PHILIPS

Collaboration Live Clinical Study

Study Sponsor:

Philips Ultrasound, Inc.
3000 Minuteman Road
Andover, MA 01810

Author Signature
Clinical Development Scientist, Clinical Affairs

Date

Signature
Principal Biostatistician, Clinical Affairs

Date

Signature
Clinical Operations Manager, Clinical Affairs

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Regulatory Affairs Specialist, Regulatory Affairs

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Table of Contents

1 List of Abbreviations

Abbreviation	Definition
AE	Adverse Event
ADE	Adverse Device Effect
ALARA	As Low As Reasonably Achievable
CFR	Code of Federal Regulations
(e)CRF	(electronic) Case Report Form
EDC	Electronic Data Capture
EN	European Norm
FDA	Food and Drug Administration
GCP	Good Clinical Practices
HIPAA	Health Insurance Portability and Accountability Act
IEC	International Electrotechnical Commission
IFU	Instructions for Use
IRB	Institutional Review Board
ISO	International Organization for Standardization
NSR	Non-significant Risk
OB/GYN	Obstetrics/Gynecology
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SRF	Site Regulatory File
USADE	Unanticipated Serious Adverse Device Effect

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2 Statement of Compliance

I agree to conduct the trial as outlined in the protocol in accordance with the Sponsor's guidelines and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB. The Sponsor's guidelines include, but are not limited to:

- Provide supervision of all testing of the device involving human subjects.
- If applicable, provide Philips with information regarding past investigations or other research that was terminated, including an explanation of the circumstances that led to the termination.
- Allow Philips and/or regulatory agencies to inspect study facilities and pertinent records at reasonable times and in a reasonable manner that ensures subject confidentiality.
- Notify Philips as soon as possible if this study is to be inspected by a regulatory agency.
- Submit the proposed clinical investigation including the protocol and the consent form to an IRB for approval, if required.
- Ensure informed consent is obtained prior to the use of any test articles.
- Submit any proposed change in, or significant deviation from, the protocol to an IRB for approval, and ensure the changes are reflected in the informed consent form, as appropriate, and also approved by the IRB.
- Document protocol deviations and violations with explanations as appropriate.
- Submit Adverse Events to the Sponsor and IRB as outlined in the protocol.
- Submit timely progress reports to the IRB and Sponsor as appropriate.
- Maintain adequate and accurate records of all study procedures, observations, results, and other related information (such as safety, protocol compliance, and product accountability).

I agree that all information provided to me by the Sponsor including protocols, verbal and written information shall be kept confidential and restricted to the personnel involved in conduct of the trial. It is recognized that this information may be conveyed to the IRB. I also understand that reports or information about the trial and its progress shall not be provided to anyone not involved in the trial other than the Sponsor or other legally constituted authority.

_____ _____

Principal Investigator's Signature Date

_____

Principal Investigator's Printed Name

PHILIPS

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Principal Investigator's Signature

11/19/19
Date

Michael S. Ro
Principal Investigator's Printed Name

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3 Protocol Synopsis

Title:	Collaboration Live Clinical Study
Study ID:	US-GIS-Collaboration Live-2019-10649
Overview:	This study is being conducted to assess the use of Collaboration Live software in conferencing, sharing and remote control of the Philips EPIQ Series Ultrasound Systems.
Objectives:	The study will evaluate the performance and safety of the Collaboration Live software in a clinical setting.
Primary Endpoint:	Percentage of cases for which the remote control functionality performs in a clinically acceptable manner.
Study Design:	This is a prospective, single-arm clinical study of subjects who provide written consent. Subjects are scanned using a Philips EPIQ 5 or EPIQ 7 Ultrasound System equipped with Collaboration Live software. The study investigator will evaluate performance of the Collaboration Live tool with regard to performance of conferencing, sharing and control capabilities. Adverse events will be reported and the study investigator will assess potential relationship to the study device or study procedure. Additionally, the utility of Collaboration Live in remote consult of study patients will be evaluated. No patient follow-up beyond the initial consultation will be conducted with the Collaboration Live software solution.
Population:	30 subjects
Key Eligibility Criteria:	Subjects must be willing and capable of providing informed consent and participating in the study. Subjects must be indicated for a routine OB/GYN ultrasound examination at the site.
Sites:	1
Anticipated Study Duration:	3 months
Participant Duration:	Single visit (1 day)

