

SONICAID FETALCARE
CLINICAL APPLICATION GUIDE

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Sonicaid™ Fetalcare Clinical Application Guide

Preface

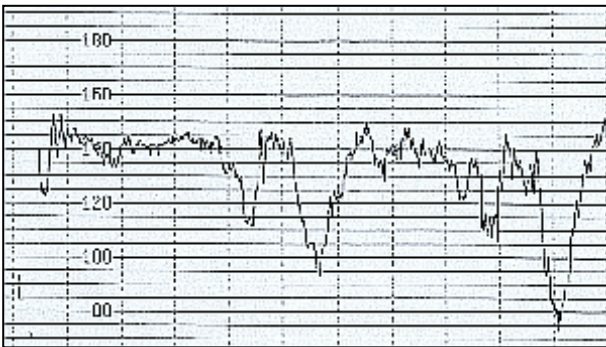
Advances in technology over the past 30 years now enable us to assess fetal health using safe and non-invasive ultrasound techniques. One such technique is fetal heart rate monitoring, and in pregnancies where there is fetal compromise the fetal heart rate contains crucial information with regard to the optimum timing of delivery. The features of the fetal heart rate are well understood, but numerous studies have shown that expert assessment of traces is prone to inconsistency. In addition, when junior or inexperienced staff review traces important features may not be noticed with the danger that critical decisions are delayed. Computer analysis of the fetal heart rate using Sonicaid FetalCare or the Care analysis built into Sonicaid fetal monitors is therefore a welcome and much-needed way of standardising interpretation to the highest standards. Such analysis, while not a substitute for clinical judgement, captures an enormous amount of clinical experience and in effect brings it to the bedside. This booklet provides some background to Sonicaid FetalCare and explains how it works and why it is useful. I hope you will find it interesting reading.

Professor C W G Redman

Oxford, UK, August 2003

Introduction

The visual assessment of an antepartum fetal heart rate (FHR) trace requires a trained individual to look at the trace, mentally fit a baseline to it, and then ask a number of questions: Are there any accelerations? Is the basal heart rate okay, and does the trace have good variability? Or are there decelerations? Is the basal heart rate too high or too low, or does the trace look a bit flat? Depending on the answers to these questions an opinion is formed as to whether the trace is reassuring or a cause for concern. In most cases this is sufficient because the baby is fine. But subjective assessments such as these are intrinsically unreliable and problems can, and sometimes do, arise. The person assessing the trace may be tired, stressed, or inexperienced. Misinterpreting traces can lead to intervention when it is not needed or, worse still, no intervention when it is urgently needed.



There is no doubt that looking at a trace and forming an opinion of it is useful, but what if we also took measurements? Could this help us to diagnose those tricky, borderline, or rare traces? This was the question that in 1977 Professors Dawes and Redman at Oxford University in the UK set out to investigate. Using a database of 8,000 traces linked to outcome their research led to the development of a computer system for the analysis of antepartum traces, and in 1989 this was released as the Sonicaid System 8000. Over the next five years the database was increased to 48,339 traces and in 1994 an improved version called the Sonicaid System 8002 appeared. Since then the database has increased to 73,802 traces and continued research has made the analysis even more powerful. It is now called Sonicaid FetalCare. The purpose of this booklet is to explain how FetalCare works and why it is useful.

How FetalCare works

Fitting a baseline

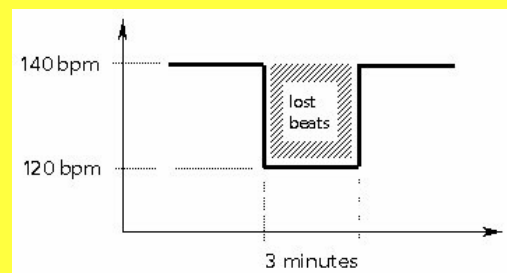
The first thing FetalCare does when analysing a trace is fit a baseline to it. The baseline is a time-varying line that shows what the resting fetal heart rate is, or would be if accelerations and decelerations are excluded. There is no gold standard for fitting a baseline, so FetalCare puts the baseline where human experts would typically place it by eye.

Accelerations and decelerations

Once FetalCare has fitted a baseline to the trace it identifies any accelerations or decelerations that are present and measures their size. The size of a deceleration is expressed in 'lost beats' as explained in the box below.

