PeriGen, Inc.

PeriWatch™ Curve™ User Guide

Version 02.08.02

Record ID: PATT 020802 - DMR-2771

Revision: 01.00 Issued: 2017-10





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Release date



2017-10

Product

PeriWatch Curve 02.08.02

Publication number

PATT 020802-DMR-2771

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Reader comments

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Trademarks

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Intended Use

PeriWatch 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 PeriWatch software suite are subject to issued and pending patents in several jurisdictions. Issued patents include:

USA	6,907,284
USA	7,113,819
USA	6,423,016
European Patent	1,505,903
European Patent	1,289,416
Canada	2,311,029



 Canada
 2,384,516

 Canada
 2,379,733



Table of Contents

1. About PeriGen	5
2. This Guide	6
2.1. Versions	6
2.2. Conventions	6
2.3. Additional Documentation	6
3. Overview	7
3.1. The PeriWatch Curve Screen	8
4. Patient Information Banner	9
4.1. The Patient Data Fields	
4.2. The Labor Comparison Profile Message	9
5. Labor Progress Assessment Module	10
5.1. The Labor Progress Message	
5.2. The Labor Progress Graph	10
5.3. Graphical Elements on the Labor Progress Graph	10
5.3.1. Dilation Curve	
5.3.2. Station Graph	
5.3.3. Exam Details Display on Graph	
5.3.4. Percentile Limits	
5.3.5. Reference Range	
6. Vaginal Exams	
6.1. Flow Sheet of Vaginal Exams	
6.2. First Vaginal Exam	
6.2.1. Selecting a First Vaginal Exam for Labor Evaluation	
6.3. Exams Display	
6.3.1. First Exam	
6.3.2. Disregarded Exams	
6.3.3. Considered Exams	
7. Prerequisite Conditions	17
7.1. Troubleshooting When the PeriWatch Curve Does Not Ap	pear or Has
Disappeared	
7.1.1. Labor Progress Messages	
7.1.2. Specific Pelvic Exam Messages	
7.2. Indicators of a Successful Calculation	
8. Using PeriWatch Curve	
8.1. Dystocia Conditions	
8.2. Important Notes	22



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, PeriWatch™ Cues™ 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 PeriWatch Curve User Guide is provided to the user:

- As a hard copy,
- As a PDF (Portable Document Format) file available in the PeriWatch Cues 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.

D-11	The sales the set of the		
Bold	Used to identify view i	nenus, 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 quide.

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

- PeriWatch Cues User Guide Provides information about using the PeriWatch Cues application.
- PeriWatch Cues Release Notes Provides information on what is new in this release and the application's limitations.
- PeriWatch Curve Release Notes Provides information on what is new in this
 release and the application's limitations.
- PeriWatch Curve integrates with PeriWatch Tracings. For further information on features of PeriWatch Tracings, see the PeriWatch Tracings user guide.



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 **PeriWatch 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.



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

The **PeriWatch 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, **PeriWatch Curve** reexamines these factors and updates its calculations.

PeriWatch 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 **PeriWatch Curve** screen, in addition to the conditions and data elements required for the calculations.



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

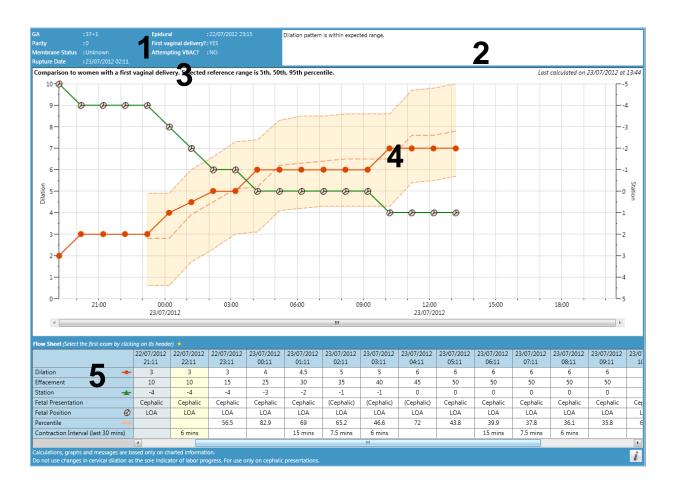


3.1. The PeriWatch Curve Screen

The PeriWatch 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 **PeriWatch 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.





4. Patient Information Banner

4.1. The Patient Data Fields

Patient information is displayed in the Patient Information Banner. These fields are readonly because the information comes from the medical record.

GA

This field indicates the patient's Gestational Age.

Parity

This field indicates the patient's Parity.

