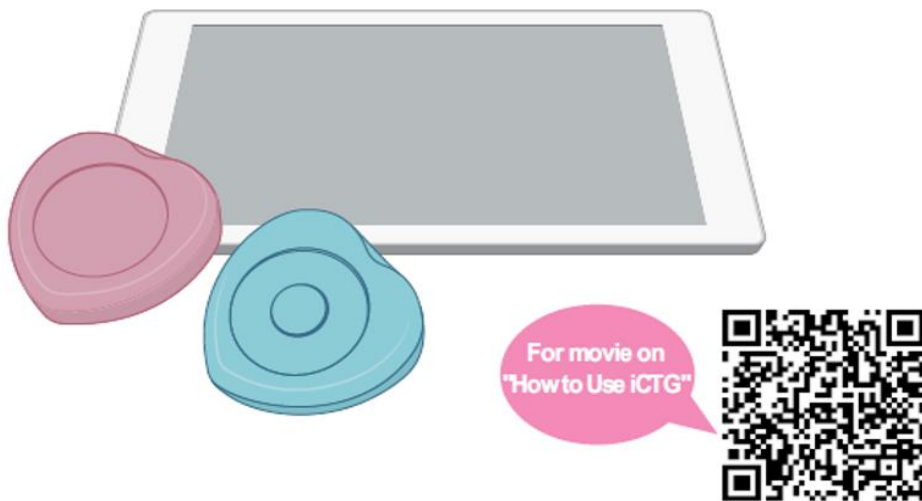




## **STANDARD OPERATING PROCEDURE- 2023**



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### Revision History

Version No	Effective Date	Reason for revision/Details of change
00	09/07/21	Original release of SOP on iCTG, DoPH 2021
01		1. Addition of clear scope, responsibilities, and process map of the activities with clear communication channels. 2. Detail clinical procedures clubbed with device operating procedures with having to cross refer different manuals. 3. Addition of templates for recording iCTG patient details.
02	02/10/23	1. Proposed change in gestation period from 28 to 26 weeks. 2. Proposed to simplify the categories of RFS (reassuring fetal status) and NRFS (non-reassuring fetal status). 3. Proposed to mention the role of KGUMSB

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## Background

The Reproductive, Maternal and Child Health services forms the crucial part of the health system and is central to Sustainable Development Goals (SDGs). Bhutan accords high importance to reduce neonatal mortality to 13.2 per 1000 live births by 2023 as per the Bhutan Every Newborn Action Plan and to reduce maternal Maternal Mortality Rate to less than 70 per 100000 live births by 2030 (SDG3.1 target).

Due to the rugged geographical conditions and limited comprehensive emergency obstetric centres (CEmONC) in the country, timely access for intervention during pregnancies and delivery is always a challenge in our health system. iCTG is a web based innovative technology that can help to improve patient's access to specialised care without having to travel to tertiary facilities. By using iCTG correctly, and with proper interpretation of CTG, it is expected to reduce unnecessary patient referrals, identify actual foetuses with problems for timely referral and interventions to reduce neonatal mortality.

### 1. Purpose

To describe a detailed procedure on the use of iCTG including the indications for use, operation and minor troubleshooting of the iCTG, interpreting iCTG report, communication of iCTG readings/tracing with gynaecologists and transfer of at-risk patients to the designated referral centre.

### 2. Scope

This Standard Operating Procedure (SOP) shall apply to all the health-care centres where iCTGs are being supplied for scanning eligible pregnant mothers with 26 weeks of gestation and above. However, this is basically developed for singleton pregnancies. iCTG is basically designed for singleton pregnancies, however in case of multiple pregnancies, each foetus can be monitored by turns.

### 3. Definitions

**Abnormal fetal heart rate (FHR):** It refers to abnormal < 110 or >160 bpm.

**Baseline heart rate:** It means FHR maintained over at least 10 minutes in the absence of accelerations or decelerations, given in beats per minute (bpm). (Normal FHR-110 to 160 bpm).

**Baseline variability:** It refers to the beat variation of foetal heart rate within a 3-5 minutes strip on the recording. (A band width amplitude of 5-25 bpm).

**C-EmONC:** It refers to a health centre where gynaecologists are present and where caesarean section services and neonatal services are available.

**Catchment area:** It refers to health centres spread around one tertiary/C-EmONC from where patients with complications are referred for further management.

**CMO:** It refers to the Chief Medical Officer responsible for overall administration of a Health-care centre.

**DPHO:** It refers to the District Health Officer responsible for the overall health activities in the district.

**GDMO:** It refers to a General Duty Medical Officer.

**ER:** It refers to the Emergency Room.

**Eligible pregnant mothers:** All pregnant women  $\geq$  26 weeks are eligible for iCTG monitoring

**High risk:** It refers to the obstetric & medical conditions of the pregnant mother as described in the MCH handbook that complicates pregnancy and poses threat to safe delivery.

**Normal Variability:** It refers to variations around the baseline in amplitude of 6 to 25 bpm during the interval when no contractions occur, on the tracing.

**Non-reassuring readings:** It means a CTG reading which does not have characteristics of normality on CTG reading.

**On-call doctor:** It refers to the Medical Officer/Gynecologist of the catchment area on duty at that particular period of time where he/she is responsible to attend to the emergencies.

**Persistent non-reassuring readings:** It refers to the repeated reading of non-reassuring iCTG.

**Reassuring/Reactive:** It refers to a CTG reading with baseline heart rate of 110 to 160 bpm with normal variability, no decelerations and with acceleration present.

