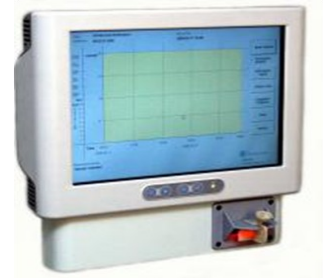


## Amniotic Fluid Lactate™ monitoring system for dysfunctional labour

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The Amniotic Fluid Lactate™ (AFL) monitoring system is designed to aid clinical decisions during dysfunctional labour. It consists of a monitor and a probe which measures the level of lactate in the amniotic fluid. This correlates with lactate levels in the uterus. High uterine lactate levels may indicate that treatment with oxytocin would be less effective and that operative delivery is more likely. The Amniotic Fluid Lactate™ monitoring system is designed to be used on the labour ward.



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Lay Summary**

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### Background

Dysfunctional labour is one of the main reasons for a woman to require intervention such as forceps, ventouse or caesarean section. The definition and diagnosis of dysfunctional labour (also known as delayed, arrested or complicated labour as well as labour dystocia) depends on the stage of labour as well as whether the woman has given birth before. There are three stages of labour; stage one is when the cervix (the neck of the uterus) dilates, the second stage is delivery of the baby and the third stage is delivery of the placenta. A diagnosis of delay in the first stage of labour needs to take into consideration the degree of dilation of the cervix, whether it is a first pregnancy or not, descent and rotation of the fetal head and changes in the strength, frequency and duration of uterine contractions<sup>1</sup>. In the second stage of labour, delayed or dysfunctional labour is diagnosed on the basis of the duration of that stage<sup>1</sup>. Dysfunctional labour may progress to spontaneous vaginal delivery or the woman may require an assisted delivery via forceps, ventouse or caesarean section.

In 2009-10 there were 58,883 diagnoses of delayed first and second stages of labour in England out of a total of 652,377 deliveries (around 9%)<sup>2</sup>. This means 113 women per 100,000 population experienced dysfunctional labour. An average GP with a list of 2,000 people may have two pregnant women who experience dysfunctional labour per year.

Of all deliveries in 2009-10, 24.8% were by caesarean section and 12.8% were instrumental deliveries. During the same year 18,646 women who experienced dysfunctional labour were delivered by caesarean section equalling 12% of all caesarean section deliveries<sup>2</sup>.

### Current Practice

The National Institute of Clinical Excellence (NICE) has produced a guideline on intrapartum care<sup>1</sup>. According to this guideline the use of the hormone oxytocin should be considered for women who have a delay in the first stage of labour after a period of observation and examination by an obstetrician. Monitoring is recommended for women with a delay in second stage of labour with an assisted delivery being performed if the delay continues or if there is concern about fetal

wellbeing. It is clinically difficult to predict how a woman with delayed labour will deliver the baby.

## New Technology

The Amniotic Fluid Lactate (AFL)<sup>™</sup> monitoring system was developed by [ObsteCare AB](#) and is distributed in the UK by [OKB Medical Limited](#) for measuring AFL levels. These are believed to give an indication of how well the uterus will respond to oxytocin or the likelihood of the woman requiring an assisted delivery. The smooth muscle of the uterus normally produces the acidic compound lactate and this production increases as blood flow (and therefore oxygen) to the muscle cell is temporarily reduced during contractions<sup>3</sup>. The resulting increase in acidity in the uterus is believed to reduce the force of further contractions which may lead to dysfunctional labour<sup>4</sup>. A raised level of lactate in the uterus is reflected by the raised level in the amniotic fluid. Therefore it is believed that raised AFL levels are associated with dysfunctional labour, where the muscles of the uterus are unable to contract forcefully enough<sup>5</sup>.

The AFL<sup>™</sup> monitoring system comprises of a stand-alone Lactate Measurement Unit with 15" touch screen and keyboard for input of patient data and partogram parameters (a partogram is a graphical depiction of cervical dilatation and fetal head position against time and its purpose is to identify people at risk of delayed labour). The AFL<sup>™</sup> monitoring system includes a single use sensor probe (to receive an amniotic fluid sample) and an optional intrauterine catheter. The catheter may be used to collect a sample of amniotic fluid from behind the baby's head where it is not free flowing. A sample of 0.25ml of amniotic fluid is needed and results are available in 15 seconds.

