RESEARCH PROTOCOL

Reliability of Simple Ultrasound Findings acquired with Hand-held Apparatuses to inform Urgent Obstetric Diagnosis in an Urban Low Resource Setting

PROTOCOL TITLE:

Protocol title	Reliability of Simple Ultrasound Findings acquired with Hand-held Apparatuses to inform Urgent Obstetric Diagnosis in an Urban Low Resource setting
Short title	
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LIST OF ABBREVIATIONS

AE	Adverse Event
AMC	Academic Medical Center
APH	Antepartum hemorrhage
AR	Adverse Reaction
CUAMM	Doctors with Africa – CUAMM
EC	Ethical Committee
GCP	Good Clinical Practice
IC	Informed Consent
ICU	Intensive Care Unit
PCMH	Princess Christian Maternity Hospital
(S)AE	(Serious) Adverse Event
US	Ultra Sound
POCUS	Point-of-care Ultra Sound

1. PROJECT SUMMARY

Rationale: The majority of obstetric emergencies are identified through clinical examination, which cannot be substituted by ultrasound. However, just as a laboratory exam, ultrasonograpy can provide swift point of care information on fetus presentation, viability, placenta position, quantity of amniotic fluid and presence of abdominal fluid to inform the clinical reasoning and therapeutic escalation. Ultrasound literature in low-resource settings has favoured antenatal care (ANC) rather than the emergency setting. Also, hand-held ultrasound machines may not be as performant as traditional machines used by expert operators but to date is still to be tested in a low resource setting.

Objective: to assess the *reliability* of **ultrasound findings** measured by hand held ultrasound probes used by operators with variable experience in a low resource hospital.

Hypothesis: There is substantial agreement between simple ultrasound findings identified using hand held ultrasound devices and the reference standard.

Study design: a prospective observational diagnostic accuracy study.

Study population: parturients admitted to the Princess Christian Maternity Hospital (PCMH) in Freetown, Sierra Leone.

Sample size: no formal sample size calculation is performed. Based on current rates of admissions to the PCMH we expect to perform obstetrical ultrasound scan in at least 300 patients during a 2–months study period.

Methods: 4 trained physicians (3 naive and 1 intermediate ultrasound users) will perform the ultrasound investigations using the hand held device and complete a structured predefined report form of obstetric ultrasound findings at patient admission or according to clinical indications after admission. These will be compared with the reference standard, i.e. an ultrasound examination performed by a specialist gynecologist/obstetrician using a conventional apparatus in the hospital ultrasound room.

Main study parameters/primary endpoints: The mean diagnostic accuracy among nine ultrasound obstetric findings collected with hand held devices versus the reference standard.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Ultrasound is a non–invasive and painless procedure without additional risks.

2. INSTITUTIONS INVOLVED IN THE PROJECT

2.1.Princess Christian Maternity Hospital

The Princess Christian Maternity Hospital (PCMH) in Freetown, Sierra Leone, is a maternity referral hospital and the only one qualified for comprehensive emergency obstetric care in the whole Western Area. The theoretical reference population amounts to 1.5 million inhabitants. PCMH is by constitution a primarily obstetric institution, with approximately 9,000 admissions per year, including 6,000 deliveries (of which 30% by cesarean section). Approximately one–third develop major obstetric emergencies, including peripartum hemorrhage, sepsis and pre–eclampsia. The PCMH has 149 beds in 7 wards. The theatre facilities are essential, anesthetic service is present with a majority of spinal anesthesia procedures. PCMH recently opened an 8–bed high–dependency unit (HDU) focusing on care for critically ill parturients.

2.2.Doctors with Africa CUAMM

'Doctors with Africa – CUAMM' (CUAMM) is an Italian non–governmental organization, which has been supporting health service delivery in Africa for over 60 years. Currently, it is active in 7 African countries. Its main focus is maternal, newborn and child health at a district level. CUAMM activities in PCMH started in 2016, focusing on strengthening of clinical and management activities.