Measuring the size of a deceleration

Consider the 'square' deceleration shown below, in which a fetal heart is beating at 140 bpm, drops suddenly to 120 bpm for 3 minutes, and then returns to 140 bpm again.



If the heart rate had stayed at 140 bpm then in 3 minutes there would have been $3 \times 140 = 420$ heartbeats. However, because of the deceleration there were only $3 \times 120 = 360$ beats. So 420 heartbeats were expected but only 360 occurred, and we say that the size of the deceleration is $420 - 360 = 60$ lost beats.

Long-term variation

The long-term variation (LTV) is a measure of the minute-by-minute 'macro' fluctuations of the FHR around the baseline. The FHR values are initially represented as pulse intervals (see box at the top of the next page) and then converted into beats per minute (bpm). To measure LTV FetalCare finds the highest and lowest FHR in each minute relative to the baseline. The difference between these values is the minute range. For example, if in one minute the FHR varies between 120 bpm and 150 bpm then the equivalent pulse intervals are 500ms and 400ms respectively and the minute range is 100ms.

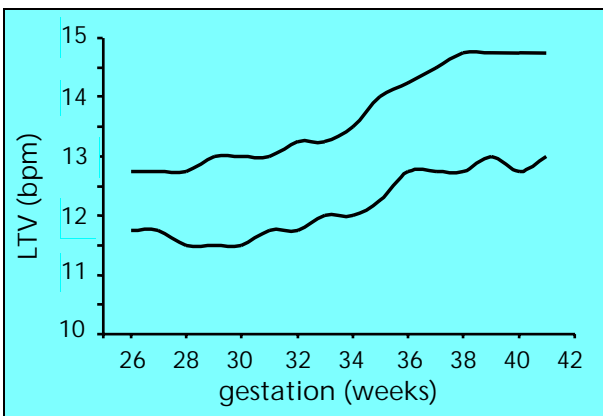
What is a pulse interval?

The time between two consecutive fetal heartbeats is called a pulse interval and is measured to an accuracy of 1/1000th of a second, or one millisecond (ms). As the fetal heart rate increases the pulse interval gets shorter, as demonstrated in these examples:

heart rate (bpm)	pulse interval (ms)
60	1000
80	750
120	500
150	400

If the heart rate is 120 bpm then the heart beats every 0.5 seconds and the pulse interval is 500ms. If the heart rate increases to 150 bpm then a heart beat occurs every 0.4 seconds and the pulse interval is 400ms.

If the minute range exceeds 32ms for at least 5 out of 6 consecutive minutes then FetalCare marks this as the start of an episode of high variation. The episode continues for as long as this 5-out-of-6-minute rule is met, and ends when it is no longer met. The average minute range for the episode is then compared against a threshold calculated from the 73,802 traces in the FetalCare database. If it exceeds this threshold then the episode of high variation is confirmed and the trace is considered reactive. This definition of reactivity is unique in two respects: first, the threshold varies according to the gestational age of the fetus as shown in the box below; and second, it does not depend on the presence of accelerations, as these are not always present in traces from healthy fetuses. Other definitions of reactivity typically require two or more accelerations within a given time.



Short-term variation

The short-term variation (STV) is a measure of the 'micro' fluctuations of the FHR that are

much shorter than the macro fluctuations measured by LTV. STV cannot be measured by eye, but FetalCare can measure it, as described in the box below. STV is a very important parameter for two reasons. Firstly, it does not depend on the baseline – unlike accelerations, decelerations, and LTV – so it is valid even in those tricky traces where a baseline is difficult to fit, either by eye or by computer. And secondly, in the absence of an episode of high variation (a non-reactive trace) low STV is strongly linked to the development of metabolic acidemia and impending intrauterine death^{1,2}.

How is STV measured?

FetalCare measures STV by dividing each minute of the trace into 16 sections. Each section is 3.75 seconds long and typically contains about 7–10 fetal heartbeats, or 6–9 pulse intervals. The average pulse interval in each section is calculated, and the change in these average values from one section to the next determines the STV. The use of 3.75 seconds is not a magic number; it is simply that division by 2, 4, 8, 16, etc., is very fast on a computer, and 3.75 seconds is 1/16th of a minute.

In healthy fetuses STV increases with gestation³.

