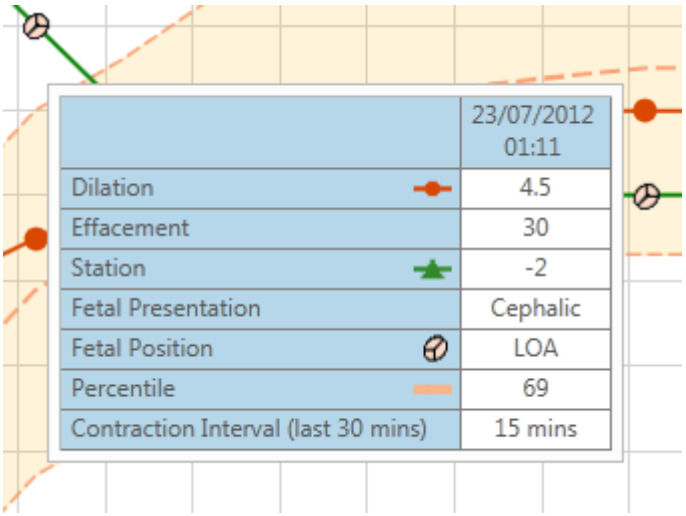
When a fetal position is charted in the **Fetal Position** row in the exams flow sheet, it is represented on the Station graph with a fetal position icon that replaces the green triangle mark.

The fetal position icons illustrate different occiput positions as described in the following table.

LOA	LOP	LOT	OA	OP	ROA	ROP	ROT

5.3.3. Exam Details Display on Graph

Details of each exam can be viewed in a tool tip by hovering the mouse over any dilation, station or fetal position points on the **Labor Progress** graph.



5.3.4. Percentile Limits

The Upper and Lower Percentile curves depict the upper and lower percentile limits and are used to compare the patient's labor progress with the selected reference population. These calculated curves are displayed with a dashed line in a light orange color. A band delimited by the Upper and Lower Percentile curves is highlighted with a light orange color.

The 50th Percentile curve is a calculated curve displayed with a dashed line in a bolded light orange color. This curve represents the mid-percentile value in the comparison of a patient with the selected reference population. The 50th Percentile line may be configured to be on or off.

5.3.5. Reference Range

The **PeriCALM Curve** upper and lower limits for the reference range are site-selected at the time of installation. The specifics of the selected reference range are displayed above the **Labor Progress Graph**.

The available choices for the reference range are:

- 3rd and 97th percentile
- 5th and 95th percentile
- 10th and 90th percentile.

Different ranges can be chosen for women attempting a VBAC versus women without a previous cesarean.

6. Vaginal Exams

All vaginal exams for the currently selected patient are displayed on the bottom of the **PeriCALM Curve** screen in a flow sheet format.

The vaginal exams flow sheet is read-only; no action can be undertaken.

6.1. Flow Sheet of Vaginal Exams

The following describe the different components of the Vaginal Exams flow sheet.

Flow Sheet *(Select the first exam by clicking on its header)*

	22/07/2012 21:11	22/07/2012 22:11	22/07/2012 23:11	23/07/2012 00:11	23/07/2012 01:11	23/07/2012 02:11	23/07/2012 03:11
Dilation	3	3	3	4	4.5	5	5
Effacement	10	10	15	25	30	35	40
Station	-4	-4	-4	-3	-2	-1	-1
Fetal Presentation	Cephalic	Cephalic	Cephalic	Cephalic	Cephalic	(Cephalic)	(Cephalic)
Fetal Position	LOA	LOA	LOA	LOA	LOA	LOA	LOA
Percentile			60.9	82.9	69	65.2	46.6
Contraction Interval (last 30 mins)		6 mins			15 mins	7.5 mins	6 mins

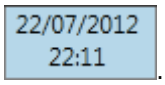
- **Header Row**: This portion of the flow sheet provides the observed time of each exam column.
- **Dilation:** This row of the flow sheet displays recorded dilation information.
- **Effacement:** This row of the flow sheet displays recorded effacement information.
- **Station:** This row of the flow sheet displays recorded station information.
- **Fetal Presentation:** This row of the flow sheet displays recorded fetal presentation information. A fetal presentation between parentheses "( )" indicates a value propagated from a previously charted value.
- **Fetal Position:** This row of the flow sheet displays recorded fetal position information.
- **Percentile:** This row of the flow sheet is calculated. It represents the percentile rank of the observed dilation compared to the selected reference.
- **Contraction Interval (last 30 mins):** This row of the flow sheet displays the average contraction interval over the last 30 minutes from this exam's time and is based on the number of contractions detected by **PeriCALM Patterns**.