**Transducer:** It refers to the heart shaped FHR and UC transducers.

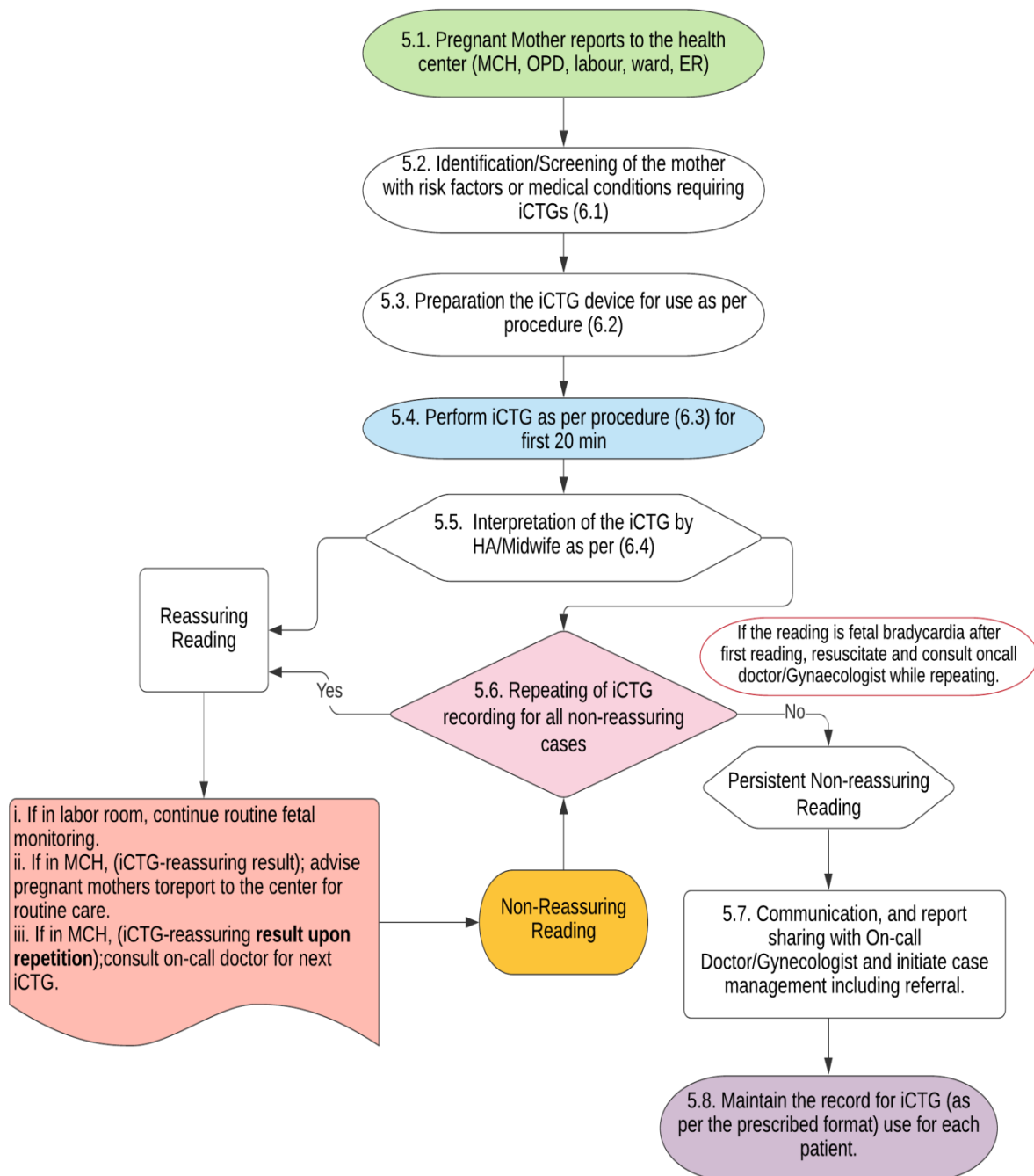
**Troubleshooting:** It is a form of problem solving, often applied to repair failed products or processes on a machine.

#### 4. Responsibilities

SN	Designation/Personnel	Responsibilities/Task
1	Health Assistant /Midwife	<ul style="list-style-type: none"> <li>● Screen all the pregnant women in the 26 week of gestation period during each antenatal visit.</li> <li>● Interpret normal iCTG readings.</li> <li>● Communicate with on-call doctors at health centres/Gynaecologists at C-EmONC for abnormal/non-reassuring results.</li> <li>● Refer patients who have been advised for further continued management in C-EmONC.</li> <li>● Maintain and ensure proper functionality of iCTG at all times.</li> <li>● Record the details of the patient on the logbook (prescribed format).</li> <li>● Hand over properly to the next shift (duty staff).</li> </ul>
2	GDMO (On- call doctors)	<ul style="list-style-type: none"> <li>● Interpret the CTG results and do timely consultation with the relevant Gynaecologist of one's catchment (C-EmONC) area for non-reassuring readings.</li> <li>● Ensure iCTG is constantly used in Mother and Child Hospital (MCH) and/or labour rooms.</li> <li>● Ensure proper record of the use of the iCTG is maintained at the facility.</li> </ul>
3	Gynecologist (On-call)	<ul style="list-style-type: none"> <li>● The on-call gynaecologist of the catchment area regularly checks for the mail received from iCTG recordings from their catchment area.</li> </ul>