Basal heart rate

The basal heart rate, in bpm, is the average fetal heart rate during the trace when accelerations and decelerations are excluded. FetalCare checks that the basal heart rate is in the normal range, which for antepartum traces is 116–160 bpm. An abnormal basal heart rate is usually due to an arrhythmia, although a sustained tachycardia may indicate fetal infection or maternal pyrexia, while a sustained bradycardia is sometimes seen prior to fetal death and requires immediate investigation. However, in compromised fetuses it is not uncommon for the basal heart rate to be normal, so its value is usually of secondary importance compared to other parameters such as STV. In healthy fetuses the basal heart rate decreases with gestation³.

Sinusoidal rhythm

FetalCare also checks that there is no evidence of a sinusoidal rhythm. This is a rare but important pattern in which the FHR trace oscillates smoothly up and down. A slow sinusoidal rhythm of one oscillation every 2–5 minutes, in conjunction with low STV, indicates pathology and poor fetal outcome. A fast sinusoidal rhythm (or sawtooth pattern) of 2–5 oscillations per minute may indicate fetal

anaemia due to Rhesus isoimmunization, fetal intracranial haemorrhage, or fetal-maternal haemorrhage⁴.

The Rules of FetalCare

Once FetalCare has analysed the trace and measured all the parameters described above, it is in a position to report its findings. However, simply presenting a list of numbers and measurements would be of limited use and may confuse more than it clarifies. What is required is a way of distilling all this information into a bottom line which states whether the trace is reassuring and can be stopped, or whether it is non-reassuring and should be continued. To do this FetalCare uses a number of rules that for historical reasons were known as the Dawes/Redman criteria. These rules take into account the standard features of visual assessment – such as accelerations, decelerations, and basal heart rate – as well as those parameters which are difficult or impossible to measure visually, such as STV, sinusoidal rhythm, and the number of minutes of high variation. Some of the rules are quite simple and some are more complex and mathematical⁵ but what they look for can be broadly summarised as follows:

- STV of 3ms or greater
- No evidence of a sinusoidal rhythm
- At least one episode of high variation
- No large or repeated decelerations
- Accelerations and / or fetal movements
- No evidence of a baseline misfit
- A normal basal heart rate (if the trace is short)

The important point about these rules is that they take into account all the measurements described above and not just visual features. With FetalCare we are now able to start a trace, start the analysis, and after ten minutes look at the results to see what the bottom line says: 'Criteria Met' or 'Criteria Not Met'.

Criteria Met

If FetalCare has found enough evidence that the trace is reassuring then it will report 'Criteria Met' and monitoring can be stopped. There is no real need to look at the numbers and measurements themselves as FetalCare has already checked that they are all normal; hence 'Criteria Met' – the trace is reassuring.

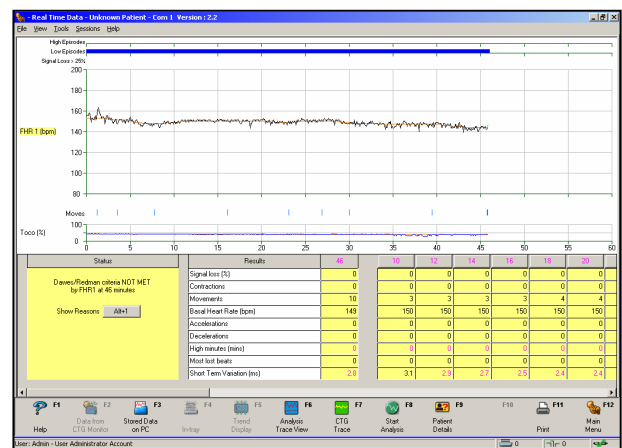
Criteria Not Met

If FetalCare has not found sufficient evidence of normality then it will report 'Criteria Not Met'

and recommend that monitoring be continued. After the first analysis at ten minutes the trace is re-analysed every two minutes, so it is important to continue monitoring to see whether 'Criteria Met' is eventually reported.