6.2. First Vaginal Exam

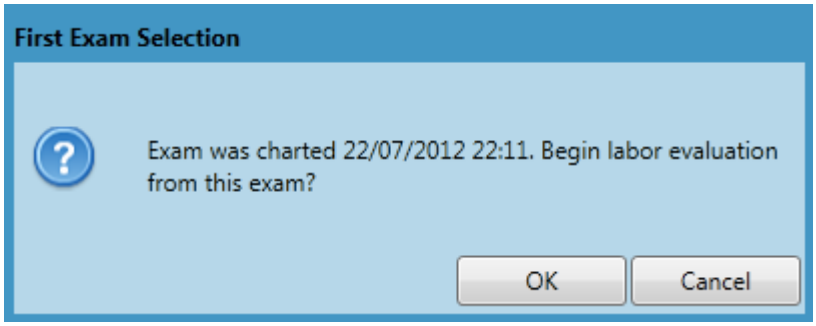
Any specific vaginal exam can be designated as the starting point for the labor evaluation using **PeriCALM Curve**. If no specific exam is explicitly designated as the "First Exam", the system will use the earliest recorded examination to begin labor evaluation by default.

6.2.1. Selecting a First Vaginal Exam for Labor Evaluation

To set the first exam, follow these steps:

1. Click on the specific exam's observed time header 

.
2. A confirmation dialog is opened.

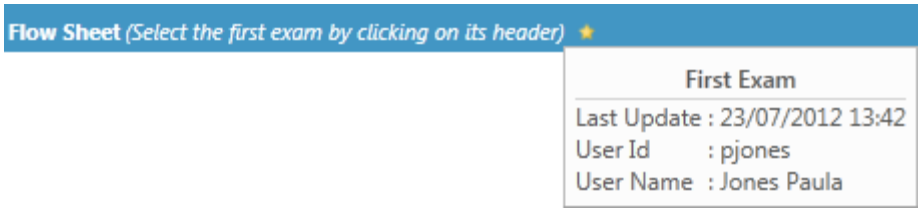


3. Select "OK" to confirm or "Cancel" to abort the action.

6.2.2. Viewing Audit Information

Once the beginning of the labor evaluation is identified with a first exam, a star marker icon ★ is displayed next to the flow sheet's title.

Information is recorded with the date and time the first exam was last selected and the identity of the person carrying out that action. That audit information can be displayed in a tool tip by hovering the mouse over the star marker icon.



6.3. Exams Display

Exams taken into account for the **PeriCALM Curve** calculation are displayed with a white background color.

6.3.1. First Exam

The selected first exam is identified in the flow sheet with a light yellow background color.

	22/07/2012 22:11
Dilation	3
Effacement	10
Station	-4
Fetal Presentation	Cephalic
Fetal Position	LOA
Percentile	
Contraction Interval (last 30 mins)	6 mins

6.3.2. Disregarded Exams

Exams not associated with the colored **PeriCALM Curve** progression band graph are shown with a grey background color.

