EDAN OBSTETRICS CHECK LIST

Revision History:

Version	Date	Created By	Details
1.0	2023.12.25	Roman	EDAN OBSTETRICS CHECK LIST

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EDAN OBSTETRICS CHECK LIST 1

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Overview of Hospital Department			
Hospital Name		Department	
Contacts		Device Model	
Phone No.		No. of Device	
■ **Monitor**			
Manufacturer		Device Model	
Serial No.		Date	

Device List			
No.	Serial No. of Main Unit	Conclusion	Remark
1		ACC☐ NG☐	
2		ACC☐ NG☐	
3		ACC☐ NG☐	
4		ACC☐ NG☐	
5		ACC☐ NG☐	
6		ACC☐ NG☐	
7		ACC☐ NG☐	
8		ACC☐ NG☐	
9		ACC☐ NG☐	
10		ACC☐ NG☐	
11		ACC☐ NG☐	
12		ACC☐ NG☐	
13		ACC☐ NG☐	
14		ACC☐ NG☐	
15		ACC☐ NG☐	

Inspector：_____ Date：_____

Auditor：_____ Date：_____

EDAN OBSTETRICS CHECK LIST

Inspection Basis	EDAN Fetal Monitor Factory Test Specification
Inspection Condition	Ambient temperature: (20±10)℃; Relative humidity: ≤80%; Power supply: (220±22)V, (50±1)Hz; There is no strong magnetic interference and mechanical vibration in the surrounding area that affects the normal work of the monitor, and it should have a good grounding device.

■ Inspection Device

Device Name	Fetus Monitor	Manufacturer	EDAN
Device Model		Serial Number	

Appearance Inspection				
Silk Printing	Label	Cover	Screen	Transducer
ACC□ NG□	ACC□ NG□	ACC□ NG□	ACC□ NG□	ACC□ NG□

Basic Function Inspection			
Display	Key	Sound	Alarm
ACC□ NG□	ACC□ NG□	ACC□ NG□	ACC□ NG□
Print	Fetal movement marker	Touch screen	Battery
ACC□ NG□	ACC□ NG□ NA□	ACC□ NG□ NA□	ACC□ NG□ NA□

Fetal Heart Rate						
Set Value(bpm)	50	90	120	150	180	230
Measurement Value(bpm)						
Error value must less than ±2bpm				Result	ACC□ NG□ NA□	

Uterine Contraction Pressure (TOCO)					
Weight(g)	50	100	150	450	500
Measurement Value					
TOCO error value range must be 34±8%				Result	ACC□ NG□ NA□

Non-invasive Blood Pressure (NIBP)			
Set Value(mmHg)	270/210（230）	275/215（235）	40/10（20）
Measurement Value			
NIBP error value must less than ±8mmHg		Result	ACC□ NG□ NA□

Heart Rate (HR)			
Set Value(bpm)	30	120	240
Measurement Value			
HR error value must less than ±2bpm		Result	ACC□ NG□ NA□

Respiration Rate (RR)					
Set Value(rpm)	0	30	60	80	120
Measurement Value					
RR error value must less than 3rpm				Result	ACC□ NG□ NA□

Blood Oxygen Saturation (SpO2)			
Set Value(%)	80	98	100
Measurement Value			
Blood Oxygen Saturation SpO2: 70%~90% error rate less than ±4%; 90%~100% error rate less than ±2%; under 70%, undefined		Result	ACC□ NG□ NA□

Pulse Rate (PR)					
Set Value(bpm)	30	120	240		
Measurement Value					
PR error value less than ± 2bpm				Result	ACC☐ NG☐ NA☐

Overall Inspection Conclusion			
Inspection Conclusion	ACC☐ NG☐	Unqualified items	☐Appearance ☐Basic Function ☐FHR ☐TOCO ☐NIBP ☐HR ☐RR ☐SpO2 ☐PR
Remark			