

# Routine Pulse Oximetry Testing for Newborn Babies

**A BAPM Framework for Practice** 

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# **Developed in Partnership with**



# **Endorsed by**



# Contents

Working group members	4
List of abbreviations	5
Language	5
Executive summary of recommendations	6
Introduction	7
Background	8
PulseOx Test protocol	9
Explanatory notes relating to the PulseOx Test protocol	10
Information for parents	12
The protocol and pathways of care	13
Special circumstances	14
Management of positive PulseOx Test (Red Pathway)	16
Equipment	17
Accuracy of pulse oximeters in individuals with darker skin tones	18
Audit and Governance	19
Appendix 1: Visual aid for cotside calculation of PulseOx Test result	21
Appendix 2: Example information sheet for parents	22
Information for parents: Newborn PulseOx Test	22
Appendix 3: Homebirth newborn PulseOx Test case examples	24
Appendix 4: End of year audit report template for PulseOx Test	25
References	26

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# List of abbreviations

ANNP	<ul> <li>Advanced Neonatal Nurse Practitioner</li> </ul>
AVSD	– Atrio-Ventricular Septal Defect
BAPM	<ul> <li>British Association of Perinatal Medicine</li> </ul>
CCHD	<ul> <li>– Critical Congenital Heart Defect</li> </ul>
CHD	– Congenital Heart Defect
CE	– European Conformity Marking
CXR	– Chest X-Ray
GBS	– Group B Streptococcus
GIRFT	– Getting It Right First Time
MHRA	<ul> <li>Medicines and Healthcare Products Regulatory Agency</li> </ul>
MSW	<ul> <li>Maternity Support Workers</li> </ul>
NNU	– Neonatal Unit
NICU	– Neonatal Intensive Care Unit
NIPE	<ul> <li>Newborn Infant Physical Examination</li> </ul>
NNAP	<ul> <li>– National Neonatal Audit Project</li> </ul>
NEWTT2	<ul> <li>Newborn Early Warning Track and Trigger2</li> </ul>
ODN	<ul> <li>Operational Delivery Networks</li> </ul>
POS	<ul> <li>Pulse Oximetry Screening</li> </ul>
PPHN	<ul> <li>Persistent Pulmonary Hypertension of the Newborn</li> </ul>
PS	– Pulmonary Stenosis
QI	– Quality Improvement
SCBU	– Special Care Baby Unit
TGA	<ul> <li>Transposition of the Great Arteries</li> </ul>
UKCA	<ul> <li>– UK Conformity Assessed</li> </ul>
UKNI	<ul> <li>– UK Northern Ireland Conformity Marking</li> </ul>

# Language

The British Association of Perinatal Medicine is committed to continuously fostering a diverse environment. We acknowledge the effect language can have on individuals and populations. For simplicity of language, the framework / toolkit uses the terms woman and mother throughout, but this should be taken to also include people who do not identify as women but who are pregnant, in labour and in the postnatal period. Please always take time to make sure you are using the preferred pronouns and terminology of the patient and their support network.

The terms used in this framework regarding race and skin tone align with current understanding. The NHS Race and Health Observatory will be conducting a consultation on terminology in the near future.

# **Executive summary of recommendations**

### Background

- Conditions associated with hypoxaemia (low blood oxygen levels) are important causes of death and morbidity in the neonatal period; detection of mild-to-moderate hypoxaemia by clinical examination alone is unreliable.
- Pulse oximetry is a non-invasive method of determining blood oxygen levels and routine testing (PulseOx Test) may identify potentially important conditions early.
- BAPM recommends routine pulse oximetry testing using a standardised protocol for all asymptomatic newborn babies born at 34 weeks gestation and above.

### Protocol for pulse oximetry testing

- BAPM recommends the same protocol irrespective of birth location. This involves measuring oxygen saturations from two sites; pre-ductal saturations from the right hand and post-ductal from either foot.
- Saturations of 95% or higher with pre/post difference of 2% or lower are considered acceptable.
- Testing should ideally be performed in the first 24 hours following birth and suggested optimal timing is between 4 and 8 hours. There are three possible pathways following the initial test Green, Amber and Red.
- Inability or significant difficulty in obtaining either pre or post-ductal saturations should not be assumed to be due to equipment/technical difficulties; it may indicate underlying poor perfusion and should trigger an urgent senior review.
- Most babies on the Red Pathway (positive result) will have a condition which requires treatment, although up to 20% of babies on the Red pathway will be healthy babies with delayed cardiorespiratory adaptation following birth who are usually easily identified.
- Respiratory conditions and infections are the most common causes of low saturations and initial assessment should look carefully for signs of these and investigate and treat appropriately.
- Routine echocardiography is not necessary unless a cardiac condition is suspected.
- Testing should be in addition to newborn examination including NIPE examination and (if appropriate) NEWTT2.
- Babies admitted to a Neonatal Unit at any time should have PulseOx Test prior to Neonatal Unit discharge, even if they have previously had reassuring pulse oximetry monitoring.
- A normal result is very reassuring but does not completely rule out the chance of a problem developing. Consider repeat testing if symptoms develop or if parents have concerns.