4 Background Information

The Collaboration Live Clinical Study is intended to evaluate the performance and safety of the Collaboration Live software in a clinical setting and will enroll 30 patients scheduled for routine OB/GYN ultrasound exams. This is a prospective, non-randomized, single-arm clinical study. No patient follow-up is planned beyond the initial exam. The anticipated study duration is three months.

Ultrasound imaging is a form of medical imaging that involves the use of high frequency sound waves. Typically used to help a physician evaluate, diagnose, and treat patients, ultrasound imaging is minimally invasive and no radiation is involved. Collaboration Live is a software solution integrated into Philips EPIQ Ultrasound Systems that enables remote viewing, conferencing and control of the system. All study scanning (including scanning performed under remote control) will be conducted using the ALARA principle to ensure the safety of the subjects. As ultrasound imaging is based on non-ionizing radiation, it is generally considered safe when used by appropriately trained health care providers.

The use of Collaboration Live as part of the study does not significantly alter the risk profile of the Ultrasound System. A description of study risks is presented in Section 13, Risk and Benefit Analysis. Under 21 CFR 812.3(m), the Sponsor requests IRB determination of the study as a Nonsignificant Risk (NSR) Device Study. There is no specific benefit to individuals participating in the study.

The ethical principles for the treatment of human subjects on this study have their origin in the Declaration of Helsinki.

This study will be conducted according to the IRB-approved study protocol, ISO 14155 Clinical Investigation of Medical Devices for Human Subjects and applicable regional/national regulations.

Institutional Review Board (IRB) review and approval will be obtained, prior to consent and enrollment of any subject, and dispense of any test article. Any additional requirements imposed by the IRB or regulatory authority will be followed, if appropriate.

5 Product Description

Collaboration Live is a nondiagnostic software solution intended for use with Philips (Philips Ultrasound, 22100 Bothell Everett Highway, Bothell, WA 98021) EPIQ and Affiniti Series Ultrasound Systems (software version 5.0.2) that allows users to communicate (by text, voice, screen share, webcam video and remote takeover) from an ultrasound system or workstation to a remote destination.

With Collaboration Live, users may:

- Get real-time remote technical and application support from Philips.
- Confer remotely with peers during an exam.
- Share screens.
- Activate remote control of the screen, touch screen, and control panel.

5.1 Regulatory Status

The Collaboration Live software solution is considered investigational (i.e., has not been cleared by the FDA). For this study, the Collaboration Live feature will be evaluated as integrated into the EPIQ 5 and EPIQ 7 Ultrasound Systems (software version 5.0.2). The EPIQ Ultrasound Systems and supporting transducers used in the study have received FDA clearance and are indicated for use in obstetric and gynecological exams. The Philips EPIQ Ultrasound System is considered safe for use in human subjects in this clinical study because extensive safety testing has been conducted to confirm the safety profile and all hardware is FDA-cleared. The hardware complies with the following medical device safety standards listed in Table 5 below.

Table 5: Compliance with Medical Device Standards

	Standard Name and Description
Electrical Safety	**EN/IEC 60601-1:2006 + A1:2013** – *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.* The Philips EPIQ System has been designed and verified to comply with the electrical safety requirements of this standard, including requirements for electrical ground bond, leakage current, and dielectric withstand.
Electromagnetic Compatibility	**EN/IEC 60601-1-2:2007** – *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.* The Philips EPIQ System has been designed and verified to comply with the radiated and conducted emission requirements of this standard.
Usability	**EN/IEC 60601-1-6:2010** – *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.* The Philips EPIQ System has been designed and verified to comply with the usability requirements of this standard.