The following exams fall into this category:

- Exams before the first exam;

	22/07/2012 20:11	22/07/2012 21:11	22/07/2012 22:11	22/07/2012 23:11	23/07/2012 00:11
Dilation	3	3	3	3	4
Effacement	10	10	10	15	25
Station	-4	-4	-4	-4	-3
Fetal Presentation	Cephalic	Cephalic	Cephalic	Cephalic	Cephalic
Fetal Position	LOA	LOA	LOA	LOA	LOA
Percentile				60.9	82.9
Contraction Interval (last 30 mins)			6 mins		

- Exams with dilation values below 3 cm, even after the first exam;

	22/07/2012 19:11	22/07/2012 20:11	22/07/2012 21:11
Dilation	2	2	3
Effacement	0	10	10
Station	-5	-4	-4
Fetal Presentation	Cephalic	Cephalic	Cephalic
Fetal Position	LOA	LOA	LOA
Percentile			79.9
Contraction Interval (last 30 mins)			7.5 mins

- Exams with dilation values of 10 cm, once the Dilatation has reached 10 cm;

	23/07/2012 13:11	23/07/2012 14:11
Dilatation	10	10
Effacement	70	75
Station	1	1
Fetal Presentation	Cephalic	Cephalic
Fetal Position	LOA	LOA
Percentile	94.2	
Contraction Interval (last 30 mins)	6 mins	

6.3.3. Considered Exams

Exam data taken into account in the calculation are validated against the **PeriCALM Curve** prerequisite conditions.

- An information icon in the exam's header identifies that the exam is not displayed with its percentile ranking, however the data is used in subsequent evaluations. A detailed message can be displayed in a tool tip by hovering the mouse over the information icon.

	22/07/2012 20:11
Dilation	
Effacement	
Station	-5
Fetal Presentation	Cephalic
Fetal Position	LOA
Percentile	
Contraction Interval (last 30 mins)	

Dilation is below 3.0 cm.

- A warning icon in the exam's header indicates that the exam contains invalid or missing values. The **PeriCALM Curve** calculation cannot proceed. A detailed message can be displayed in a tool tip by hovering the mouse over the warning icon.

	22/07/2012 21:11
Dilation	
Effacement	
Station	
Fetal Presentation	Cephalic
Fetal Position	LOA
Percentile	
Contraction Interval (last 30 mins)	

Station is missing.
Dilation has descended.
Dilation is below 3.0 cm.

7. Prerequisite Conditions

The PeriCALM Curve calculations and associated labor progress messages will function only when a complete set of required information is available and certain prerequisite conditions are met as described in the tables below.

The following table lists the required basic data to verify that the mother is eligible for analysis and to determine which comparison profile is appropriate.

FIELD	CONDITION
Estimated Delivery Date (EDD)	There must be a specified date in order to determine the patient's gestational age.
Gestational Age	Gestational age must be 35 weeks or more.
Parity	A value must be entered.
First Vaginal Delivery?	A value must be entered.
Attempted VBAC?	A value must be entered.
Number of Fetuses	**PeriCALM Curve** calculations are performed only for singleton pregnancies.

The following table lists the necessary data in the Pelvic exams flow sheet for the **PeriCALM Curve** calculation.

FIELD	CONDITION
Presentation (required)	**PeriCALM Curve** calculations are performed only when the presentation is Cephalic.
Dilation (required)	**PeriCALM Curve** will not provide assessments for cervical dilations that are under 3 cm.
Effacement (required)	A value must be entered.
Station (required)	A value must be entered.
Epidural (optional)	The system will default to no Epidural unless a specific value is entered.

The following table lists other conditions that are necessary to the **PeriCALM Curve** calculation.

CONDITIONS	DESCRIPTION
Data from at least two pelvic exams must be entered after and including the first exam.	**PeriCALM Curve** calculations assess progress in dilation from the previous examination. Thus an evaluation is possible only after two or more validated examinations with one at 3 cm or more have been entered. A percentile ranking will appear in the table.
Contractions must be present.	Calculations will appear only when contractions have been detected subsequent to the exam set as the beginning point of labor evaluation (first exam).

Some conditions will cause the **PeriCALM Curve** to disappear. This usually arises when incomplete or conflicting data has been entered. Refer to the following section for troubleshooting options.

7.1. Troubleshooting When the PeriCALM Curve Does Not Appear or Has Disappeared

7.1.1. Labor Progress Messages

To help you understand why **PeriCALM Curve** has not produced a calculation, specific messages appear in the **Labor Progress Message** box following *"The comparison curves will not be calculated until these issues have been resolved:"*.