3. BACKGROUND AND JUSTIFICATION

3.1.Ultrasound implementation in low and middle income countries

Ultrasound examinations in obstetric have been indispensable in high-income countries for many years. However, it has been shown recently that its use for antenatal visits in low- and middle-income countries (LMICs) did not necessarily mean improvements in perinatal outcomes. In fact the use of ultrasound did not improve maternal and neonatal mortality based on the results of a large cluster-randomized control trial in five LMICs (1). Furthermore, they found that there was no significant improvement in attendance rates of antenatal care of pregnant women, thus suggesting that resources should not be used for the introduction of ultrasound practices in resource limited settings.

Unexpected severe findings such as multiple pregnancy, breech presentation, or intra uterine fetal demise at the time of delivery are commonly found (2). These complications often resulted in high morbidity and mortality of pregnant women and newborn babies. As it may take long to improve capacity to screen out high-risk pregnancies at antenatal contacts, enhancing diagnostic and treatment capacity of the tertiary hospital to cope with these unexpected conditions will currently be most required.

3.2.Point of care and hand held ultrasonography

Point-of-care ultrasonography (POCUS) has recently been recognized as a powerful tool to support bedside clinical diagnosis mostly in emergency settings. As technology advances, ultrasound devices became more compact to the point of being hand carried also by physicians not specialized in ultrasound. Their use in resource–limited settings has been studied in emergency departments in tertiary care hospitals in Rwanda and Tanzania with substantial impact on clinical decision making processes (3,4).

Hand held ultrasound devices usually have a low frequency probe (2-5 MHz) with a smart phone or tablet functioning as an interface. The interface of the device is designed to handle simple functions as freeze, zoom, basic measurements and gray-scale adjustment. It can also perform obstetric calculations e.g. for estimation of gestational ages based on the measurements of bi-parietal diameter (BPD) or femur length (FL).

3.3.Feasibility issues with POCUS

Feasibility of POCUS in obstetric emergencies has also been studied mostly in high-income countries and shown to be useful for physicians not specialized in obstetrics to identify normal pregnancy and identify differential diagnoses for parturients who present at the emergency department with acute symptoms (6-10). Application of POCUS in antenatal settings has been studied in Kenya where a trained midwife successfully conducted screening of high–risk pregnancies (5). However, there is paucity of information of POCUS obstetric application in resource limited settings especially to manage emergency cases and detect simple but important obstetric findings.

3.4.Current challenges with obstetric diagnostics in PCMH

Princess Christian Maternal Hospital (PCMH) is only the tertiary perinatal hospital in Freetown, Sierra Leone, which accommodates nearly 9000 admissions a year (11). More than 6000 deliveries a year are managed at the hospital, with more than one third of cases being major obstetrical emergencies including eclampsia and peri-partum hemorrhages. Furthermore, the hospital accepts emergency referrals from 6 hospitals and 112 peripheral clinics in the Western region of the country. Major causes of maternal mortality at PCMH include postpartum and antepartum hemorrhage, eclampsia and infection (12).

In the 2017 Annual Report (12), it was shown that diagnoses made at admission by house doctors at outpatient department were frequently different from the final diagnoses made by the house officers specialized in obstetrics. For example, approximately 40% of the patients admitted to the hospital were initially diagnosed with anemia, but most of them were subsequently found to be in fatal conditions caused by placenta abruption (12). It is obvious that confirming a diagnosis is not the

only step needed to avoid mortality, but it is pivotal to establish a functional system to save critically ill patients. Lack of access to ultrasound in the delivery room often resulted in late diagnosis of malpresentation, breech presentation or multiple pregnancies. Intra-uterine fetal death (IUFD) was frequently observed but unnoticed until they were delivered by unnecessary cesarean sections.