	Standard Name and Description
Diagnostic Ultrasound Imaging	**EN/IEC 60601-2-37:2007** – *Medical electrical equipment – Part 2-37: Particular requirements for basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.* The Philips EPIQ System has been designed and verified to comply with the diagnostic ultrasound imaging requirements of this standard.
Risk Management	**EN/ISO 14971:2012** – *Medical devices: Application of risk management to medical devices.* The risk assessment and mitigation procedures for the Philips EPIQ System has been conducted in compliance with the requirements of this standard.
Clinical Investigation	**EN/ISO 14155:2011** – *Clinical investigation of medical devices for human subjects: Good clinical practice.* This clinical study of the Philips EPIQ System with investigational Collaboration Live software is designed and conducted to comply with the content and human protections requirements of this standard. This compliance ensures that clinical investigations adhere to current Good Clinical Practice (GCP) guidelines.
Device Labeling	**EN/ISO 15223-1:2016** – *Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.* The labelling associated with the Philips EPIQ System with investigational Collaboration Live software has been designed and verified to comply with the requirements of this standard.

The use of Collaboration Live as part of the study does not significantly alter the risk profile of the Ultrasound System. A description of study risks is presented in Section 13, Risk and Benefit Analysis. Under 21 CFR 812.3(m), the Sponsor requests IRB determination of the study as a NSR Device Study. In addition, clinical readiness testing of the ultrasound system with investigational software will be performed prior to study initiation and will include an assessment of acoustic pressure and intensity output values to ensure thermal and mechanical indices remain below established FDA thresholds.

6 Study Design Rationale

The Collaboration Live Clinical Study is designed to demonstrate the safety and performance of the Collaboration Live software in a clinical setting. The results may be used to support global regulatory submissions and publication.

7 Study Objectives and Purpose

The study objective is to evaluate the performance and safety of the Collaboration Live software in a clinical setting. The study will assess the use of Collaboration Live in conferencing, sharing, and remote control of the Philips EPIQ 5 and EPIQ 7 Ultrasound Systems (software version 5.0.2) in performing routine OB/GYN ultrasound examination.

Collaboration Live is not intended to be used as a diagnostic tool. The clinical site's standard practices regarding image review and in-person consultation shall be followed as required to aid in diagnosis of medical conditions.

7.1 Endpoints and Additional Measures

The primary endpoint is the percentage of patient exams for which the remote control functionality performs in a clinically acceptable manner, where clinically acceptable is defined as:

- The system responds to the remote input as intended and without a delay interfering with the conduct of the exam. Additionally, a clinically acceptable exam would also result in no adverse events related to the control feature.

Additional measures will be evaluated including:

- Adverse events, including investigator assessment of seriousness and relationship to the study device or study procedure
- Assessment of technical issues
- Success rates for key tasks in the collaborative exam
- Travel reduction attributable to use of Collaboration Live
- Ease of use
- User feedback regarding streaming, image quality and overall experience
- Patient feedback regarding remote consultation
- Impact of remote consultation on reimbursement

8 Study Design

This is a prospective, single-arm, clinical study and will enroll 30 subjects undergoing a routine OB/GYN ultrasound examination. No additional interventions or follow-ups to the subject will be conducted as part of the study.

8.1 Steps in Study Visit

Subjects meeting all of the inclusion criteria and none of the exclusion criteria will be asked to provide informed consent. Only after informed consent has been obtained, may the study procedures begin.

8.1.1 Informed Consent Process

Study participation is voluntary. Potential subjects, and/or their legal representatives, are given the most current IRB-approved consent form) to read. They will be provided ample time for review and an opportunity to ask questions about the study. If they agree to participate, they will sign the consent form and be given a copy of the signed document for their records. The original signed copy of the consent form will be retained by the Principal Investigator. Each of these actions/steps will be documented. Only after Informed Consent has been obtained, may the study procedures begin.