### Additional recommendations

- Pulse oximeters should display a valid CE, CE UKNI or UKCA mark and compatible re-usable pulse oximeter probes are recommended.
- Any member of the team caring for mothers and babies can perform the test if they have been appropriately trained.
- The baby's parents should be informed about the test in advance of the test being performed, in a language that meets their needs. Written information should also be made available.
- Audit of pulse oximetry testing confers significant benefits locally and nationally and should be incorporated.

# Introduction

Hypoxaemic conditions such as cardiac, respiratory and infective diseases remain a significant cause of death in the early neonatal period.<sup>1</sup> Hypoxaemia is readily detected by pulse oximetry. Pulse oximerty screening has been shown to be a safe, quick, simple, non-invasive, cost-effective test with high specificity and moderate sensitivity for detecting critical congenital heart defects (CCHD) in predischarge newborn babies.<sup>2-4</sup> As such, it has been adopted as routine practice by numerous countries around the world including USA, Canada and much of Europe.<sup>5</sup> Measurement of pre-discharge oxygen saturations using pulse oximetry in this way has also been shown to identify important non-cardiac hypoxaemic conditions such as congenital pneumonia and early onset sepsis.<sup>6-8</sup>

The UK National Screening Committee undertook a UK pilot study<sup>8</sup> but does not currently recommend newborn pulse oximetry screening (POS) as a screen for CCHD due to concerns regarding the identification of non-cardiac conditions.<sup>9-11</sup> However, identification and treatment of both cardiac and non-cardiac conditions prior to onset of symptoms may be life-saving and so most UK Neonatal Units now routinely measure oxygen saturation with pulse oximetry in all asymptomatic newborn babies before discharge from hospital.<sup>11</sup> The recent Neonatal Getting it Right First Time (GIRFT) report recommended the roll-out of pulse oximetry testing to identify potential illness characterised by lower oxygen levels.<sup>12</sup>

### The Framework for Practice has the following aims:

- To provide standardised guidance for routine pulse oximetry testing (PulseOx Test) of all *asymptomatic* newborn babies of 34 weeks and above born in any setting the UK.
- To identify and manage babies with persistently low oxygen saturations enabling timely investigation and treatment if appropriate.
- To minimise unnecessary investigations in babies with delayed cardio-respiratory adaptation (i.e. healthy babies) and prevent unnecessary parent-baby separation.
- To provide guidance for parents on the nature of the PulseOx Test.
- To provide guidance on audit and governance regarding pulse oximetry testing.

# Background

Pulse oximetry is a method of indirectly determining arterial oxygen saturations which has been in widespread clinical use for over 40 years. Pulse oximetry testing is a simple, safe, non-invasive test that can rapidly identify babies with low oxygen saturations.<sup>2-4</sup>

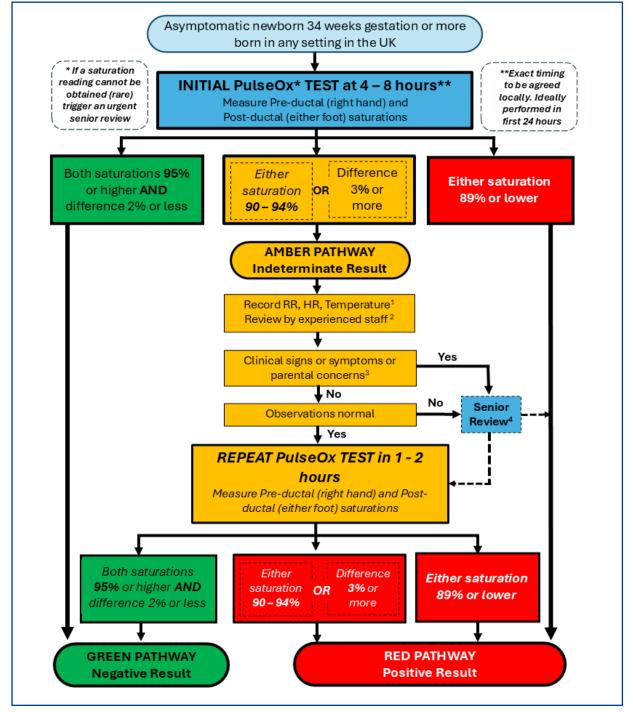
Undetected illnesses including infection, respiratory conditions and congenital heart disease are among the causes of low saturations in newborn babies.<sup>6-8</sup> If left untreated, these conditions can lead to increased neonatal morbidity and mortality.<sup>1</sup> In the UK, in 2021, congenital malformations and antepartum infections accounted for 42·7% of all neonatal deaths.<sup>1</sup> Congenital heart defects (CHDs) are the commonest congenital malformations. Critical CHDs (CCHDs), make up about a quarter of CHD and are the main cause of death in babies with CHDs.<sup>2,11,13</sup>

The majority of babies with hypoxaemic pathological conditions would benefit from early diagnosis and, if appropriate, treatment of the underlying condition.<sup>10</sup> Pulse oximetry screening has been shown to increase the early identification of CCHD<sup>2,3</sup> and to reduce mortality from these conditions.<sup>14</sup> In addition, other potentially life-threatening non-cardiac causes of low saturations such as congenital pneumonia, early-onset sepsis and pulmonary hypertension are also detected.<sup>6,7,10</sup>