At the emergency outptient department of PCMH, clinical examinations and history taking are the only means to reach diagnoses, based on which subsequent management strategies are planned. Measurement of hemoglobin and lactate are the only modality available for in-house doctors to support their diagnosis. Ultrasound machine is intermittently available but the frequent low quality of the images acquired and the unstable electric supply of the hospital hampers repeatability and reliability of the ultrasound examinations.

Stethoscope or doppler devices are seldom available or functional. Traube's monoaural stethoscope is the only the device available for the in-house doctors or midwives to listen to the fetal heart. Prompt diagnosis and treatment decisions are frequently required in the case of obstetric emergencies, in which delay in the recognition of the conditions of the fetus and mothers often resulted in demise of both.

3.5.The present project

Despite its clear operator dependency (13) and potential usefulness in the decision making process, feasibility and accuracy of portable ultrasound devices in obstetrics has been scarcely investigated. The objective of the study is to evaluate the reliability of simple pre–specified ultrasound findings acquired at the bedside with a hand–held apparatus with regards to five clinical scenarios most commonly encountered in the hospital, i.e. vaginal bleeding in early pregnancy, pre–eclampsia, prolonged/ obstructed labor, antepartum hemorrhage (APH) and high risk pregnancies encountered in ANC. These will be compared to a reference standard, constituted by a conventional ultrasound examination performed by an expert gynecologist with a standard apparatus in the hospital dedicated scanning room.

4. STUDY GOAL AND OBJECTIVES

4.1. Objectives

4.1.1. Primary Objective

To determine the composite reliability of simple obstetric ultrasound findings collected by hand held ultrasound devices in a busy urban low resource setting.

4.1.2.Secondary Objectives

1. To assess the reliability for each pre–defined ultrasound finding.
2. To ascertain if the reliability varies between naïve and intermediate operators.

3. To establish the feasibility of examinations and quality of images acquired with the hand held apparatus.

4.1.3.Primary Hypothesis

There is substantial composite agreement between simple ultrasound findings identified using hand held ultrasound devices and the reference standard.

4.1.4.Secondary hypothesis

1. The diagnostic accuracy will be significantly higher for specific 'easier to detect' *individual ultrasound findings* such as intrauterine pregnancy, amniotic fluid estimation, cephalic presentation, and presence of abdominal fluid.
2. The diagnostic performance of the ultrasound *naive operator* is significantly different from the intermediate operator only for more complex ultrasound findings such as fetal heart, presence of retroplacental hematoma, placenta location, estimation of gestational age and detection of multiple pregnancy.
3. The proportion of complete examinations is >90% and quality of images as estimated by a simple visual scoring system is high (more or equal to 3).

5. STUDY DESIGN

This is a prospective observational study in parturients admitted to the emergency department, outpatient department and antenatal care of the PCMH in Freetown, Sierra Leone.

5.1.Population

5.1.1.Inclusion criteria

In order to be eligible to participate in the observational study, a patient must meet the following criteria:

- Admitted to the emergency department, outpatient department, in-patient department or antenatal care (ANC) of the PCMH during the study period.
- Fulfills one or more of the five inclusion categories defined in Table 1.
- (Verbal or written) informed consent of the patient or his/her formal representative, if required by ethical committee (decision is pending whether informed consent, either verbal or written, is required from individual patients).

5.1.2.Exclusion criteria

The following exclusion criteria will apply in the observational study:

- Ultrasound examination not feasible, e.g., due to electricity breakdown, or physical absence or unavailability of the trained sonographers.

Table 1. Inclusion categories as defined by National Protocols and Guidelines for Emergency Obstetric and Newborn care (14) or hospital protocol.