8.1.2 New Information About the Study

As this study only requires a one-day visit and there is no follow up, it is unlikely that any new information will influence a subject's decision to participate. However, as ultrasound technology is constantly evolving it may be necessary from time to time to update the consent form so the subject may be informed of any new information. This will be done in conjunction with IRB approval, as appropriate.

8.1.3 Inability to Provide Consent

For this study, eligible subjects must be willing and physically able to undergo all study procedures. If they are unable to provide consent, they may not participate.

8.1.4 Demographics and History

Standard subject demographics (e.g., age, gender, race and ethnicity) and medical history will be collected.

8.1.5 Ultrasound Exams: Remote Viewing and Remote Control

All subjects are indicated for a medically-necessary routine ultrasound exam and will undergo this exam as conducted by a qualified ultrasonographer. Using the Collaboration Live software installed on the ultrasound system, the study investigator will remotely view the exam, including images acquired, in real time. As necessary, the investigator may use the system's capabilities (including text, voice, screen share and webcam video) to provide feedback to the ultrasonographer. The investigator or delegates will also provide assessment regarding use of the Collaboration Live software on a 5-point (Likert) scale, including:

- Streaming and image quality
- Ease of use
- Overall experience

The Collaboration Live software's remote control capability will also be used to adjust system settings during the exam. Systems settings may be adjusted by the investigator to assist in the following tasks:

- Image optimization (e.g., image depth, focal depth, gain)
- Pulsed-wave or Color Doppler Imaging
- M-Mode Imaging

To assess the primary endpoint, clinical acceptability, the investigator and qualified ultrasonographer will monitor the system response relative to input changes and record any adverse events occurring during remote control.

8.1.6 Remote Patient Consult

Following the ultrasound exam, the investigator will use the Collaboration Live software's remote control capability to review acquired images with the patient and/or ultrasongrapher. The investigator will also consult the patient using the system's audio and video capabilities.

Study subjects will be asked to complete a Telemedicine Satisfaction Questionnaire to capture feedback regarding information related to use of the Collaboration Live software in remote patient consult. The time spent in the remote consult and the distance (in miles) between the patient and consulting physician will be recorded. Billing data will be evaluated to assess impact of remote consultation on reimbursement.

8.1.7 Additional Measures

Additional information as assessed by the investigator or delegates will be reported throughout the exam, remote control evaluation, or remote consult, including:

- Adverse events, including seriousness and potential relationship to the study device or study procedure
- Technical issues using the Collaboration Live system
- Success rates for key tasks in the collaborative ultrasound exam, including:
    - Establishing remote connection
    - Establishing text chat
    - Establishing voice call
    - Establishing webcam feed
    - Establishing screen share
    - Establishing remote control

8.1.8 Adverse Events Reporting

The Principal Investigator or delegate must report any Adverse Events (AE) from the time the subject signs the Informed Consent Form until the conclusion of the study-related activities.

8.1.9 Subject Compensation

Subjects will receive compensation for their participation in the study.

8.1.10 Subject Dismissed

After the study scan, remote consultation and patient questionnaire have been completed, subjects are dismissed. No follow up is planned.

8.1.11 Study Termination

This study may be suspended or terminated at any time, at the will of the Sponsor.

8.1.12 Sponsor Representatives

None of the study procedures will be completed by Philips representatives. Philips representatives will be available during the study to provide training on the Collaboration Live software and to ensure connectivity.

8.2 Device Accountability

The site will document receipt/return and disposition of investigational products using the product accountability log.

9 Selection and Withdrawal of Subjects

9.1 Selection of Subjects

Subjects will be enrolled based on these inclusion/exclusion criteria. The Principal Investigator is responsible for screening all subjects to determine the eligibility for participation.

Inclusion Criteria:

1. Subject is at least 18 years of age
2. Subject in indicated for a routine OB/GYN ultrasound examination at the site.
3. Subject is willing and capable of providing informed consent and participating in this study.

Exclusion Criteria:

1. A medical condition or co-morbidity that would be unduly affected by study participation, per investigator discretion.