The following table lists those messages, the reason for the issue and how to correct it.

LABOR PROGRESS MESSAGE	REASON
The patient's parity has not been entered.	There is no value for Parity for this patient. Correct this by charting a value for Parity.
The Number of Fetuses is not set to Singleton.	This is a multiple gestation. The number of fetuses entered is more than 1.
The EDD has not been entered.	The Estimated Delivery date is missing for this patient. Correct this by charting a value for EDD.
Gestational Age is below 35 weeks.	The calculated Gestational Age is below 35 weeks. It is too early in the pregnancy to use **PeriCALM Curve**.
The Attempted VBAC option has not been entered.	The value for Attempted VBAC is not set for this patient. Correct this by selecting the appropriate option for Attempted VBAC.
The First Vaginal Delivery option has not been entered.	The value for First Vaginal Delivery is not set for this patient. Correct this by selecting the appropriate option for First Vaginal Delivery.

Insufficient number of applicable vaginal exams.	Correct this by charting additional pelvic exams for the patient.
Dilation is missing from one or more exams.	There is at least one pelvic exam missing a value for dilation. Correct this by editing or striking out the incorrect pelvic exam(s).
Effacement is missing from one or more exams.	There is at least one pelvic exam missing a value for Effacement. Correct this by editing or striking out the incorrect pelvic exam(s).
Station is missing from one or more exams.	There is at least one pelvic exam missing a value for Station. Correct this by editing or striking out the incorrect pelvic exam(s).
Presentation is missing from one or more exams.	Fetal presentation was not entered. Correct this by editing or striking out the incorrect pelvic exam(s).
Not all Presentations are Cephalic.	There is at least one Fetal Presentation entered or propagated that is not Cephalic. If applicable, correct this by editing or striking out the incorrect pelvic exam(s).
Dilation has descended.	A dilation value has decreased when compared to previous entries. If this was done in error, correct this by editing or striking out the incorrect pelvic exam(s). Note: Decrease in dilation may result from the development of edema. **PeriWatch Curve** will not work with edema.
No contractions have been detected since the first exam.	No contractions were detected in-between exams. This will disappear if the mother is having contractions that are detected by **PeriCALM Patterns**.
Dilation is invalid in one or more exams.	At least one value of dilation is not within the acceptable range of 0 cm to 10 cm. Correct this by editing or striking out the incorrect pelvic exam(s).
Effacement is invalid in one or more exams.	At least one value of Effacement is not within the acceptable range of 0% to 100%. Correct this by editing or striking out the incorrect pelvic exam(s).
Station is invalid in one or more exams.	At least one value of Station is not within the acceptable range of -5 to +5. Correct this by editing or striking out the incorrect pelvic exam(s).
The patient's parity must be at least 1 if this is not a VBAC attempt and the patient has had at least one previous vaginal delivery.	The selected combination of Parity, Attempted VBAC and First Vaginal Delivery is not acceptable. Correct this by editing the selected options for Parity, Attempted VBAC and/or First Vaginal Delivery.

The patient's parity must be at least 1 if this is a VBAC attempt and the patient has never had previous vaginal deliveries.	The selected combination of Parity, Attempted VBAC and First Vaginal Delivery is not acceptable. Correct this by editing the selected options for Parity, Attempted VBAC and/or First Vaginal Delivery.
The patient's parity must be 0 if this is not a VBAC attempt and the patient has never had previous vaginal deliveries.	The selected combination of Parity, Attempted VBAC and First Vaginal Delivery is not acceptable. Correct this by editing the selected options for Parity, Attempted VBAC and/or First Vaginal Delivery.
The patient's parity must be at least 2 if this is a VBAC attempt and the patient has had at least one previous vaginal delivery.	The selected combination of Parity, Attempted VBAC and First Vaginal Delivery is not acceptable. Correct this by editing the selected options for Parity, Attempted VBAC and/or First Vaginal Delivery.
The patient's parity is invalid.	The value of Parity is not equal or greater than 0. Correct this by editing the value of Parity.