		<ul style="list-style-type: none"> <li>• Communicate with HA/GDMO/Midwife for the non-reassuring iCTG recordings and provide proper advice regarding immediate further management of the patient.</li> <li>• Ensure periodic audit/monitoring of the use of iCTGs in their catchment area and communicate with RH/DPHO of MoH for further needful actions.</li> </ul>
4	Biomedical Engineer	<ul style="list-style-type: none"> <li>• Include iCTG devices in the hospital's inventory. (i.e., Keep record of all the centres with iCTG regarding the functionality of the devices)</li> <li>• Provide immediate technical support to centres having problems with iCTG.</li> <li>• Conduct timely repair and maintenance of iCTGs.</li> <li>• Conduct Planned Preventive Maintenance and calibration of iCTG. <i>(If trained and authorised by Melody International)</i></li> </ul> <p>Develop replacement plan for the iCTG machines.</p>
5	Reproductive Maternal and Newborn Health Program (RH), MoH	<ul style="list-style-type: none"> <li>• Monitor regular use of the iCTGs in all healthcare-centres.</li> <li>• Provide support to all health centres with competency development, for replacements and repair of iCTGs.</li> <li>• Maintain a database on the use of iCTG in all centres.</li> <li>• Initiate mobilisation of iCTGs for effective utilisation in needful health centres with a higher number of pregnant mothers.</li> </ul>
6	DPHO/CMO	<ul style="list-style-type: none"> <li>• Monitor regular use of the iCTGs at Primary healthcare centres.</li> <li>• Provide support to all health centres with competency development, for replacements and repair of iCTGs.</li> <li>• Provide resources for data recharge for use of iCTG SIM.</li> <li>• Mobilise iCTGs for effective utilisation in needful health centres with higher numbers of pregnant mothers in their respective districts in consultation with NMS.</li> </ul>
7	Faculty of Nursing and Public Health (FNPH), Faculty of Postgraduate Medicine) (FoPGM), KGUMSB	<ul style="list-style-type: none"> <li>• Incorporate iCTG in the curriculum of courses offered in FNPH.</li> <li>• Ensure sustainability of iCTG through inclusion of it in academics.</li> <li>• Expose the resident doctors in the Department of Obstetrics and Gynecology on the use of iCTG.</li> </ul>

## 5. Process Flow: Use of iCTG for monitoring the foetal status





## 6. Procedure

### 6.1. Identification of the pregnant mother above 26 weeks of pregnancy

- i. Identify 26 weeks and above pregnant mothers and also pregnant women with high risks.
- ii. Screen routinely all pregnant women with iCTG during their antenatal visits.
- iii. In addition to MCH handbook high risk criteria; select pregnant mothers with abnormal foetal heart sound and those **mothers with existing risks** such as;

Diabetes, hypertension  
Kidney diseases  
Intrauterine fetal growth restriction (IUGR)  
Oligohydramnios  
Post-dated pregnancies  
Preeclampsia  
Abnormal vaginal bleeding in labor

Maternal pyrexia  $\geq 38$  degree Celsius  
Meconium/blood stain amniotic fluid  
Absent/ reduced AFI following rupture of membrane  
Prolonged labor  
Uterine tachysystole  
Uterine hypertonus  
Uterine Hyperstimulation  
Pre-labor rupture of membrane

### 6.2. Preparation of the iCTG device for use

Ensure the following assembly set of iCTG is present in the bag as per Figure1

#### Fetal monitor iCTG Set includes



Figure1: iCTG Set

Check the functionality of the two transducers and the display of the tablet and press zero reset button on the UC transducer or on the tablet control as per Figure 2.

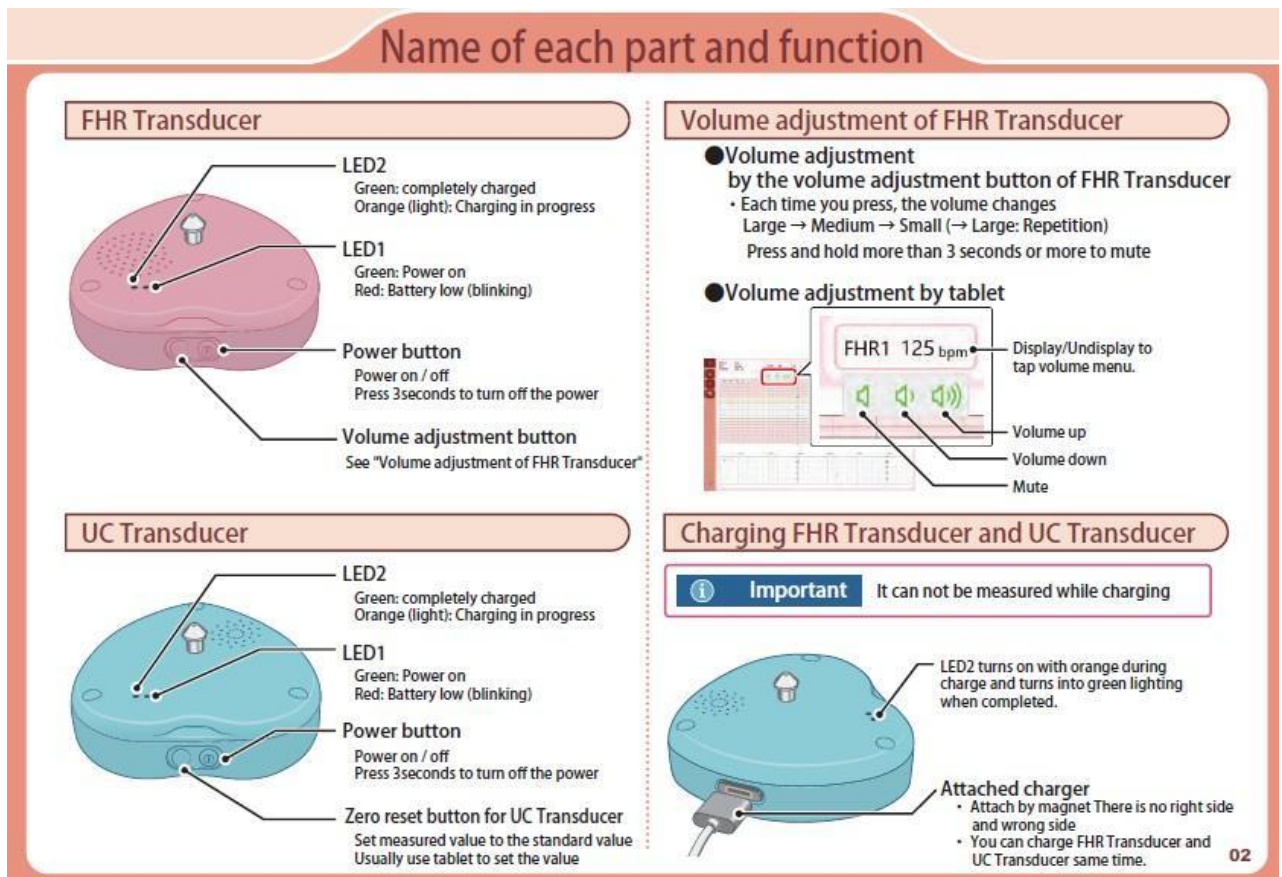


Figure 2: Parts and function of iCTG

Register or select the pregnant mothers (if already registered) from the list on the tablet and add mother's information to the patient list. Enter MCH ID no. for patient ID on the Tablet control (iPad control)