9.2 Vulnerable Populations

The research subjects for this study will include pregnant women. Participation in the study will require informed consent, as described in Section 8.1.1 and the study will be reviewed by an Institutional Review Board (IRB). Ultrasound imaging is based on non-ionizing radiation and is generally considered safe when used appropriately by trained health care providers. The investigational software (Collaboration Live) is intended to facilitate remote viewing or remote control of the EPIQ 5 and EPIQ 7 Ultrasound Systems (software version 5.0.2) which has been FDA cleared.

9.3 Point of Enrollment

Potential study subjects meeting all inclusion criteria and none of the exclusion criteria will be asked to provide informed consent. Potential subject whom agree to provide informed consent are considered to be enrolled in the study.

9.4 Withdrawal of Subjects

Study participation is voluntary. The subject may refuse to consent or may withdraw from the study at any time without penalty or loss of benefits to which he/she is otherwise entitled.

The Investigator may discontinue a study subject's participation in this study without his/her consent. If, in the opinion of the investigator, the health or safety of a subject is affected adversely by participation in the study, the subject will be removed.

All subjects completing the study will be included in the primary endpoint analysis. No follow-up is required beyond the initial study visit and therefore, no loss to follow-up or withdrawal is anticipated. However, if subject withdrawal were to occur prior to evaluation of clinical acceptability, additional subjects will be enrolled to compensate for the withdrawn subjects.

10 Management of Subjects

The subject's involvement in the study includes the OB/GYN ultrasound exam, remote consultation and patient questionnaire. No study follow-up visits are planned.

There are no restrictions to patient participation regarding concomitant medications or treatments.

11 Assessment of Safety and Performance

The variables necessary for evaluation of the primary endpoint and additional measures are specified in the Table 11 below.

Table 11: Data Required for Assessment of Endpoints and Additional Measures

Endpoint or Additional Measure	Required Variables
Primary Endpoint: Clinically Acceptable Performance of Remote Control Functionality	During remote control, it will be recorded whether the system responds to the remote input as intended and without a delay interfering with the conduct of the exam. Additionally, a clinically acceptable exam would result in no adverse events related to the control feature (see Adverse Events below).
Adverse Events	Adverse events will be reported on the appropriate case report form. The investigator will assess the seriousness of the event and relationship of event to study device and study procedure.
Assessment of technical issues	Device deficiencies will be reported on the appropriate case report form.
Success rates for key tasks in the collaborative exam	Success of the following tasks will be recorded: - Establishing the remote connection - Establishing text chat - Establishing voice call - Establishing webcam feed - Establishing screen share - Establishing remote control
Travel reduction attributable to use of Collaboration Live	Distance between the scanning facility and the investigator's location will be recorded (in miles).
Ease of use	5-point (Likert) scale data will be reported by the investigator.
User feedback regarding streaming, image quality and overall experience	5-point (Likert) scale data will be reported by the investigator.

Endpoint or Additional Measure	Required Variables
Patient feedback regarding remote consultation	Telemedicine Satisfaction Questionnaire[1] (to be completed by subject following remote consultation).
Impact of remote consultation on reimbursement	Submitted charges and reimbursement rates for remote patient consultation will be reported and compared to standard rates for in-person consultation.

[1] Yip MP, AM Chang, J Chan and AE Mackenzie. Development of the Telemedicine Satisfaction Questionnaire to evaluate patient satisfaction with telemedicince: a preliminary study. Journal of Telemedicine and Telecare 2003; 9: 46-50.

12 Sites

This is a single site study being conducted at Perinatal Associates of New Mexico. The site includes multiple facilities under the direction of the Principal Investigator.

13 Risk and Benefit Analysis

The investigational systems have passed quality assurance testing according to international regulatory guidelines; therefore, the risk of using the device is no greater than the standard risk of using any commercially available ultrasound imaging equipment.