Although routine pulse oximetry testing has been increasingly adopted across the UK, there are still gaps in its provision.<sup>11,15</sup> In 2023, a survey demonstrated that 78% of Neonatal Units across the UK were undertaking pulse oximetry testing.<sup>11</sup> The Getting it Right First Time (GIRFT) Programme National Specialty report for Neonatology highlighted the inequity of pulse oximetry testing provision across England.<sup>12</sup> The report also noted that visual detection of cyanosis is more difficult in babies of non-white ethnicity and reliance on visual inspection might therefore disproportionately disadvantage babies from racially-minoritised populations who have a higher risk of CHDs.<sup>12</sup> The NHS Race and Health Observatory report on assessment of newborns also recommends routine pulse oximetry testing.<sup>16</sup> In addition, the NHS Long Term Plan has a commitment to reduce child mortality; it is BAPM's view that the introduction of routine pulse oximetry testing (PulseOx Test) will contribute to achieving this aim.

# **PulseOx Test protocol**

#### Figure 1: Protocol for PulseOx Test



\*Occasionally it is not possible to obtain both a pre and post-ductal saturation reading. This should prompt an urgent senior review. This may arise because the baby's circulation is compromised. It may also arise from technical issues with the equipment but the baby must have a clinical review.

<sup>1</sup> NEWTT2 or equivalent would also be suitable

<sup>2</sup> The purpose of this review is to determine whether the baby can safely stay with parents. Experienced staff refers to staff who can identify an unwell baby. Examples include senior midwife, senior neonatal nurse, or tier 1 clinician. This is not an exhaustive list and will depend on local service provision

<sup>3</sup> If a newborn is unwell or there are parental concerns, they need an urgent clinical assessment irrespective of their PulseOx Test

<sup>4</sup> Senior staff refers to a middle grade clinician or equivalent

# Explanatory notes relating to the PulseOx Test protocol

There are a number of slightly different screening protocols (pathways or algorithms) in the published literature.<sup>17,18</sup> BAPM have recommended an algorithm based on that used in the UK PulseOx study<sup>19</sup> and the NSC pilot<sup>8</sup> as it is best suited to UK discharge practice, has potential advantages over others reported<sup>17</sup> and is currently the one most commonly used in UK units.<sup>15</sup>

### **Principles of the test**

- PulseOx Test refers specifically to the previously described protocol and not to routine continuous pulse oximetry measurement.
- PulseOx Test involves measuring oxygen saturations (breathing room air) in the right hand (preductal) and either foot (post-ductal) using a pulse oximeter. (See section on equipment.)
- The test result is defined by using the final value from each site and/or the difference between the two (see protocol). It is important to use both measurements as they may maximise identification of conditions where cardiac shunting occurs e.g., pulmonary hypertension, coarctation of the aorta.<sup>17</sup> An easy visual guide to support interpretation of results is included in Appendix 1.
- All newborn infants 34 weeks gestation and above born in hospital or at home should have a routine PulseOx Test offered and performed soon after birth.

### Timing

There are advantages and disadvantages to testing saturations early or late (see Table 1).

	Potential advantages	Potential disadvantages
Early PulseOx (within first 24 hours after birth)	Identify pathology before infant becomes unwell May lead to better infant outcomes, including improved survival	May identify infants who are undergoing normal transition May prompt unnecessary investigations (e.g., blood tests)
Late PulseOx (After 24 hours)	Less likely to identify infants who are undergoing normal transition	May miss the opportunity for early intervention in an infant with pathology Infant may be more unwell at presentation and require more stabilisation May ultimately result in worse outcomes

#### Table 1: Potential advantages and disadvantages

Most babies will have adapted to birth and have normal oxygen saturations by one hour after birth.<sup>20</sup> Identifying low saturations in the first 24 hours after birth is likely to improve outcomes for many of the conditions causing hypoxaemia, because this facilitates earlier initiation of treatment prior to the development of significant clinical symptoms.<sup>10</sup> Therefore performing PulseOx Test within the first 24 hours after birth is important.<sup>17</sup> The working group consensus was that the test is more advantageous if it is performed earlier within the first 24 hours, e.g., around 4-8 hours after birth. This approach can identify the majority of apparently well babies who have underlying (potentially significant) pathology before they become unwell, without unnecessary treatment or separation of healthy babies from their parents.<sup>6-8,10,17</sup>

#### Timing of PulseOx Test

- The exact timing should be specified locally depending on staffing practicalities and availability of services but we have proposed the following guidance:
  - Optimal timing is likely within 4 8 hours of birth.
  - Ideally within the first 24 hours and not before 2 hours.
- PulseOx Test should always be done prior to discharge home, even if early discharge anticipated.
- A locally agreed timeframe for planned testing would help staff to successfully implement PulseOx Test.
- PulseOx Test can be performed by any health care professionals who have received appropriate training. This includes, but is not limited to, the following key staff members:
  - o Midwives.
  - Maternity Support Workers (MSW).
  - Nursery nurses.
  - Neonatal nurses.
  - Paediatric/Neonatal doctors/ Advanced Neonatal Nurse Practitioner (ANNPs).

Trusts and organisations should support local training on how to perform PulseOx Test (see section on equipment).