7.1.2. Specific Pelvic Exam Messages

To help identify the reason that an exam may result in failure of displaying the **PeriCALM Curve** calculation, specific messages can be viewed by hovering the mouse over Warning or Information icons in the headers of the pelvic exams.

The following table shows those exam specific messages.

PELVIC EXAM MESSAGE	REASON
Dilation is missing.	The Pelvic exam is missing a Dilation value.
Effacement is missing.	The Pelvic exam is missing an Effacement value.
Station is missing.	The Pelvic exam is missing a Station value.
Presentation is missing.	The Pelvic exam is missing a Fetal Presentation value.
Presentation is not Cephalic.	The Fetal Presentation entered or propagated in that exam is not Cephalic.
Dilation has descended.	The Dilation value has previously reached 3 cm, but has decreased when compared to previous entries.
Dilation is below 3.0 cm.	The Dilation value has not yet reached 3 cm.
Dilation must be between 0 cm and 10.0 cm.	The Dilation value for this exam is not within the acceptable range.
Effacement must be between 0% and 100%.	The Effacement value for this exam is not within the acceptable range.
Station must be between -5 and +5.	The Station value for this exam is not within the acceptable range.

7.2. Indicators of a Successful Calculation

If the prerequisite conditions are satisfied, the following indicators will confirm that the **PeriCALM Curve** calculations were performed successfully:

- A percentile ranking will appear in the **Percentile** row in the vaginal exams flow sheet.
- One of the following **PeriCALM Curve** status messages will appear in the **Labor Progress Message** box:

LABOR PROGRESS MESSAGES
Dilation pattern is within expected range.
Dilation is over the upper percentile limit.
Dilation pattern is within the dystocia zone. Dilation remains at x cm for y.y hrs. Last percentile ranking is z.z%.
Labor progress is slow. However the patient has not reached the duration criteria for dystocia. Last percentile ranking is z.z%.
Dilation pattern demonstrates a lack of progress, remaining unchanged for x.x hrs. However the patient has not reached the percentile criteria for dystocia. Last percentile ranking is z.z%.

8. Using PeriCALM Curve

8.1. Dystocia Conditions

- The **Dystocia** message will appear when 3 conditions are met.
  - There has been an arrest of dilation for a specified period of time AND
  - The last percentile ranking falls below a specified level AND
  - Dilation has reached 3 cm or more.
- The specified period of arrest of dilation and percentile ranking level that will trigger a **Dystocia** message are chosen by your institution and configured in the software setup at the time of the installation of **PeriCALM Curve**. These parameters will remain in effect for all patients unless there is a change made to the system configuration. Available choices are 2, 3 or 4 hours for duration of arrest and 3rd, 5th and 10th for percentile thresholds.
- The **Dystocia** message for women undergoing a trial of labor after a previous cesarean section is based on the same factors; however, the thresholds that trigger the **Dystocia** message may be set to different values at the time of the system configuration.

8.2. Important Notes

PeriCALM Curve does not make predictions for the future or indicate the chances of having a vaginal delivery or chances of having a cesarean.

The model requires that the patient's contractions be monitored by electronic fetal monitoring (external is adequate).

- **PeriCALM Curve** is not intended to be used in the second stage of labor, with twins, with any non-vertex presentation or before the 35th week of gestation.
- Changes in cervical dilation and the **PeriCALM Curve** are not the only indicators of labor progress. Clinicians should also consider all other clinically relevant information.
- None of the information generated within **PeriCALM Curve** will update the patient record in the hosting clinical system. **PeriCALM Curve** only reads information from the hosting system.
- By selecting the hosting system's configured link or menu item, **PeriCALM Curve** will be launched for the currently selected patient and will use the currently logged-in user credentials to track changes.

A modification to a patient's admission or pelvic exams data in the hosting system will require up to 60 seconds to be reflected in **PeriCALM Curve**.

- User charted data in **PeriCALM Curve**, such as the **Labor Comparison** profile and first exam selection, can only be viewed within a period of time after the patient is discharged, as they are permanently deleted after a configurable number of hours (usually 72 hours after discharge).
- **PeriCALM Curve** provides no print or archiving capability in this version of the software.