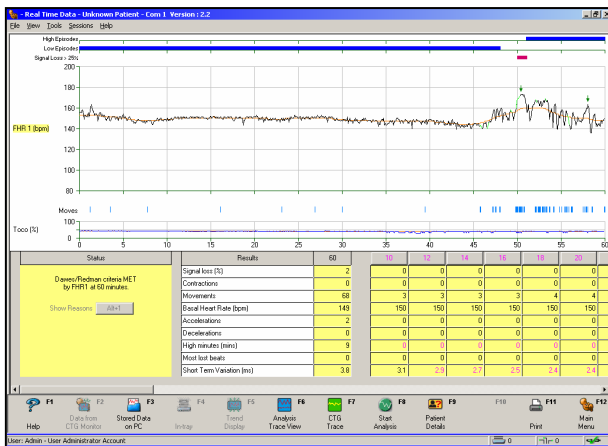
How long should we monitor for?

From about 28 weeks gestation a healthy fetus cycles between episodes of active and quiet sleep. Active sleep is associated with accelerations, increased FHR variation and clusters of fetal movements, so the appearance of these features – a reactive trace – is a primary indication of fetal wellbeing. Quiet sleep is associated with reduced variation and reduced fetal movements, so during quiet sleep it is not possible to assess fetal wellbeing. This is because the non-reactive trace of a healthy fetus in quiet sleep is indistinguishable from the trace of a compromised fetus. To make the distinction monitoring must continue until a time when we would expect to see the appearance of a reactive trace, but this time will vary depending on the point in the fetal sleep cycle at which monitoring begins. Episodes of quiet sleep can last for up to 50 minutes, so if the start of monitoring coincides with the start of quiet sleep it may be up to 50 minutes before a reactive trace starts to appear. However, if the same fetus is monitored again later the same day it may already be in active sleep and a 10–15 minute trace will be sufficient to confirm reactivity. A study of over one thousand traces⁶ concluded that a reactive trace is indicative of fetal wellbeing irrespective of the time required to detect reactivity, up to a limit beyond which it becomes abnormal that the trace is not reactive. In FetalCare this limit is set to 60 minutes for the reasons given above.



The trace shown above was recorded at 36 weeks gestation and has been running for

about 45 minutes. But is it reassuring or not? If the trace is stopped at this point FetalCare reports 'Criteria Not Met', STV less than 3ms, no episode of high variation, and no accelerations. However, if monitoring is continued, as shown below, the trace finally becomes reactive and FetalCare reports 'Criteria Met'. But this only happens during the final 10–12 minutes, so stopping prematurely would have led to an incorrect assessment.



Again, once the criteria are met the actual numbers and measurements do not need to concern us. Only if FetalCare is still reporting that the criteria are not met at 60 minutes does it make sense to look at the numbers and start considering what may be amiss.

FetalCare in Practice

Indications for monitoring

Typical indications for fetal heart rate monitoring, irrespective of whether we are using FetalCare or not, are as follows:

- reduced fetal movements
- intrauterine growth restriction
- antepartum haemorrhage
- twins
- uterine pain
- hypertension or pre-eclampsia
- reduced amniotic fluid volume
- abnormal umbilical artery Doppler velocimetry
- suspected fetal anomalies
- suspicion of substance or alcohol abuse
- maternal accident or injury
- previous questionable FHR traces
- poor obstetric history

What FetalCare can and cannot tell us

Some of the things FetalCare can tell us are listed below.

- The fetus is acidaemic or hypoxic
- The fetus is anaemic
- The fetal central nervous system is impaired
- The fetus may have an infection
- The fetus has an arrhythmia
- Further investigation is required

However, even a normal trace does not give an absolute guarantee that a fetus is safe. A woman may present with reduced fetal movements and a trace is done which seems normal, but hours later an intrauterine death occurs. Fortunately this is rare, but that is of no consolation to those involved in such a tragic event. Both staff and mother may feel the trace should have warned them, but this perception is incorrect. A reassuring trace cannot anticipate a placental abruption that happens some time later, without warning, and with devastating suddenness. Neither a human expert nor FetalCare can predict such catastrophes. But in pregnancies affected by conditions such as placental insufficiency, where the deterioration is gradual, FetalCare can help us to predict when delivery is likely to become necessary.