# Information for parents

The baby's parents should be informed about PulseOx Test in advance of the test being performed. Written information should also be available (see Appendix 2) and could be given prior to birth at a routine antenatal appointment. Verbal assent should be obtained prior to testing.

Patients should be told:

- Why their baby is having the test.
- What happens during the test.
- What happens if their baby's oxygen levels are normal.
- What happens if their baby's oxygen levels are lower than normal.

Consideration should be given to the possible differences in timing of PulseOx Test for babies born at home (see section on homebirths).

If, following a test, a baby requires a retest, further examination or treatment, the baby's parents should be told what will happen next and why.

It is also important to explain that a negative test is reassuring but does not completely eliminate the risk of the baby having a problem. If parents have any concerns about their baby after the test they should seek urgent advice.

### **Declining PulseOx Test**

If parents decline testing despite counselling of the benefits and risks, the discussion and final outcome should be recorded in the notes.

# The protocol and pathways of care

Based on the saturation readings from PulseOx Test, the baby will be assigned to one of three possible pathways as per the protocol: Green, Amber or Red (see Appendix 1).

#### Green pathway – Negative Result

- 97% of newborns will be on the Green pathway after the initial test.
- This is reassuring and no further action is required **but this does not completely rule out potential illness** or an underlying condition.
- If there are parental concerns, or the baby develops clinical signs or symptoms, the saturations should be re-checked as part of a full clinical assessment.

#### Amber pathway – Indeterminate Result

- Around 3% of all newborn infants will have borderline low or differential saturations (difference 3% or more)
   Most of these (~80%) will have normalised when re-checked 1-2 hours later
- All infants on the Amber pathway must have a set of observations performed, including as a minimum; heart rate, respiratory rate and temperature.
- Infants should then have a review by a team member experienced in recognising ill babies (e.g. senior midwife/neonatal nurse/ANNP or tier 1 doctor). The purpose of this review is to ascertain if the baby is currently well. If there are no additional concerns the baby can remain with parents and have a repeat PulseOx Test 1–2 hours after the initial test. It is not necessary to re-check the saturations at this review, unless there are clinical or parental concerns about the baby.
- Regular observations are not required **if initial observations are normal**, unless new concerns arise.
- A review by a senior clinician is required if there are:
  - o clinical or parental concerns
  - signs suggestive of an underlying pathology

This review may prompt admission to Neonatal Unit for further monitoring and investigations as deemed appropriate (See Management of a positive test section).

• After a repeat PulseOx Test, there are only 2 potential pathways: Green or Red. If the saturations remain borderline or there is a difference of 3% of more, the newborn cannot be allocated the amber pathway again, they should be treated through the red pathway.

#### Red pathway – Positive Result

- A minority of newborn infants (0.5-0.8%) will have low saturations on their PulseOx Test (Red pathway).
- All infants on the Red pathway must have an urgent clinical review and the default is usually admission to the Neonatal Unit.
- Occasionally there may be equipment or technique issues and it is important to verify that the saturations are low. *We recommend immediately re-checking the saturations in any newborn on the Red pathway prior to separating from parents at this urgent review*.
  - If the saturations at this immediate re-check are normal (green) the baby should be fully examined and, if well, can stay with parents on the postnatal ward and saturations should be re-checked again 1-2 hours later to ensure they remain within acceptable limits.
- The investigations and management of an infant on the Red pathway need to reflect the wide differential diagnoses and a careful history and examination are very important.
- Only 8-10% of newborns admitted via the Red pathway with low saturations will have cardiac pathology so routine echocardiography is **not** advised.

#### Difficulty in obtaining saturation readings

Occasionally it may be very difficult or not possible to obtain both a pre and post-ductal saturation reading from a baby. **This situation should prompt an urgent senior review**. An important reason for this is poor perfusion or a compromised circulation in a baby and it can indicate that the baby is ill. Equipment issues and suboptimal technique can also account for difficulties obtaining a saturation reading in a baby, but these must not be assumed, and therefore a senior review is advised.

# **Special circumstances**

The majority of births will occur in a maternity unit and the protocol as outlined will be appropriate. Some modifications or special considerations may be needed in specific circumstances, and these are outlined below.

It is important to note that the saturation cut-offs of the protocol and the pathways remain the same, regardless of the circumstances.

### Baby admitted to the Neonatal Unit

Approximately 10% of babies born will be admitted to a Neonatal Unit and this should not preclude PulseOx Test at an appropriate time.

The working group recommend that infants admitted to a Neonatal Unit at any time have PulseOx Test prior to Neonatal Unit discharge, even if they have previously had reassuring pulse oximetry monitoring. The exception to this recommendation would be a preterm baby being discharged with home oxygen therapy, as these babies will have had advanced saturation monitoring investigations.

### Planned early discharge from hospital

Aim to test these babies as close as possible to discharge (assuming everything else is satisfactory). Testing before 2 hours slightly increases the risk of an amber test initially<sup>21,22</sup> and this should be explained to the parents. It is not appropriate to allow a baby with abnormal saturations to go home and the algorithm should be followed as described.

#### Birth in a stand-alone midwifery led unit

A baby born in a location without immediate access to medical staff can and should still have a PulseOx Test. This is important as it ensures equity of access to pulse oximetry testing.