13.1 Risks Associated with an Ultrasound Scan

Ultrasound imaging is based on non-ionizing radiation and is generally considered safe when used by appropriately trained health care providers. Ultrasound energy has the potential to produce biological effects on the body and the waves can heat the tissues slightly. In some cases, it can also produce small pockets of gas in body fluids or tissues (cavitation). The long-term consequences of these effects are still unknown.

13.2 Risks Associated with Study Participation

The study involves use of an investigational software solution that allows users to communicate (by text, voice, screen share, webcam video and remote takeover) from an ultrasound system or workstation to a remote destination. The potential risks associated with use of Collaboration Live include interruption of the procedure due to poor connectivity or network performance and exposure of patient data by a remote user.

13.3 Risk Minimization Actions

According to the As Low As Reasonably Achievable (ALARA) principal a physician should expose the patients to ultrasound energy “As Low As Reasonable Acceptable” to perform an ultrasound diagnosis. Mechanical Index and Thermal Index are displayed on the image, and the Healthcare Provider is instructed to monitor those values and keep them to a minimum.

Study risks can be further minimized through compliance with this protocol, compliance with instructions for use (IFU), and performing procedures in the appropriate clinical environment by healthcare professionals per standard of care, specifically:

- Collaboration Live will only be used by those properly trained and qualified as required by the institution. The local system user remains responsible for patient safety while a Collaboration Live session is in progress.
- All Collaboration Live users should follow the applicable patient privacy and data security policies required by their country and institution.

13.4 Anticipated Benefits

Subjects may not receive any direct benefit from participating in this study. Future patients may benefit due to image quality improvements in the ultrasound system.

14 Deviations

All non-compliance to protocol procedures shall be reported as a protocol deviation. The Principal Investigator is not allowed to deviate from the protocol unless prior approval from the Sponsor and the IRB is granted. Only protocol deviations made to protect the rights, safety and well-being of subjects are allowed without prior approval from the Sponsor and the IRB.

Examples of protocol deviations include, but are not limited to:

- Failure to obtain consent before scanning with the investigational system
- Enrollment of ineligible subject
- If subject's images from the investigational system are used for primary diagnosis

All protocol deviations shall be recorded on the Protocol Deviation Form. Deviations that affect the rights, safety, and well-being of the subject must be reported within 24 hours to the Philips clinical monitor by the Principal Investigator.

15 Safety and Device Deficiency Reporting

Definitions for safety-related terms are included in Appendix 1 - Definitions.

15.1 Routine Reporting

Subjects should be evaluated for AEs from the time Informed Consent Form is signed until conclusion of study-related activities. Documentation of the outcome of all safety events, assignment of relatedness, and seriousness is the responsibility of the Principal Investigator

All AEs (including AE, SAE, ADE, SADE or USADE) and Device Deficiencies occurring during the study are to be recorded on the Adverse Event CRF as soon as possible following awareness of the event.

The Investigator is responsible for reporting AE to the appropriate IRB as dictated by the guidelines defined by the IRB.

15.2 Expedited Reporting

All SAEs must be reported to Philips within 24 hours of the Investigator becoming aware of the event.

Additionally, any medical device deficiencies that might have led to a SAE if:

- suitable action had not been taken;
- intervention had not been made; or
- circumstances had been less fortunate

must also be reported to Philips within 24 hours of the Investigator becoming aware of the event.

Furthermore, any new findings or updates in relation to previously reported SAE or device deficiencies which may have potentially led to SAE must be reported to Philips within 24 hours of the Investigator becoming aware of the new findings or updates.

16 Statistical Methods

Continuous variables will be summarized using the number of non-missing observations, mean, standard deviation (SD), median, minimum, and maximum; categorical variables will be summarized using the frequency count and the percentage of subjects in each category. No formal statistical hypothesis test is planned and the primary endpoint will be presented as descriptive statistics only.

The Primary Endpoint is clinically acceptable performance of remote control functionality. A total of 30 subjects undergoing routine OB/GYN exams will be enrolled in the study. Clinical acceptability of the Collaboration Live software will be evaluated for each subject during remote control of the ultrasound system.