The monitoring system is designed to aid the obstetrician in making clinical decisions on how to proceed when dysfunctional labour is diagnosed. Knowing the AFL level may help the obstetrician decide if and when to use oxytocin as well as when to reduce the dosage administered. According to the company this dose reduction gives the uterus time to recover and results in reduced AFL levels. They state that knowledge of AFL levels may therefore lower the rate of instrumental delivery as well as predict when vaginal delivery is less likely to be possible.

The AFL<sup>™</sup> monitoring system has a unit cost of around £8,400 and each single use disposable sensor costs about £22. Additional costs may be incurred when the intrauterine catheter is needed. The system is CE marked and was launched in the UK in 2010; however there are currently no units in use in UK hospitals.

## Clinical Studies and Research Questions

A study of 825 women with full term and normal pregnancies who were in spontaneous active labour aimed to determine whether the lactate concentration in amniotic fluid together with the partogram is a useful predictor of operative intervention in dysfunctional labour<sup>6</sup>. The amniotic fluid, which was collected at every vaginal examination, was either spontaneously flowing or a catheter was used to collect the fluid vaginally. The obstetrician, midwife and labouring woman were not told the results of the AFL<sup>™</sup> monitoring system. Of the women included in the study, 385 (47%) were diagnosed as having dysfunctional labour by the partogram and 193 (50%) of these women were delivered operatively. Only 28 (6%) of the 440 women who were diagnosed as non dysfunctional were delivered operatively. The first amniotic fluid sample taken after the partogram had diagnosed a woman as being in dysfunctional labour was used in the analysis as a predictor of labour outcome. If a lactate concentration of more than 10.1mmol/l when labour was arrested was taken as a predictor of dysfunctional labour and hence operative delivery, the AFL<sup>™</sup> monitoring system correctly predicted 80% (95% CI 73-86) of the caesarean sections and 57% (95% CI 49-64) of spontaneous natural deliveries. Nulliparous women with a lactate concentration of more than 10.1mmol/l had over five times higher odds (adjusted OR 5.4, 95% CI 3-9.9) of having a caesarean section than those whose lactate concentration was lower than 10.1mmol/l. Multiparous women had higher odds with an adjusted odds ratio of 6.2 (95% CI 1.06-19.10).

There is currently no trial evidence to demonstrate whether the AFL™ monitoring system improves clinical decisions during dysfunctional labour. Studies are needed which compare the current use of oxytocin based on clinical examination and the partogram with the use of clinical examination, the partogram and the AFL™ monitoring system as suggested by the company. Investigations need to be made into how acceptable the extra process of using the AFL™ monitor will be to women in labour especially if the intrauterine catheter is to be used.

### Technical Data

	AFL™ Monitoring system <sup>9</sup> (95% CI)* (n=372)
Sensitivity	80% (73-86)
Specificity	57% (49-64)
PPV	62% (55-69)
NPV	76% (68-83)

\*Values are based on women with AFL level greater than 10.1mmol/l after a diagnosis of dysfunctional labour by the partogram.

### Potential Impact

If proven to aid in clinical decisions during dysfunctional labour, the AFL™ monitoring system may lead to reduced delivery times for women with dysfunctional labour and fewer operative deliveries through more effective use of oxytocin. It should be noted that use of the intrauterine catheter for sample collection may not be acceptable to some women.

If the AFL™ monitoring system reduces the number of operative deliveries as the company claims, this would lead to cost and resource savings for the health service. Savings would be in the form of shorter hospital stays, less need for theatre time and decreased morbidity for the woman and child. The potential savings would need to be set against the recurring and fixed costs of the monitoring system and requirements for staff training.

It is too soon to say whether the AFL™ monitoring system will be beneficial in clinical decision making during dysfunctional labour.

### Lay summary

The *Amniotic Fluid Lactate™ (AFL) monitoring system* carries out a new medical test which is designed to help doctors and midwives make better decisions for the mother and baby during difficult labours. The system measures the level of a chemical in the amniotic fluid (water around the baby) which is believed to give important information about how well the womb is contracting. The company that developed the system say that this may help doctors to make decisions about whether the mother needs help in delivering the baby (for example by lifting it out with forceps or surgically through a caesarean section). They hope it may even reduce the risk of needing these procedures. Early studies show that the test results can help in predicting whether there will be a normal delivery, but more studies are needed to see if this system will really be helpful in these difficult labours.

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