The working group advise that PulseOx Test is performed using the standardised protocol, but that careful consideration is given to the local processes for how babies on the Amber or Red pathway access medical assessment, and treatment if required. Many of the considerations outlined in the homebirth section are applicable to babies born in a midwifery led unit (see section 4 below).

### PulseOx Test following a homebirth

Homebirth should not be a barrier to an infant having PulseOx Test. However, the differences in clinical care provision within this setting require a pragmatic approach and some modifications to the protocol may be required. Where an unplanned homebirth has occurred, local services should decide how post-birth care is provided, including PulseOx Test.

#### Timing of PulseOx Test

The exact timing for PulseOx Test following homebirth is a decision for those delivering this service. However, evidence suggests this can be safely performed within the 2-3 hours that the midwife would normally be in attendance following birth.<sup>21-24</sup> Evidence from studies on babies born out of hospital in the UK,<sup>21</sup> USA<sup>23</sup> and Netherlands<sup>22,24</sup> showed that testing from 2 hours after birth did not compromise the sensitivity of the test or result in significantly increased false positive rates.

#### Management of an infant with an Amber Pathway PulseOx Test

An Amber pathway result indicates further action is required. To support the midwife in their decision making, a discussion with their local neonatal team would be advised. A decision will be required on where and how the repeat PulseOx Test will be performed in an otherwise well baby.

#### Consider:

- Can this be performed by the midwife currently in attendance in 1-2 hours?
- If not, can another member of the community midwifery team attend in 1-2 hrs to repeat the test? Have the parents been provided with appropriate escalation advice while awaiting another midwife to attend?
- If the repeat PulseOx Test cannot be performed in the home, where will this be performed e.g., what is an appropriate local clinical location?
- How will the baby get to this location (i.e., with the parents or is alternative transport required)?

#### Management of an infant with a Red Pathway following a PulseOx Test

An urgent review in an appropriate hospital location would be advised. Local guidance for the urgent transfer of an unwell baby following a homebirth to an appropriate location should be followed.

There are variations in the provision of community midwifery care across the UK and the location and availability of hospital services. Some examples are provided in Appendix 3.

# Management of positive PulseOx Test (Red Pathway)

Approximately 0.5 - 0.8% of all newborns undergoing a PulseOx Test will test positive, that is, they will have low saturations on one occasion (Red pathway) or borderline saturations on two occasions (Amber pathway then amber result on retest). The investigations and management of a baby admitted following Red pathway need to reflect the wide differential diagnoses. The most common causes of low saturations are shown in Table 2.

Table 2: Common causes of low saturations detected by PulseOx Test in newborn infants

Respiratory >50%	Cardiac 8-10%	Infectious / Miscellaneous
Congenital Pneumonia	CCHD e.g., TGA, Critical PS etc.	Culture negative infection
Pneumothorax	Non-critical CHD e.g., Fallot's, AVSD	GBS septicaemia
Meconium Aspiration		Transitional circulation* (20%)
PPHN		

CCHD – critical congenital heart defect, TGA – transposition of the great arteries, PS - pulmonary stenosis AVSD – atrio-ventricular septal defect GBS – Group B streptococcus PPHN – persistent pulmonary hypertension of the newborn \*Transitional circulation is a diagnosis of exclusion and refers to low saturations which improve spontaneously over time and without evidence of infection or an alternative pathological process

Oxygen and continuous saturation monitoring should be provided where appropriate. Investigations should be aimed at excluding or confirming the above but there is no definitive list of investigations. These should be targeted to the most likely potential diagnosis given the clinical findings in an individual case, taking into consideration whether the saturations are borderline or low, and the trend (i.e., are they improving) over time and whether there is a response to supplemental oxygen.

Up to 20% of test positives will be well babies with delayed postnatal cardiorespiratory adaptation. In such cases, saturations usually improve quickly and if assessment is otherwise normal a further repeat test before admission may show improvement of the saturations.

#### When to consider a cardiac diagnosis

The majority of newborns admitted after a positive PulseOx Test via the Red pathway will not have cardiac pathology, so routine echocardiography is not advised. Findings which may suggest a cardiac condition are shown in Table 3:

#### Table 3: When to consider a cardiac diagnosis

Consider a cardiac cause for low saturations if:				
• There is absence of respiratory signs with marked or worsening hypoxia				
There is minimal or no response to supplemental oxygen				
٠	There are other indicators suggestive of cardiac lesion			
	o Murmur			
	<ul> <li>Poor perfusion</li> </ul>			
	<ul> <li>Weak /absent peripheral pulses</li> </ul>			
	<ul> <li>Unexplained acidosis</li> </ul>			
•	There is no other reasonable explanation for hypoxia (after investigation)			

If a cardiac diagnosis is suspected:

- early discussion with local paediatric cardiology services is advised, as per local pathways.
- Do not delay starting a Prostaglandin infusion (Dinoprostone) if there is clinical suspicion of duct-dependent CHD while waiting for Paediatric Cardiology opinion or echocardiogram. Refer to local or regional guidance for the appropriate starting dose.

# Equipment

### **Pulse oximeters**

Research studies have utilised a variety of devices for pulse oximetry screening and there is no clear distinction in superiority according to manufacturer. All equipment should meet relevant MHRA requirement for clinical use<sup>25</sup> and be used in accordance with manufacturers' instructions. Pulse oximeters intended for clinical use are regulated as medical devices and should display a valid CE, CE UKNI or UKCA mark.