Inclusion criteria	Case Definition
Vaginal bleeding in early pregnancy	Vaginal bleeding or cramping, with amenorrhea or positive pregnancy test <22 weeks of gestation
Pre-eclampsia	Blood pressure ≥140/90 (at least 2 recordings, 4 hours apart) PLUS any of: proteinuria (at least 2+ on dipstick, headache, generalized oedema, visual disturbance).
APH third trimester:	Vaginal bleeding after 22 weeks of pregnancy or in labour before giving birth. May have final diagnosis of abruptio placentae, placenta previa and ruptured uterus.
Prolonged/ Obstructed labour:	Prolonged latent or active phase, cephalopelvic disproportion, obstructed labor, inadequate uterine activity, prolonged expulsive phase.
High risk pregnancy in ANC	Fulfils any of the following criteria (as defined by hospital protocol): 1. Previous Cesarean Section 2. Previous still birth 3. Age below 18 years 4. Short stature (height < 150cm) 5. Grand Multipara: Gravida more than 5. 6. Fundal Height >40cm 7. Suspected breech

5.2.Sample size calculation

Sufficient information to perform a formal sample size calculation is lacking. During a 2–month period all patients meeting the inclusion and exclusion criteria will be recruited. Based on current rates of admissions in the mentioned services, we expect to recruit at least 300 patients (75 patients per operator, 15 for each of the 5 inclusion categories) during a 2 months data collection period.

5.3.Study period

The enrollment period will last two months. Demographic and baseline clinical data are recorded on admission while outcome data are captured at hospital discharge. The hospital discharge of the last patient enrolled will be considered the end of the data collection period for this study. The study period will end at completion of data analysis.

6. METHODS

6.1.Study parameters/endpoints

6.1.1.Main study parameter/endpoint

The primary endpoint is the mean aggregated diagnostic accuracy between the ultrasound findings collected via hand held devices as compared to the conventional apparatus.

6.1.2. Secondary study parameters/endpoints

1. Detailed diagnostic accuracy for each of the nine ultrasound findings.
2. Inter-observer agreement on ultrasound findings between naïve and intermediate operators.
3. Mean 'quality of image score' (0-4) for each of the nine ultrasound findings.
4. Proportion of complete ultrasound examinations i.e. with all pre specified findings allocated for the category being completed.

6.1.3.Data to be collected

The following data will be collected:

- **Prespecified ultrasound findings as described in Table 2.**
- Other data to be collected: demographic characteristics: age, weight, height, parity; admission type: medical or surgical; if surgical, type of surgery; date and outcome at hospital discharge (transferred to another hospital or home, death).

6.1.4.Randomization, blinding and treatment allocation

Patients are prospectively recruited on a consecutive basis. No randomization will be performed. The reference standard operator will be blinded to the results of the ultrasound examinations made with the hand held apparatus and vice–versa.

6.2.Study groups

Not applicable.

6.3.Study procedures

6.3.1. Training of operators

The ultrasound operators will receive a 2–week training course. The 1st week training consists of lectures on basic science of ultrasound and tomography, demonstrations by an expert obstetrics sonographer, and hands-on practice at the scanning room of PCMH. The second week of training will focus on how to operate the hand-held ultrasound device, training on the standard operating procedure (SOP) and case report form (CRF) completion.

Table 2. Ultrasound findings. Abreviations: GA, gestational age; FH, fetal heart; MVP, maximum vertical pocket, APH, antepartum hemorrhage; ANC, antenatal clinic.

	Inclusion category	Finding 1	Finding 2	Finding 3	Finding 4
1	Vaginal bleeding in early pregnancy	Intra–utherine pregnancy: yes/no	FH: yes/no	Free fluid in abdomen: yes/ no	None
2	Pre-eclampsia	FH: yes/no	Amniotic fluid MVP<2cm: yes/ no	GA: ≤34 or >35 weeks	Cephalic presentation: yes/no
3	APH in third trimester	Placenta low lying: yes/no	FH: yes/no	Retroplacental hematoma: yes/no	Amniotic Fluid MVP<2cm: yes/no
4	Prolonged/ obstructed labor	FH: yes/no	Multiple pregnancy: yes/ no	Cephalic presentation: yes/no	Amniotic Fluid MVP<2cm: yes/no
5	ANC High Risk Pregnancy*	Cephalic presentation: yes/no	Multiple pregnancy: yes/ no	FH: yes/no	Amniotic Fluid MVP<2cm: yes/no
				Placenta low lying: yes/no	GA: ≤34 or >35 weeks