Turn on the FHR transducer and UC transducer by pressing the power button and check the status of the device with the icon on the menu bar (Figure 3)



Figure 3: Checking the status of the device

Scan the following QR code for the demonstration of how to use foetal monitor iCTG:  
Use QR scanner application of WeChat app, share it app and other QR scanner applications; this is linked to YouTube 6 min-video).



### **6.3. Application of iCTG on the pregnant mother**

- Perform hand hygiene,
- Place a pair of transducer belts on the bed.
- Advise the pregnant mother to empty her bladder and make her lie in the supine position or semi-fowler's position for a few minutes to tie the belts.
- Apply gel on the FHR transducer and tie the belt on the mother's abdomen where placements confirm and attach the transducer belt.
- Place the UC transducer at the uterine height of the fundus and tie it with the belt. Press the zero reset button to set the standard value. Do not use gel on UC transducers.
- Confirm the waveform and heart rate graph has stabled around 140 and heartbeat sound is clearly heard.
- Tap the measurement start icon and select the measurement time. Normally, 40 minutes measurement time should be selected.
- Ensure tablet control is kept within 5 metres of less from the transducers/pregnant mothers to prevent loss of signals.
- When the measurement time elapses, you will hear the end sound to finish the measurement after that, a confirmation message will be displayed. Tap "OK" to confirm the measurement.
- If you want to stop the measurement in the middle, tap the "stop" button. Then, tap "yes" to the message "Do you want to stop?"
- Observe any abnormalities on the iCTG reading after 20 minutes as per Figure 4 and Table 1. The threshold that separates each range can be changed from the settings

(general) screen. The background is set to 3 colours to help identify whether the measured value falls in danger range.

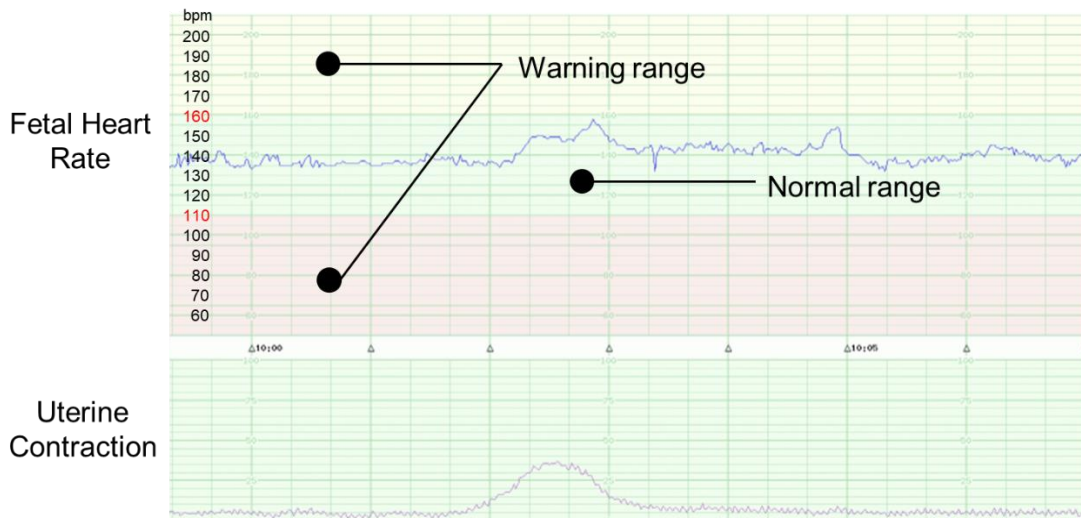


Figure 4: iCTG graph with colour code and threshold values

#### 6.4. Interpretation of the iCTG (Cardiotocograph) (Where there is no gynaecologist)

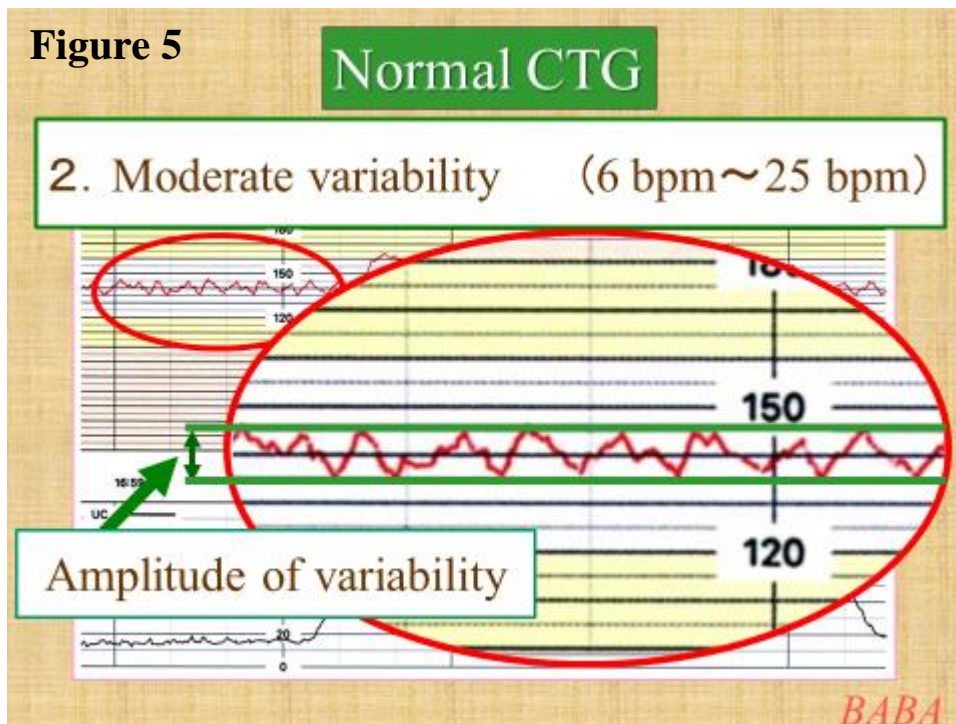
Interpret the iCTG graph as per the following table (Table 1, Figures 5 - 13)