Oximeters with the following characteristics are recommended:

- Appropriate for use in babies.
- Measure functional oxygen saturations with acceptable accuracy.
- Are motion-tolerant.
- Function well in lower perfusion conditions.
- Those with waveform/signal strength indicators are preferred.

#### **Oximetry probes**

Reusable probes will reduce the cost of testing, but they must be compatible with the oximeter and appropriately cleaned according to manufacturers' guidance between uses to minimise the risk of cross-infection.

Probes should be applied carefully to ensure close contact with the flat surface of the skin in the hand or foot. Only probes recommended for use in babies should be used.

### Training and competencies for individuals performing PulseOx Test

Any member of the team caring for mothers and their babies can perform PulseOx Test. However, training and assessment of competence should be provided by individual trusts.

Particular emphasis should be paid to:

- Correct placement of the oximeter probe.
- Obtaining a good quality, consistently reliable signal/trace.
- Avoid disbelieving low results in well looking babies.
- Correct interpretation of the result.
- Appropriate escalation of care through the different pathways.

# Accuracy of pulse oximeters in individuals with darker skin tones

There is increasing evidence (mainly from adults) to suggest that pulse oximeters may not be as accurate in individuals of non-white ethnicity and can overestimate oxygen levels in those with hypoxaemia.<sup>26</sup> A recent NHS review has called for greater awareness among clinicians of the possibility of falsely reassuring saturation readings in darker skinned patients, and for the manufacturers of pulse oximeters to modify the software in the machines to reduce this bias.<sup>27</sup> There are limited data in infants, but available evidence suggests the biases in newborn babies may be less pronounced.<sup>28,29</sup> This of course still has important implications for any pulse oximetry testing algorithm.

There is currently no evidence of any ethnic bias (such as an increase in false negative tests) in any of the published data on newborn pulse oximetry screening. We would however make the following comments:

- Whatever the limitations of pulse oximetry in dark-skinned babies it is highly likely to remain superior to visual inspection.
- The bias appears to be more pronounced at lower saturations (<90%) so the differences around the cut-off for PulseOx Test (95%) are likely to be reduced.
- Published evidence shows that pulse oximetry screening (for CCHD) is not a perfect test and approximately 1 in 4 defects will be missed.<sup>2-4</sup> All clinical staff should remain vigilant even if the test is negative.
- Subsequent national audits or research may increase our understanding of the effect of skin tone on the test.

# **Audit and Governance**

### **Role of Audit and Governance**

Local and regional provisions for performing and recording PulseOx Test will vary widely, and thus the aim of this subsection is to provide pragmatic, practical advice on why and how individual centres may choose to audit these data, as well as tools to support local teams in initiating this process.

Audit of PulseOx Test confers significant benefits locally and nationally. Local data provide insights into the success of implementation and can highlight common pitfalls in the process, outcome recording and result interpretation. This can subsequently be used to provide targeted feedback and training, ensuring the best outcomes for all babies. Audit also provides insights into patterns of identified pathologies and can facilitate individual case review of missed antenatal diagnosis of congenital heart disease. Data can also be used to benchmark against published outcome data for PulseOx Test, allowing prediction of likely number of cases in a given population, which may be important for local service provision.

Additionally, there is significant value in collecting PulseOx Test outcome data, particularly for test positive newborns. This will provide further information for the National Screening Committee in any review of their decision to include it within a future national newborn screening program.

### Data points for collection

There is currently no national audit system for PulseOx Test data, and thus how data are collected will vary from unit to unit. Given the aim for all newborn infants in the UK to receive PulseOx Test, the scale of audit will be sufficiently large in any given region to necessitate automated data collection. In regions of the UK where the NIPE SMART electronic recording system is used (currently England, Wales and Northern Ireland), there is pre-existing capability to record and extract data on test completion and test outcome (pass/fail). Test positive cases who proceed to NNU admission can then be cross checked with BadgerNet, whose admission categories include 'failed pulse oximetry'.

Below we include a suggested list of essential and desirable data points for collection:

**Essential** (data points currently recorded in NIPE SMART and their terminology are highlighted in red):

- Test completed (Pulse Ox Test: Pass/Fail/Outstanding)
- Age in hours at test (Date/time of test)
- Ethnicity
- Outcome of Test 1 (Red/Amber/Green) (Pass/Fail)
- Outcome of Test 2 (Red/Green)

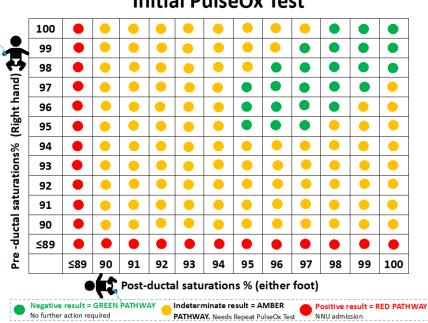
Desirable (specific considerations for these in italics):

- Location of birth: hospital consultant or midwifery led unit, or home
- Birth gestation
- All babies: pre-/post-ductal saturations + saturations differential for test 1 and 2 (if applicable)
- For babies on Amber pathway:
  - Clinical review undertaken at test 1?
  - Outcome at test 2 (Pass/Fail)
- For babies on Red pathway:
  - Neonatal Unit admission (*as marker of testing process*)