Membrane Status

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

Rupture Date

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

Epidural

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

First Vaginal Delivery

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

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. Based upon the value of this field, the message above the labor graph will change.

4.2. The Labor Comparison Profile Message

The reference population selected for comparison and the site-selected **PeriWatch Curve** reference range (see <u>Reference Range</u>) 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

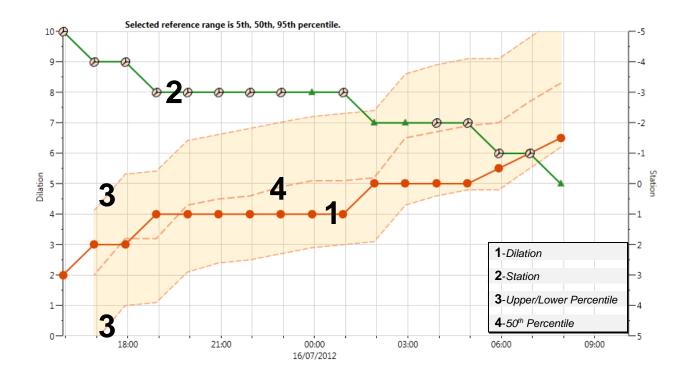
The **Labor Progress Message** provides advisory messages about the status or errors associated with the **PeriWatch Curve** definitions. See <u>Prerequisite Conditions</u> chapter for details.

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

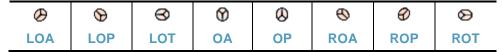
The Dilation curve plots a patient's dilation values recorded in the **Dilation** row on the patient's exams flow sheet. The Dilation curve is displayed in a dark orange color and each dilation value is identified with a dark orange circle mark.

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.



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 **PeriWatch 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 **PeriWatch 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						
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 **PeriWatch Cues**.

6.2. First Vaginal Exam

Any specific vaginal exam can be designated as the starting point for the labor evaluation using **PeriWatch 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.

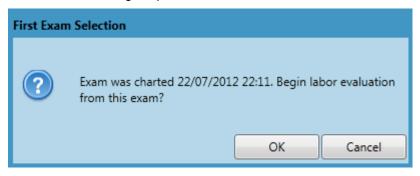


6.2.1. Selecting a First Vaginal Exam for Labor Evaluation

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 $\stackrel{\checkmark}{\sim}$ 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 **PeriWatch 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 **PeriWatch 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 <u></u>	-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;

	0 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



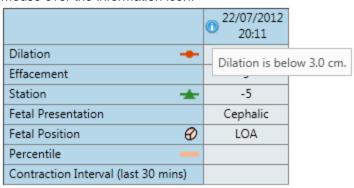
• Exams with dilation values of 10 cm, once the Dilatation has reached 10 cm;

	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	

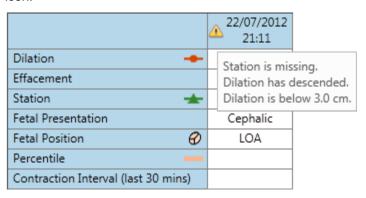
6.3.3. Considered Exams

Exam data taken into account in the calculation are validated against the **PeriWatch 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.



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





7. Prerequisite Conditions

The PeriWatch 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	PeriWatch Curve calculations are performed only for singleton pregnancies.

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

FIELD	CONDITION
Presentation (required)	PeriWatch Curve calculations are performed only when the presentation is Cephalic.
Dilation (required)	PeriWatch 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 **PeriWatch Curve** calculation.

CONDITIONS	DESCRIPTION
Data from at least two pelvic exams must be entered after and including the first exam.	PeriWatch 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 **PeriWatch 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 PeriWatch Curve Does Not Appear or Has Disappeared

7.1.1. Labor Progress Messages

To help you understand why **PeriWatch 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 PeriWatch 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 PeriWatch Cues .
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 **PeriWatch 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 **PeriWatch Curve** calculations were performed successfully:

- A percentile ranking will appear in the **Percentile** row in the vaginal exams flow sheet.
- One of the following PeriWatch 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 PeriWatch 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 **PeriWatch 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



PeriWatch 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).

- **PeriWatch 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 PeriWatch Curve are not the only indicators of labor progress. Clinicians should also consider all other clinically relevant information.
- None of the information generated within PeriWatch Curve will update the patient record in the hosting clinical system. PeriWatch Curve only reads information from the hosting system.
- By selecting the hosting system's configured link or menu item, PeriWatch 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 **PeriWatch Curve**.

 User charted data in PeriWatch 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).



• PeriWatch Curve provides no print or archiving capability in this version of the software.