The importance of STV

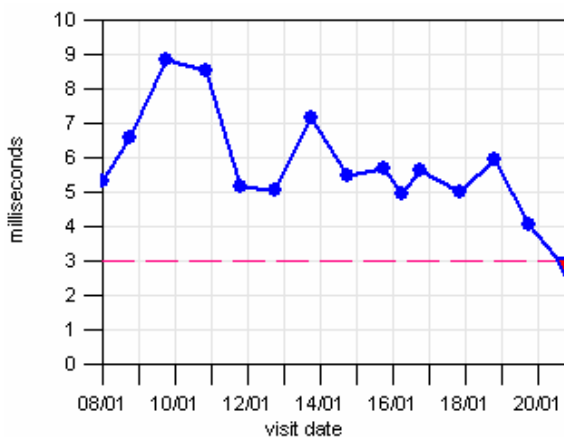
The importance of STV was established in two studies of compromised babies where traces were obtained within the 24 hours prior to intrauterine death (IUD) or delivery by caesarean section without labour^{1,2}. The table below shows the outcomes for these pregnancies. When the STV was less than 2.6ms there was a dramatic increase in the likelihood of metabolic acidaemia (as defined by an umbilical artery blood pH less than 7.12 and base deficit greater than 12mmol/L) or intrauterine death.

STV (ms)	<2.6	2.6–3.0	>3.0
Gestation (weeks)	25–38	26–38	27–37
Metabolic acidaemia	10.3%	4.3%	2.7%
IUD	24.1%	4.3%	0.0%

This is a key finding because with STV FetalCare is not just doing what the human eye does. FetalCare does detect accelerations and decelerations, but we can see those ourselves. However, the human eye cannot detect the precise amount of STV, and it is the precise amount, as the table above demonstrates, which is important.

Using STV to time delivery

One of FetalCare's most powerful features is the ability to plot STV values obtained over a period of days or even weeks and fit a trend line to them. If the trend is downwards it can be used to predict when the STV is likely to drop below 3ms and delivery is likely to become necessary. The example below shows STV values for nine traces recorded from one patient over a six-day period at 31–32 weeks gestation. It was known that intervention was likely to be necessary, and by monitoring the progressive reduction in STV the baby was delivered safely by caesarean section without labour (arterial pH 7.11, base deficit 10.0 mmol/L) shortly after the final trace.



Criteria Not Met for no apparent reason

Sometimes a trace is not right and FetalCare reports 'Criteria Not Met' but we cannot decide what the problem is. This is an indication that further investigation is required. This may mean extending our range of information about the fetus using other tests such as umbilical artery Doppler velocimetry or a biophysical profile. Or it may be as simple as repeating the trace later on. Perhaps this was just a very quiet period for the baby. But if FetalCare still reports 'Criteria Not Met' and all the other tests are normal, then it may be necessary to consider the possibility of impaired brain function. The point here is that there is no substitute for clinical diagnosis, where a conclusion is formed using information gathered from different sources.

A note about corticosteroids

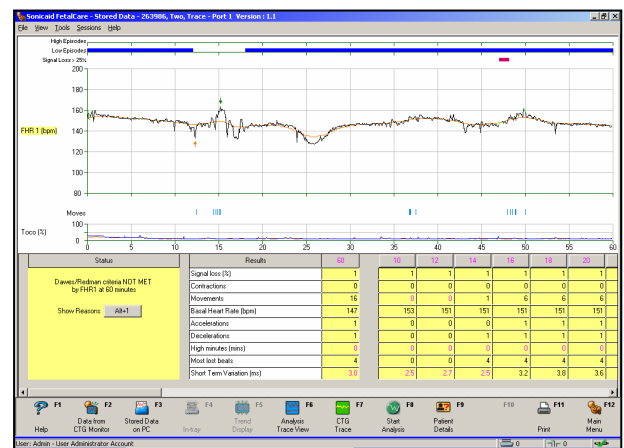
Betamethasone or Dexamethasone may be administered to accelerate fetal lung maturation when there is a risk of premature delivery. During the past decade a number of studies have reported significant changes in FHR variation and fetal movements following steroid administration. Most of these studies reported decreased FHR variation and some reported decreased fetal movements, but they all

reported that the changes returned to their pre-treatment values after treatment was discontinued. It is therefore important that these changes are recognised as a physiological response of the fetus to the corticosteroids. Misinterpreting these changes as a sign of deteriorating fetal condition could lead to the unnecessary delivery of preterm fetuses.