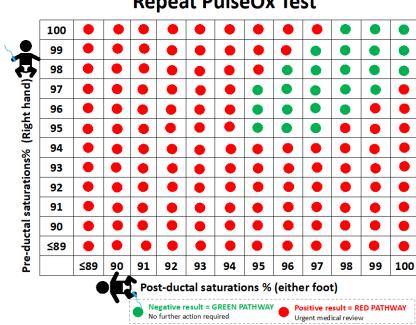
- If admitted, core set of medical interventions (implications for service provisions and potential harms to infants with positive test and no identifiable pathology):
  - Bloods tests
  - Administration of IV antibiotics
  - Lumbar puncture
  - CXR
  - Echocardiogram
  - Level of care
- Final diagnosis for test positive cases:
- Critical Congenital Heart Disease (CCHD)
  - Other CHD
- Respiratory
- Infection (culture positive sepsis or clinician decision for antibiotic treatment >48 hours)
- Delayed transition respiratory support required
- Delayed transition no respiratory support required
- Other identifiable pathology (e.g., meconium aspiration syndrome, noncardiac congenital anomaly)
- Was PulseOx Test the first time concerns were raised about this baby?
- Length of NNU admission for babies with final diagnosis of delayed transition who did not require respiratory support
- Antibiotic course >48 hours

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# Appendix 1: Visual aid for cotside calculation of PulseOx Test result



# **Initial PulseOx Test**



# **Repeat PulseOx Test**

# **Appendix 2: Example information sheet for parents**

NHS Trusts should consider the provision of easy read and translated versions of any printed materials to help equality of access to this information. We recommend that the information is given to parents before the birth.

### Information for parents: Newborn PulseOx Test

#### Introduction

Your newborn baby will have a test known as PulseOx Test. This is a routine test offered to all babies within the first 24 hours after birth.

The team looking after you will explain the test before it is done and will answer any questions you have.

#### Why is your baby having this test?

We are trying to find the small number of babies who have medical problems that can cause their oxygen levels to be lower than usual. Some babies can appear healthy when they are born but have lower oxygen levels than expected.

This test will tell us which babies have lower oxygen levels. We can then consider additional tests and assessments to see if your baby has a condition that needs treatment. This will mean that treatment (if appropriate) can be offered as early as possible.

#### What happens during the test?

PulseOx Test is completely harmless and painless, and takes less than 5 minutes. It measures the oxygen levels (sometimes called oxygen saturations) in your baby.

We do this by wrapping a small sensor around your baby's right hand. This sensor is connected to a device called a pulse oximeter, which measures the oxygen levels by shining a light through your baby's skin. We will then take a second reading with the sensor – this time wrapped around your baby's foot. It's important to get both these readings for the test.

We aim to do PulseOx Test within the first few hours after your baby is born. The precise timing may vary between hospitals.

#### What if my baby's oxygen levels are normal?

If your baby's oxygen levels are normal, no further PulseOx Tests are needed at this time. Your baby will have all the usual care before being discharged, including their routine newborn examination.

A normal result is very reassuring but it doesn't completely rule out the chance of a problem developing. If you have any concerns about your baby's colour, breathing, feeding or the way your baby is behaving after the test seek urgent advice.

#### What if my baby's test shows lower than normal oxygen levels?

There are two reasons why your baby might be showing lower than normal oxygen levels:

1. About 3 in every 100 babies (3%) will have slightly low oxygen levels on the first test. We know this might be worrying for you, but the lungs of some babies adapt to being born more

slowly than others – this is normal and these babies are healthy. Because we know this, if your baby's oxygen levels are only slightly lower than normal in the first test and your baby appears healthy, then we will do the test again a second time about one or two hours later. This is called a retest.

2. About 3 in every 1000 babies (0.3%) will have oxygen levels that are much less than expected. These babies will be seen by a doctor or specialist nurse straight away. They will examine your baby and may do tests to try to find out why their oxygen levels are low.

#### What happens if my baby needs a retest?

Nine out of every ten babies who need a retest will have normal oxygen levels at their second test, and no further tests are needed. It is important that your baby's oxygen levels are normal before they are discharged, so very occasionally the need to do the retest will lead to a slight delay in your discharge.

#### What will happen next if my baby needs further examination or treatment?

In total (including first tests and retests) about 7 in every 1000 babies (0.7%) will need further investigations and these babies will probably be admitted to the Neonatal Unit (sometimes called Baby unit, Neonatal Intensive Care Unit (NICU) or Special Care Baby Unit (SCBU)). This may make you feel worried, but you will be able to see your baby on the unit and the doctors or nurses will tell you what is happening at every stage.

On the Neonatal Unit, your baby may have blood tests and x-rays to try to find out why their oxygen levels are low. Some babies may also have an ultrasound of their heart (called an echocardiogram or echo for short).

Of the babies admitted to the Neonatal Unit:

- 2 in every 10 will be healthy these babies are usually in the Neonatal Unit for less than 12 hours.
- 7 in every 10 will have a breathing problem or infection, and they will benefit from early diagnosis and treatment.
- 1 in every 10 will have a heart problem, and they will benefit from early diagnosis and treatment.