6.3.2.Ultrasound procedure

Eligible patients will receive:

- a structured point of care ultrasound examination immediately at admission in emergency (or at the point of visit in ANC or ward) by the medical officer using the hand held device and following a simple checklist (Table1).
- the ultrasound examination will be repeated by an expert operator using a standard ultrasound machine in the scanner room of PCMH.

6.3.3.Portable Ultrasound Device

The portable ultrasound device to be used in the study is a convex probe type which work with compatible smart devices run by Android OS. Its frequency range is 3.5 MHz and maximum depth is 30cm. The screen of the smart phone or tablet is the interface, designed to be easy to use, focusing on minimum functions such as freeze, zoom, simple obstetric measurements and gray-scale adjustment. Detailed information on the device are provided in Appendix 2.

6.4.Safety consideration and follow up

6.4.1.Withdrawal of individual subjects

Patients can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study

for urgent medical reasons, e.g. when it becomes impossible to perform the ultrasound examination or this is deemed to interfere with patient care.

The study participants have the right to contact the ethics and review committee if they raise any issue or concern with the study (Office of the Sierra Leone Ethics and Scientific Review Committee, Ministry of Health and Sanitation, Directorate of Policy, Planning & Information (DPPI) Youyi Building, Fifth Floor, East Wing).

6.5.SAEs

Because all proceedings in the method of this study are based on common clinical practice and ultrasound is a non–invasive procedure that cannot injure patients, there are no serious adverse events (SAEs) expected.

7. DATA MANAGEMENT AND STATISTICAL ANALYSIS

7.1.Data management

All patients will be identified with a unique study identification code. A logbook with the matching between patient number and name will be stored digitally and in paper. The paper version will be stored behind a lock and the digital form will be protected with a password. The logbook will be the only document containing patient identifier information. Data will be stored an additional 15 years after the study's completion.

7.1.1.Data capture

Data is collected on paper checklists and case report forms (CRFs) and subsequently transcribed onto an Internet–based electronic CRF (https://www.kobotoolbox.org). Access to the data–entry system is protected by a personalized username and password. Patients are identified with a study identification code, hence there will be no patient identifier data transcribed on the online CRF.

7.1.2.Data sharing

Data derived from this study will be shared with the clinical team directly responsible for patient's care and with hospital leadership and management team for monitoring and/or audit purposes. **Specifically, a copy of the final expert report performed with the conventional apparatus will be attached to the patient's clinical chart to be visualized by the clinical team responsible for patient's care.** After publication of the primary results, on request the pooled dataset will be available for secondary analysis, after judgment and approval of scientific quality and validity of the proposed analysis by the steering committee.

7.1.3.Data handling and record keeping

The anonymized data will be stored in a secure database to guarantee the privacy of study subjects. Only local investigators will have access to the database and matching log–book.

7.2.Statistical analysis

Data will be reported as mean and standard deviation or median with interquartile range (continuous data), and as frequency and percentage (categorical data). The agreement between the hand–held device and the conventional apparatus on categorical findings scoring will be assessed using diagnostic accuracy and Cohen's K statistics. When appropriate, comparison between subgroups will be perfomed using Student's t test, ANOVA, Mann-Whitney test or Kruskal-Wallis test for continuous data, and with Chi-square test or Fisher's test for categorical data. A p-value less than 0.05 will be considered statistically significant. Statistical analyses will be performed using R (R Foundation for Statistical Computing, Vienna, Austria). The sensitivity, specificity, positive predictive value, and negative predictive value for each dichotomous ultrasound finding acquired with hand held devices against the reference diagnoses with conventional apparatus will be assessed when appropriate.
Quality of images will be assessed by standardized scoring system from 0 to 4 (0= no meaningful images; 1 = poor, not sufficient for interpretation; 2 = good, acceptable for interpretation; 3= excellent, minor suggestions for interpretations; 4 = outstanding, no suggestions for interpretations). All analyses will be conducted after the end of patient recruitment and no interim analyses are planned.