SN		RFS (reassuring fetal status)	NRFS (non-RFS)
1.	Baseline heart rate	110-160 bpm	<110 or >160
2.	Baseline variability	6-25 bpm	<5 or >26
3.	Acceleration	2 times in 20 minutes	No acceleration
4.	Deceleration	No deceleration	Severe variable deceleration Late deceleration Prolonged deceleration

Table 1: iCTG classification criteria and interpretation

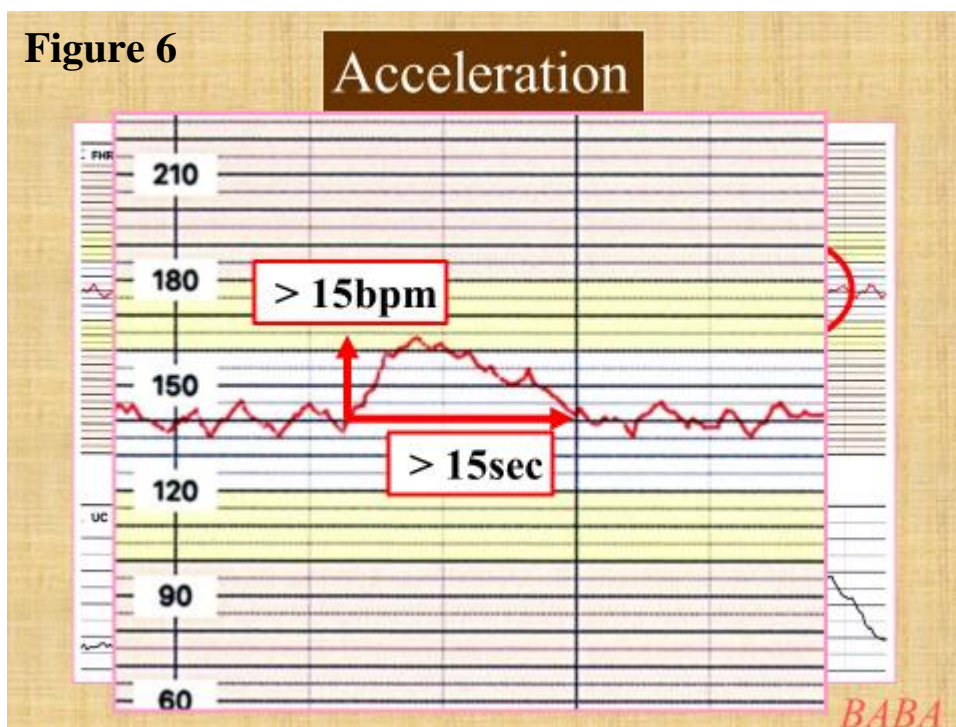


Figures 5-8: Normal: Reassuring foetal status (RFS)