Case Studies

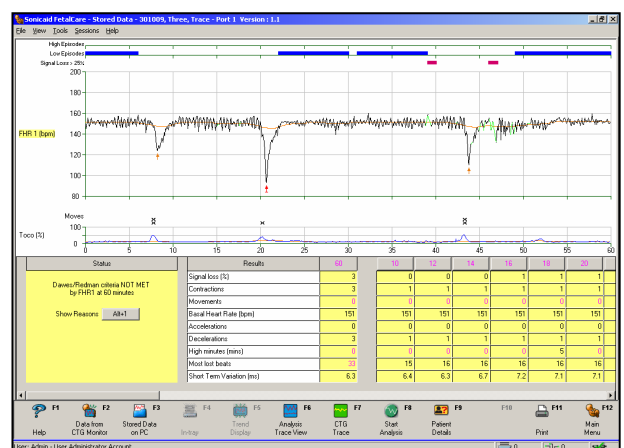
Low STV

The trace shown below was recorded at 34 weeks gestation. FetalCare reported an STV of 3.0ms and the next day the baby was delivered by caesarean section without labour. Acidaemia was confirmed (arterial pH 6.99, base deficit 13.3 mmol/L) and the baby was resuscitated using intermittent positive pressure ventilation.



Sinusoidal rhythm

The trace shown below was recorded at 38 weeks gestation. FetalCare reported a fast sinusoidal rhythm and the baby was delivered less than two hours later by caesarean section without labour (arterial pH 7.19, base deficit 7.0 mmol/L). Thick meconium was noted, fetal-maternal haemorrhage was confirmed (fetal Hb 5.0g / dl), and a blood transfusion was given.



Why use FetalCare?

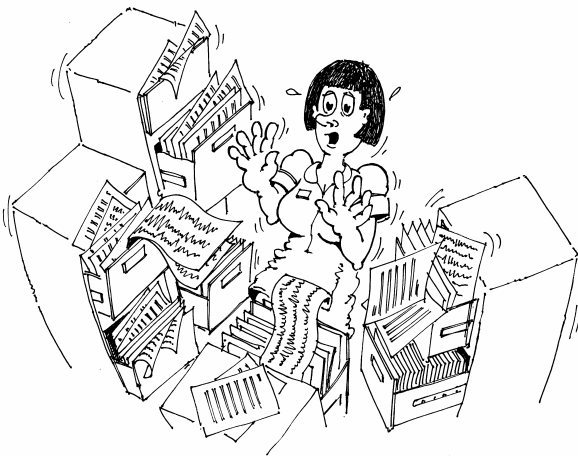
Measurement, not opinion

FetalCare makes measurements. Humans form opinions. So in clinical practice what are the relative merits of measurement and opinion? An opinion could be that a patient looks a bit pale, but is she anaemic? A measurement will tell us. If her haemoglobin is 7.5g / dl then we know she is iron deficient. The measurement has not replaced our clinical skill, but it has helped us to make the correct diagnosis. Similarly, an opinion might be that a fetal heart rate trace is a bit flat. Is this cause for concern? Again, a measurement will tell us. If FetalCare reports 'Criteria Not Met' and the STV is 2.9ms then we know there is a problem.

'The trace is a bit flat.' Numerous studies have shown that opinions on fetal heart rate traces are unreliable. Observers differ from each other, and are not even consistent with themselves. When shown the same trace six months later their opinion has sometimes changed. Opinions are subjective and unreliable while measurements are objective and consistent. So measurements are needed.

Reassurance

There are always borderline traces where a colleague's opinion would be welcome, but a colleague is not always to hand. Is the trace acceptable or not? Do others need to be alerted and further tests conducted? FetalCare provides a second opinion that is backed by a database of 73,802 antepartum traces. It is easier to run a trace through FetalCare than to worry unduly over it.



Short-term variation

FetalCare measures STV, which the human eye cannot do. Low STV is the best predictor of fetal acidemia, and tracking STV changes over time can be crucial for the timing of delivery.

Reduced monitoring times

FetalCare advises staff when monitoring can be safely stopped because a reassuring trace has been obtained. A comparative study of visual assessment versus computer analysis found that average monitoring times were reduced from 35 minutes using visual assessment to 16 minutes using computer analysis⁷.

Staff training

A question that is frequently asked is whether FetalCare is better at assessing traces than a skilled human. The answer is that it is better in some ways and not so good in others. For example, FetalCare can measure STV which a skilled human cannot, but a skilled human can exercise clinical judgment in a way that a computer cannot. However, if we compare FetalCare with less experienced staff then it has two clear benefits. First, it provides an accurate assessment of the trace irrespective of the skill and experience of the operator. The trace itself must be of a reasonable quality, but that is all. And second, by using FetalCare less experienced staff rapidly develop an understanding of what normal and abnormal traces look like. Simply by using FetalCare they quickly gain experience.