A way to describe the statistical properties of the study design is in terms of 95% confidence interval of the true rate of clinical acceptability based on the observed data. Table 16 provides the two-sided 95% confidence interval (CI) for the true rate of clinical accepatability among 30 enrolled subjects using Clopper-Pearson Exact method. If clinical acceptability is observed in all 30 patients, then the 95% exact two-sided lower confidence bound for the rate of such response in this population would be > 80% (with lower bound of 95% CI = 88.4%). Alternatively, it means if the observed accepatability rate is 100%, then the range of 88.4% - 100% will contain the true acceptability rate, with 95% probability.

Table 16: Ninety-five Percent Confidence Intervals for True Rate of clinical accepatability by Observed Acceptability Rate

N	Observed Acceptability Rate	95% CI for True Acceptability Rate
30	30/30 (100%)	(88.4%, 100%)
	29/30 (96.7%)	(82.8%, 99.9%)
	28/30 (93.3%)	(77.9%, 99.2%)
	27/30 (90.0%)	(73.5%, 97.9%)
	26/30 (86.7%)	(69.3%, 96.3%)
	25/30 (83.3%)	(65.2%, 94.3%)
	24/30 (80.0%)	(61.4%, 92.3%)

All subjects completing the study will be included in the primary endpoint analysis. No follow-up is required beyond the initial study visit and therefore, no loss to follow-up or withdrawal is anticipated. However, if subject withdraw were to occur prior to evaluation of clinical acceptability, additional subjects will be enrolled to compensate for the withdrawn subjects. The study will end when 30 subjects have been enrolled and data collection is complete. The anticipated study duration is three months.

17 Labeling

The investigational device(s), the instructions for use, or the packaging shall indicate that the investigational device(s) is exclusively for use in a clinical investigation, as required by national regulations.

18 Direct Access to Source Data/Documents

A unique source record will be available for each study participant including documentation of the informed consent form review process, HIPAA completion to ensure patient privacy (United States), and medical history. In some cases (e.g., user feedback data may be entered directly into the CRFs, as appropriate. The sponsor will be allowed access to source data to ensure compliance to the protocol.

The investigator(s)/institution(s) will permit study-related monitoring, audits, IRB review, and regulatory inspection(s) by providing direct access to source data/documents.

18.1 Monitoring

Monitoring will be performed, using a risk based approach, over the course of the study to assess continued compliance with the protocol and applicable regulations. Monitoring will also ensure that documents used to originally record subject data (source documents) are maintained, and to verify that transcribed data are accurately reflected on the Case Report Forms (CRFs).

18.2 Confidentiality

Subject study information will remain confidential. Subjects enrolled on study will be assigned a study ID code. All data will then be reported per the unique Subject ID, ensuring all subject identifiers have been redacted before transmission to Sponsor, thus providing the Sponsor a 'coded' data set. Only authorized personnel associated with the conduct and/or review of the study and the resultant data will have access to information that links subject identifiers to the corresponding assigned study code. Documentation of privacy and confidentiality training (e.g., data privacy, data protection laws, HIPAA, etc.), to site study team members will be maintained in the Site Regulatory File (SRF) or a centralized site record, accessible to sponsor and external monitors and/or auditors. All Collaboration Live users, including the remote user, should follow the applicable patient privacy and data security policies required by their country and institution. The results of this research project may be presented at meetings or in publications; however, subject identity will not be disclosed in such publications.

19 Case Report Forms

Subject data will be reported to the sponsor via electronic case reports, using an electronic data capture (EDC) system. The study data, including adverse events, will be summarized for final reports. Should any subject images be acquired for use by Philips, all subject names and identifiers will be removed. Only staff that have been delegated by the Principal Investigator will be able to enter or make changes to data in the case report forms.

19.1 Electronic Data Capture

The electronic data capture (EDC) system is a secure, validated, US CFR Part 11 compliant EDC program provided by the Sponsor. It is an internet-based EDC system for reporting clinical data to the Sponsor (eCRFs). All subjects who consent to participate will be registered in the EDC system.