Baseline heart rate: 110 – 160 bpm

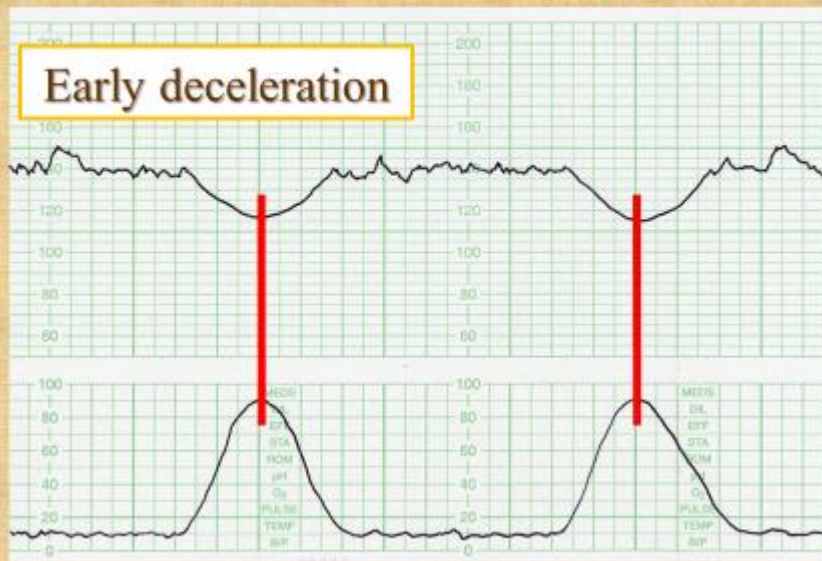
Baseline variability: 6 – 25 bpm



Acceleration: 2 accelerations in 20 minutes

**Figure 7**

**Normal CTG**

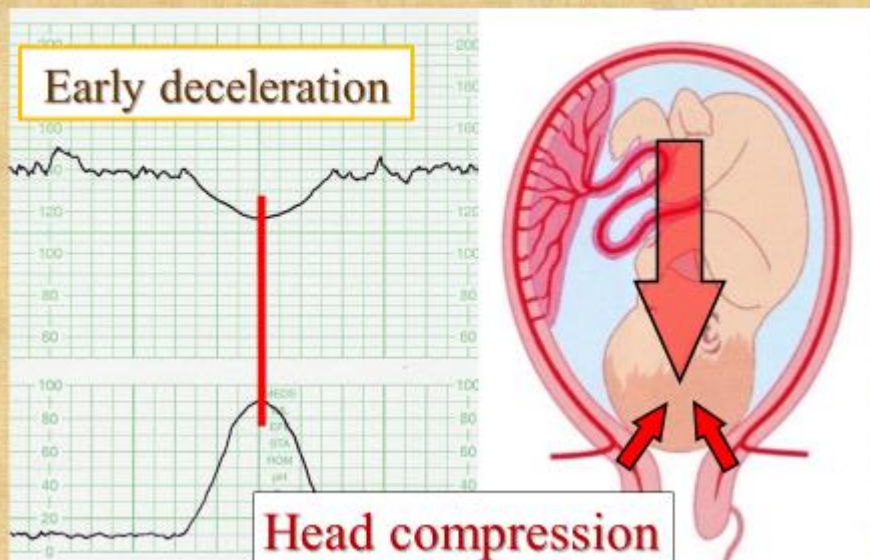


*BABA*

Deceleration: No deceleration  
Early deceleration is not pathologic.

**Figure 8**

**Normal CTG**



*BABA*



Figures 9-13: Abnormal: Non-reassuring foetal status (NRFS)

Figure 9

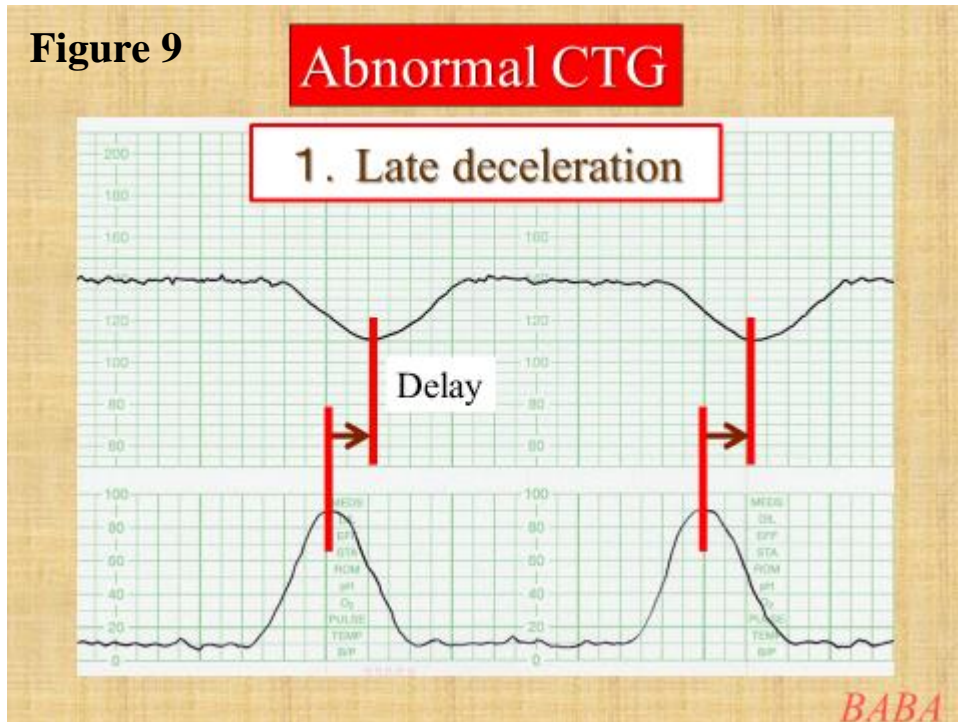


Figure 10

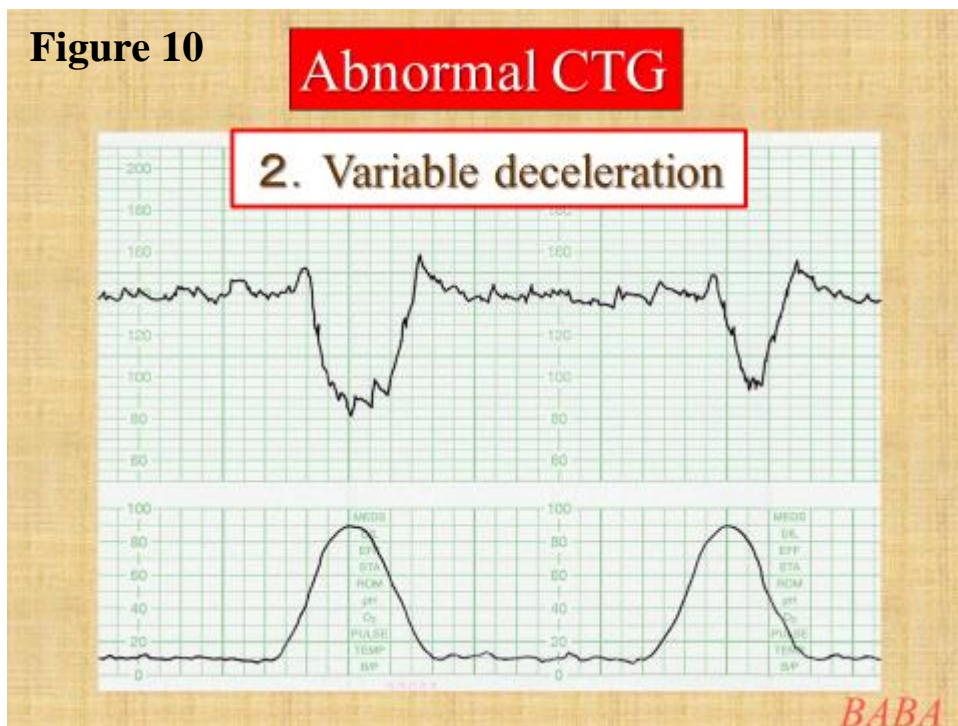
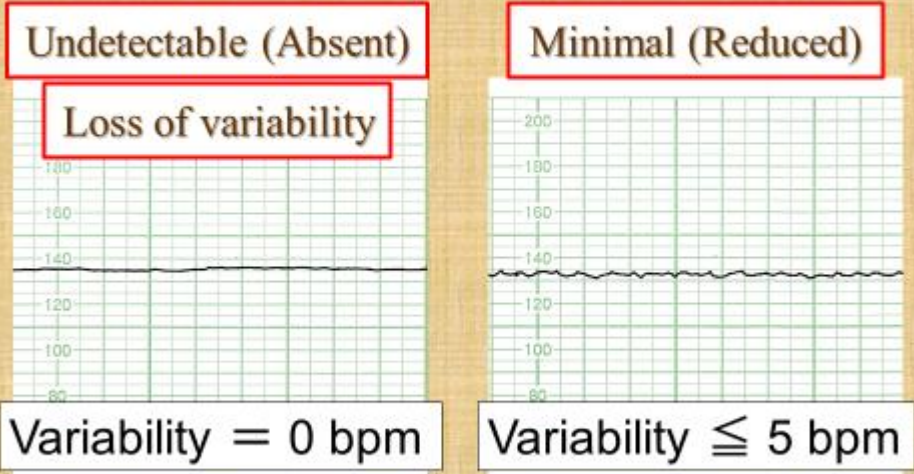