#### What if my baby is born at home?

All babies born at home will have PulseOx Test, but there may be a few differences. Your baby's test may take place a bit earlier or a bit later than for babies born in a hospital but will still be in the first 24 hours of your baby's life. This is within the accepted time where PulseOx Test works well.

If your baby is born at home and their PulseOx Test shows slightly lower than normal oxygen levels, they will be retested. You may need to come to hospital for the retest, as we can't guarantee your midwife will be able to come back to perform the retest.

If your baby is born at home and their test shows their oxygen levels are lower than normal you may need to come to hospital urgently (e.g., in the same hour). Some babies may need to travel to hospital by ambulance. Your midwife will tell you if this is the case. In hospital, your baby will be seen by a doctor or specialist nurse straight away.

#### What should I do if I have questions about my baby's PulseOx Test?

If you have any questions, please ask any of the team who are looking after you. Translations of this guidance are available in the following languages... (insert local examples).

# Appendix 3: Homebirth newborn PulseOx Test case examples

Location	Green Pathway	Amber Pathway	Red Pathway
Homebirth in a	PulseOx Test	PulseOx Test performed at 5am.	PulseOx Test performed at
city centre	performed at 5am (3	Pre-ductal 99% and post-ductal	5am. Pre-ductal 94% and
location at 2am.	hours after birth). Pre-	96% = Amber Pathway result.	post-ductal 88% = <b>Red</b>
	ductal 99% and post-	Clinical assessment performed-	Pathway result. Baby
	ductal 98% = Green	respiratory rate is 80/min with	appears clinically well.
	Pathway result so no	indrawing/sternal recession.	Follows local protocol for
	further action	Requires Senior Review and	referral and management
	required.	follows local protocol for referral	of unwell newborn in born
		and management of unwell	at home.
		newborn in community.	
Homebirth in a	PulseOx Test	PulseOx Test performed at 4.30am.	PulseOx Test performed at
rural location at	performed at 4.30am	Pre-ductal 96% and post-ductal	4.30am. Pre-ductal 97%
2am.	(2.5 hours after birth).	94% = Amber Pathway result.	and post-ductal 89% = <b>Red</b>
	Pre-ductal 100% and	Clinical assessment performed with	Pathway result. Baby
	post-ductal 98% =	no concerns identified. Contacts	appears clinically unwell.
	Green Pathway result	their local Neonatal Unit for advice.	Follows local protocol for
	so no further action	Repeat PulseOx Test performed at	referral and management
	required.	6am. Pre-ductal 95% and post-	of unwell newborn in
		ductal 92% = <b>Red Pathway</b> Result.	community. Consider what
		Follow local protocol for referral	additional urgent support
		and management of unwell	they may need in a rural
		newborn in community.	location.
Homebirth in a	PulseOx Test	PulseOx Test performed at 4am.	PulseOx Test performed at
remote location	performed at 4am (2	Pre-ductal 99% and post-ductal	4am. Pre-ductal 90% and
at 2am.	hours after birth). Pre-	96% = Amber Pathway result.	post-ductal 84% = <b>Red</b>
	ductal 98% and post-	Clinical assessment performed with	Pathway result. Baby
	ductal 96% = Green	no concerns identified. Contacts	appears clinically well.
	Pathway result so no	their designated Neonatal Unit for	Follows local protocol for
	further action	advice. Repeat PulseOx Test	referral and management
	required.	performed at 6am and Green	of unwell newborn in
		Pathway result obtained- no	community.
		further action required.	Considers what additional
			urgent support they may
			need in a remote location.

\*For the purposes of this example a 'rural' setting is defined as a geographic location that is outside towns and cities and a 'remote' setting is defined as an isolated location a significant distance from the local Neonatal Unit.

# Appendix 4: End of year audit report template for PulseOx Test

- Number of eligible births in region:
- Number of completed PulseOx Tests:
- Percentage of all eligible births tested:
- Number and percentage of overall test positive tests:
  - Percentage of test positive tests obtained on test 1 and test 2
- Number and percentage of test positive tests resulting in NNU admission:
  - Medical interventions for babies admitted to NNU:
    - Bloods tests
    - Administration of IV antibiotics
    - Lumbar puncture
    - CXR
    - Echocardiogram
    - Level of care
  - Length of NNU admission for infants with final diagnosis of delayed transition not requiring respiratory support
- Final diagnoses of infants admitted to NNU:
  - Critical Congenital Heart Disease (CHD)
  - $\circ$  Other CHD
  - o Respiratory
  - Infection (culture positive sepsis or clinician decision for antibiotic treatment >48 hours)
  - Delayed transition respiratory support required
  - o Delayed transition no respiratory support required
  - Other identifiable pathology (e.g., meconium aspiration syndrome, non-cardiac congenital anomaly)

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BAPM is a membership organisation that is here to support all those involved in perinatal care to optimise their skills and knowledge, deliver and share high-quality safe and innovative practice, undertake research, and speak out for babies and their families.

We are a professional association of neonatologists, paediatricians, obstetricians, nurses, midwives, trainees, network managers and other health professionals dedicated to shaping the delivery and improving the standard of perinatal care in the UK.

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