7.3.Quality assurance

Data will be cross–checked for completeness by the researcher on the field (YK) and independently by a second investigator. A random sample of 20 examinations (5 per operator) will be analyzed offline by an independent expert in obstetric ultrasound, blinded from the first investigator ultrasound report, patient clinical conditions and laboratory results.

8. PROJECT MANAGEMENT

8.1.Project steering committee

There will be a project steering committee led by the principal investigator and project coordinator to follow up all the project phases and to overcome possible problems. Yuichi Kodaira, Michael Koroma, Giovanni Putoto, Luigi Pisani and Marianna Zanette are responsible for study design, quality assurance and report writing. Local investigators and coordinators of data collection: Yuichi Kodaira.

8.2.Dissemination of results and publication policy

The results of this study will be published in a peer–reviewed medical journal. We have no restrictions in publication of outcomes of this study.

8.3.Problems anticipated

No significant problems are foreseen in this observational study.

8.4.Timeline of project

Ethical Clearance: January-February 2019
Training of operators: February 2019

Data Collection and Data entry: March 2019
Data analysis: May-June 2019
Preliminary results: July 2019
Final report: September 2019

8.5.Amendments

Amendments are changes made to the research protocol after a favorable opinion by the accredited ethical committee has been given. All amendments will be notified to the EC that gave a favorable opinion. Non-substantial amendments (typing errors and administrative changes) will not be notified to the accredited EC and the competent authority, but will be recorded and filed by the sponsor.

8.6.Temporary halt and (prematurely) end of study report

In the unlikely event of a temporary halt or early stopping of the study, the investigator/sponsor will notify the accredited EC of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient included. The investigators will notify the EC immediately of a temporary halt of the study, including the reason of such an action. In case the study is ended prematurely, the investigators will notify the accredited EC within 15 days, including the reasons for the premature termination. Within one year after the end of the study, the investigators will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited EC.

9. ETHICS AND INFORMED CONSENT

9.1.Regulation statement

This study will be conducted according to the principles of the Declaration of Helsinki (revision Fortaleza, Brazil, October 2013). Approval to carry out this study will be sought from the relevant Review Board of Sierra Leone Ethics and Scientific Review Committee and from Doctors with Africa – CUAMM board of directors.

9.2.Recruitment and consent

No ethical concern is attributable to this study due to its observational nature. No direct therapeutic intervention on patient is part of the study design. Personal information (name, age, community, etc.) from patient chart will be anonymized and no patients will be recognizable during the realization or dissemination phases of the study. Serial obstetrical ultrasound examinations are already standard of care in obstetric patients in PCMH and point of care ultrasound is also normally performed in emergency settings at the outpatient department of the hospital. The report of the expert ultrasound scan would be attached to the clinical chart, as already routinary when an ultrasound is performed in the PCMH scanning room. For these reasons, and considering the medical urgency characterizing most inclusion criteria, a waiver of patient individual informed consent is kindly requested to this EC. Sharing of patient data will follow Good Clinical Practice guidelines and ethics review committee advice.

9.3. Benefits and risks assessment

Because all proceedings in the method of this study are based on common clinical practice and ultrasound is a non–invasive procedure that cannot injure patients, the risk of this study is considered very low. The ultrasound performed for this study are not charged to the patient or to the hospital administration.

As this study aims at assessing the reliability of obstetric findings, we cannot choose another patient population. Patients included in this study may benefit in terms of systematic ultrasound monitoring in a setting where obstetric imaging modalities are still hampered by technical and non–technical difficulties.