Figure 11

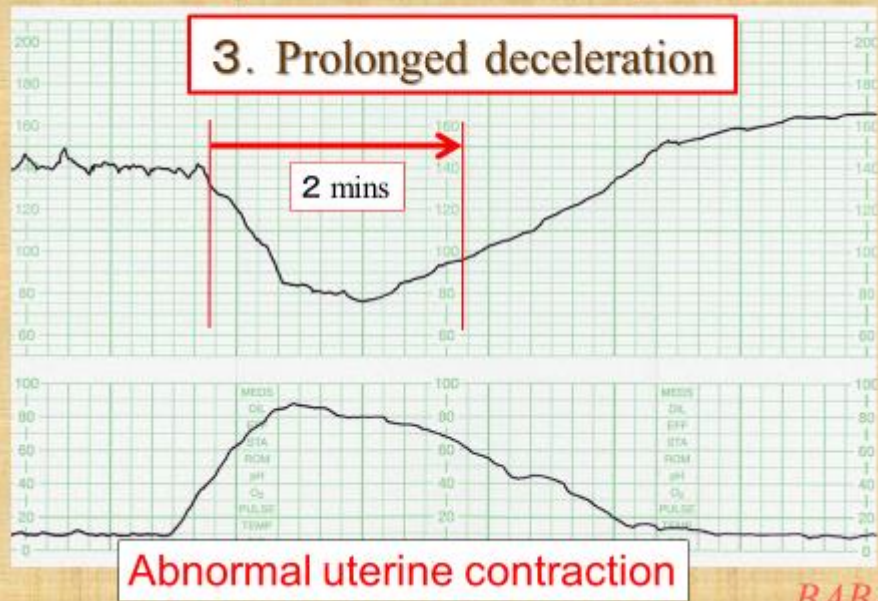
**Abnormal CTG**



BABA

Figure 12

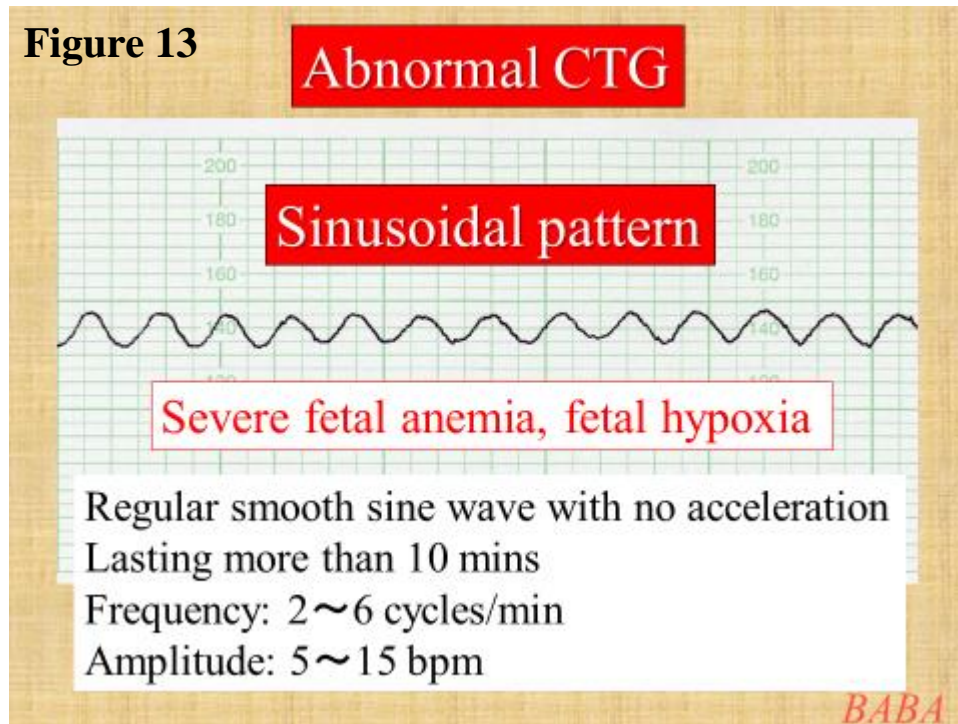
**Abnormal CTG**



BABA



**Figure 13**



Repeat the procedure/scan to confirm the non-reassuring findings. If the iCTG reading is found abnormal requiring urgent/immediate intervention, consult an on-call doctor.