Access to the EDC system will be protected by login identification and password. The Sponsor will train delegated Site personnel on procedures for data entry into the web-based system. Following, delegated staff will be provided ID codes and passwords unique to each team member's delegated study role and blinding requirements. They will be trained on Philips guidelines for maintenance of electronic ID codes and passwords. A staff member's ID code/password will never be shared or used by another staff member, in any circumstance.

19.2 Data Review, Cleaning and Query Resolution

After study data is recorded and submitted to the system, automated edit checks, programmed to ensure the collection of consistent and complete data, may be raised.

In addition, post data submission, Philips (or contracted) Monitors, Project Statistician, and/or the Philips Clinical Data Management group will remotely review data listings generated at different time points during the study. Data queries will be generated to resolve any discrepancies or concerns.

Data transcribed to eCRFs will be source data verified by the Sponsor/designee(s) on a percentage of the subject population, per a risk-based monitoring approach. Data queries will be generated to resolve any discrepancies or concerns.

Designees will be trained on the query issue and resolution process. It is the responsibility of the Site designated personnel to respond to all edits checks and queries. Submitted data as well as all data modifications to submitted data will be documented by the system and available in audit trails. Upon conclusion of the study, after eCRFs are marked as complete and all discrepancies are resolved, the Principal Investigator will be notified to review and the case books and provide electronic signatures.

20 Publication Policy

The results of this clinical study may be submitted for publication.

The Principal Investigator must request permission from Philips prior to initiating any publication. Permission must be requested and received in writing. Review and approval of any data, abstract or manuscript is required. Philips reserves the right to delay publication to review the presentation of study methodology, data collection, data analysis, interpretation of data, proprietary information or patented technology. A request for delay and the reason(s) shall be communicated by Philips to the Principal Investigator in writing. Philips ultimately reserves the right to deny any request to publish.

21 Ethical Considerations

This study is conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. The protocol and all study materials are to be reviewed by an Institutional Review Board (IRB), prior to enrollment of any subject. Any additional requirements imposed by the IRB shall be followed. Any amendments to the protocol must be reviewed and approved by the study Sponsor, and subsequently, by the designated IRB, according to the approval committee's requirements.

Only authorized personnel associated with the conduct and/or review of the study and the resultant data shall have access to information that links subject identifiers to the corresponding assigned study code. Disclosure of subject information to personnel other than those permitted by Philips, its designees or representatives, or appropriate regulatory agencies is prohibited.

22 Data Handling and Recordkeeping

Study records, including each subject's signed informed consent, and other study-related documents pertaining to the conduct of the study shall be kept in a secure area. Documents related to the study are to be kept for a minimum of two years after study completion in a secure area, or off site with a qualified vendor.

23 Registration

Philips will be registering this clinical study on ClinicalTrials.gov, as the study results may be submitted for publication.

24 Appendix 1 – Definitions

Adverse Device Effect (ADE) – An adverse event related to the use of an investigational medical device (Includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device. Also includes any event resulting from use error or from intentional misuse of the investigational medical device.)

Adverse Event (AE) - Any untoward medical occurrence in a study subject which does not necessarily have a causal relationship with the study product or procedures.

Device Deficiency - Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance such as malfunctions, misuse or use errors and inadequate labeling.

Serious Adverse Device Effect (SADE) – An ADE that has resulting in any of the consequences characteristic of a SAE

Serious Adverse Events (SAE) - Defined as an AE that:

- Led to Death
- Are Life-threatening
- Led to Hospitalization (in-patient or prolonged)
- Resulted in Disability or Permanent Damage
- Led to Fetal Distress, Fetal Death or Congenital Anomaly/Birth Defect
- Required Intervention to Prevent Permanent Impairment or Damage

Unanticipated Serious Adverse Device Effect (USADE) - Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report (Anticipated Serious Adverse Device Effect or ASADE is an effect which by its nature, incidence, severity or outcome has been identified in the risk analysis report.)