Ease of use

FetalCare is simple and easy to use. It is much less complicated than the equipment used in other methods of fetal assessment. And if a trace gives us cause for concern we can repeat it, as often as we like.

Archiving and audit

FetalCare enables traces to be electronically archived for later retrieval and auditing. Are we monitoring for long enough or for too long? Was an abnormal trace missed? This can all be audited.

Intended use

The intended use of Sonicaid FetalCare is for the analysis of antepartum FHR traces in pregnancies from 26 weeks gestation onwards (32 weeks in the USA). It can be used on women who are experiencing Braxton-Hicks contractions but is not intended for use in established labour as the fetus is then exposed to additional factors such as labour contractions, pharmacological agents, and epidural anaesthesia. Sonicaid FetalCare is intended as an adjunct to, and not a replacement for, an expert's visual assessment of an FHR trace. Sonicaid FetalCare is an aid to clinical management but not a diagnosis, which remains the responsibility of an appropriately qualified expert. Both the expert's visual assessment and the analysis provided by Sonicaid FetalCare should be considered within the context of a full clinical assessment before decisions are made regarding management. Such an assessment may include further tests such as umbilical artery Doppler velocimetry or biophysical profiling.

Glossary

Terms in *italics* are defined under their own entry. Some definitions are specific to FetalCare.

Acceleration An increase in *fetal heart rate* above the *baseline* that lasts for more than 15 seconds and has a maximum excursion above the *baseline* of more than 10 bpm.

Basal heart rate The resting *fetal heart rate* when it is not in an *acceleration* or *deceleration*.

Baseline A time-varying line superimposed on a *fetal heart rate* trace to show the resting *fetal heart rate* when *accelerations* and *decelerations* are excluded.

Cardiotocograph (CTG) A trace showing the *fetal heart rate* and uterine contractions.

Dawes / Redman criteria A set of rules used in *Sonicaid FetalCare* to minimise monitoring time by advising staff when monitoring can be stopped because the trace is reassuring.

Deceleration A decrease in *fetal heart rate* below the *baseline* that lasts for more than 60 seconds and has a maximum excursion below the *baseline* of more than 10 bpm, or lasts for more than 30 seconds and has a maximum excursion below the *baseline* of more than 20 bpm.

Fetal heart rate (FHR) The number of times the fetal heart beats in one minute, measured in beats per minute (bpm).

High variation A section of *fetal heart rate* trace in which the *long-term variation* exceeds a pre-defined threshold. This threshold varies with the gestational age of the fetus.

Long-term variation (LTV) The average *minute range* during all or part of a *fetal heart rate* trace.

Lost beats The units of measurement used to describe the size of a *deceleration*.

Minute range The difference in milliseconds between the longest and shortest *pulse intervals* in one minute of a *fetal heart rate* trace.

Non-reactive trace A *fetal heart rate* trace that does not satisfy the definition of a *reactive trace*.

Nonstress test (NST) The name given to an antepartum trace in the United States.

Pulse interval The time in milliseconds between two consecutive fetal heartbeats.

Reactive trace A *fetal heart rate* trace that contains at least one episode of *high variation*.

Short-term variation (STV) The difference in milliseconds between the mean *pulse intervals* in consecutive time periods of 1/16th of a minute, averaged over a *fetal heart rate* trace.

Sinusoidal rhythm A rare FHR pattern in which the trace oscillates smoothly up and down. A slow sinusoidal rhythm may indicate

pathology and poor fetal outcome, while a fast sinusoidal rhythm may indicate fetal anaemia.

Sonicaid System 8000 A computer system for the analysis of antepartum traces that was developed at Oxford University in the UK between 1978 and 1989 using a database of 8,000 antepartum traces and incorporating the *Dawes/Redman criteria*.

Sonicaid System 8002 The upgraded version of the *Sonicaid System 8000* that was developed between 1989 and 1994 using a database of 48,339 antepartum traces.

Sonicaid FetalCare The new improved version of the *Sonicaid System 8002* that uses a database of 73,802 antepartum traces.

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sonicaid™ FetalCare

ANTEPARTUM ANALYSIS



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