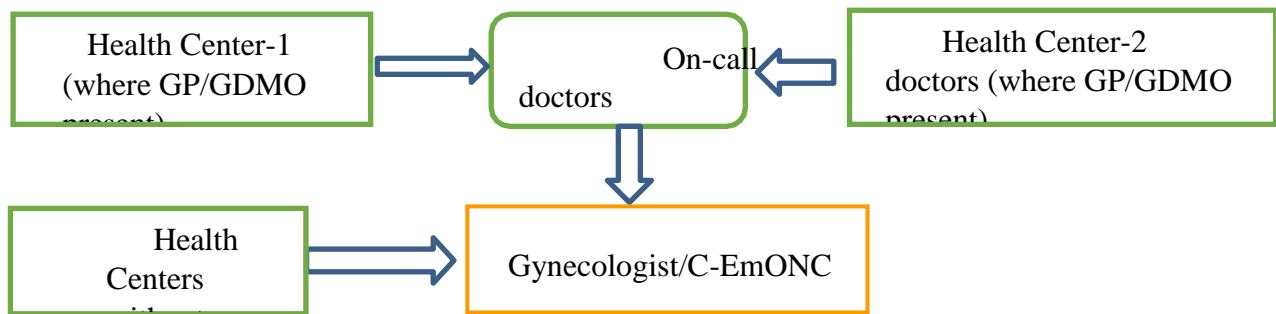
#### **6.5. Reassuring iCTG Reading**

- For the pregnant mothers in the labour room, continue routine foetal monitoring. For pregnant mothers in MCH, where the iCTG-reassuring result was reassuring on first scan only, advise mothers to report to the centre for routine care.
- For pregnant mothers in MCH, where the iCTG-reassuring result was reassuring upon repetition (2<sup>nd</sup>scan); consult an on-call doctor for the next schedule for iCTG.

#### **6.6. Non-reassuring CTG reading/tracing**

- If the iCTG reading/trace shows persistent non-reassuring readings, the midwife in health centres where GDMOs are present, should report to on-call doctor.
- For the Primary Health-care Centre; the health assistants should report to C-EmONC- Gynecologist through email and confirm the receipt of the iCTG reading through telephonic communication.

## Communication/Transmitting and consultation



- All the health care centres with the iCTG machine must create one common E-mail ID which can be used during the on-call duty.
- The Health Assistant or On-Call Doctor shall activate the referral system (ambulance, escort nurse etc.) following the advice of the Gynecologists as and when required.
- Record the patient detail, indication, date and time with remarks in the log book/google sheet as in Annexure-1(sample template/format).

### 6.7. Cleaning of the iCTG device/transducers and storage

- After completion of measurement, remove the FHR and UC transducer and belts from the pregnant women and turn off FHR and UC transducer.
- Wipe off any gel or stains with a soft cloth or paper towel moistened with water or warm water. ***Do not use solvents such as betadine, thinner and disinfectants, povidone iodine; it may result in damage, discoloration, or malfunction of the device.***
- Store the equipment properly and handover to the next shift duty staff.

## 7. Troubleshooting and maintenance

### 7.1. Transducers and tablet (iCTG set)

<b>Problem</b>	<b>Solution</b>
Tablet cannot be turned <b>ON</b>	<ul style="list-style-type: none"> <li>● Try to turn ON after fully charging the device (Charging method: See paragraph 3.1(User Manual))</li> <li>● Check if the power button has been pressed. (See Section 4.1.1(User Manual))</li> <li>● Press and hold the power button for a few seconds until you hear a beep.</li> <li>● Further contact BMED if it does not solve the problem.</li> </ul>
Device was dropped and subjected to impact	<p>If the following problems are observed in the device, do not use the device and contact regional foals (Western, BMED Thimphu, Central, CRRH &amp; Eastern ERRH)</p> <ul style="list-style-type: none"> <li>-Tablet is damaged</li> <li>-Device cannot be turned ON.</li> <li>-Tablet emits a strange noise</li> <li>-Measurements are not accurate</li> </ul>
<b>Connectivity</b>	
Transducer cannot connect to tablet	<ul style="list-style-type: none"> <li>● Check if Bluetooth is turned ON in the tablet, if not turn on the Bluetooth.</li> <li>● Check the connection status.</li> <li>● Turn on the transducer after the main screen is displayed on the tablet.</li> <li>● Move the tablet closer to the transducer.</li> </ul>
<b>Measurement</b>	
Foetal heart rate cannot be measured properly	<ul style="list-style-type: none"> <li>● Confirm that the device is FHR transducer (pink)</li> <li>● Check if the FHR transducer is turned ON.</li> <li>● Check if the FHR transducer is connected to the tablet.</li> <li>● Check if the FHR transducer is accurately capturing the foetus position.</li> <li>● Check if the belt that secures the FHR transducer is loose.</li> <li>● Check if the maternal heart rate is being measured.</li> <li>● Check if gel has been applied.</li> </ul>
Uterine contraction cannot be measured properly	<ul style="list-style-type: none"> <li>● Check if the device is the UC transducer (blue).</li> <li>● Check if the UC transducer is turned ON.</li> <li>● Check if the UC transducer is connected to the tablet.</li> <li>● Check if the UC transducer is correctly placed over the base of the uterus.</li> <li>● Check if the belt that secures the UC transducer is loose.</li> </ul>

## **7.2. Maintenance during Warranty Period**

- If the iCTG device is not functional/even after troubleshooting activity as per section 7.1, report to Biomedical Engineers/BMETs of concerned health centres within 24 hours.
- Depending on the severity of the malfunction of iCTG machines; BMED should convey the problem to Melody International for rectification during the warranty period.

## **8. References**

1. iCTG Operation manual, Melody International
2. How to Read a CTG available in the link here: <https://geekymedics.com/how-to-read-a-ctg/>

Annexure-1: Log Book on use of iCTG (Sample format)

Date and Time	Pt. ID (MCH no.) same as iPad control	Name and age	Indication for iCTG and POG	Done by (Name)	Outcome/Remarks
					<input type="checkbox"/> Normal iCTG <input type="checkbox"/> Repeat iCTG  .....times (mention the number of times iCTG was used) <input type="checkbox"/> Referred  Others.....