10. BUDGET AND OTHER SUPPORT FOR THE PROJECT

Funding is actively being sought. However if funding is not obtained the following resources will be utilized. Investigators time will be given voluntarily. Doctors with Africa – CUAMM, will fund ethical committee fees. Waiver for costs for publication based on low–income country status will be sought from the relevant international journals.

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12. APPENDIX
Ultrasound probe to be used in this study

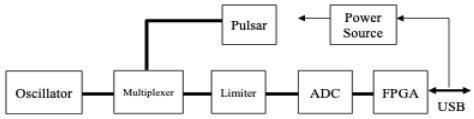
Specification for Ultrasound Probe "US-304"

Ver 2. 0. 1
July 25th, 2018

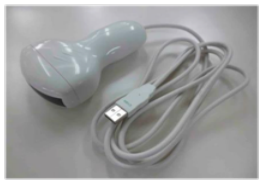
1. **General Description**
This device allows you to receive the high-resolution ultrasound images by utilizing the power from a general purposed laptop/tablet.

2. **System**
2.1 Operation
The probe on this device is installed with ultrasound frequency sender and receiver, amplifier and ADC circuit which send ultrasound image data as USB signals. The signal gets processed through PC viewer software to be projected as image on the screen. This device also has scanning, mode control, and measuring functions.
In addition, this device has recording-functions for tomographic images and results of measurement and connecting-functions for sending images and transferring data to outside network.

2.2 Diagram



2.3 Model Picture



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3. **Functional Specification for Abdomen**

3.1	Device	
	Size	W 85 x L 180 x Thickness 18 mm (Main body only)
	Weight	167 g (cable included)
	Cable Length	1.5 m
3.2	Oscillator	
	Configuration	Convex (Curved array)
	Curvature	Radius 60mm
	View Angle	60 degree
	Element Count	64 Elements
	Element Pitch	1.0 mm
	Element Width	12 mm
	Acoustic Matching Layer	1 Layer
	Lens Focal Point	100 mm
3.3	Function	
	Sending Frequency	2.5 - 4.0MHz
	Display Mode	B, B/B, BM
	Measurement	Distance, Area, Circumference
	Special Measurement	Obstetrics Measurement
	Sync View*	Convertible
		*A function to synchronously record ultrasound images for the internal body and camera images for the external body

4. **Display Device**

4.1	Recommended Device	Panasonic ToughPad FZ-G1 Series
4.2	OS	Windows 8.1 Windows 10
4.3	CPU	Intel Core i3 (CLK 2GHz and above) AMD A4 (CLK 2GHz and above)
4.4	RAM	4GB and above

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5. **Power Source**

5.1	Outlet	5V Max. 350mA USB Power Source
5.2	Operational Duration	Estimated 120 minutes when the battery is fully charged

6. **Circuit Configuration**

6.1	Sending	
	Excitation Element Number	8 Elements
	Excitation Voltage	±48V and above
	Sending Pulse	1.5 Wave Length Square Wave
	Focus	Single / fixed
6.2	Receiving	
	Number of Receiving Circuit	A similar processing output to 16 sensor elements, using an 8 sensors circuit twice.
	Focus	Dynamic Focus

7. **Image Processing**
7.1 Line interpolation
7.2 Frame correlation

8. **Estimated lifetime with appropriate use**
7 years

3

The device “US-304” can be connected to the smartphone which fulfills certain requirements. Any smartphone run by Android OS can be used for the portable ultrasound device after the application developed by the same manufacture to run the program for ultrasound examination is installed. Once the application is installed in the smartphone, it will be an interface to control the device to optimize the images acquired by ultrasound examinations and to perform obstetric calculations for estimation of gestational ages based on the measurements of bi-parietal diameter (BPD) or femur length (FL). In the study, the ultrasound device (probe type: convex type with 3.5 MHz) and a smartphone (ASUS; Taiwan), in which the application has already been installed, will be provided for practical training sessions.

The manufacture information is given below:

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