Clinical Validation Protocol

Philips HeartStart Intrepid 12-lead ECG Study – The ICE study

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Author: Barbara Fink, MS, CCRP; Associate Director of Clinical Affairs
Approver: See Page 2

Prepared for:

Emergency Care - Professional

22100 Bothell Everett Highway, Bothell, WA 98021

Sponsor Approval

[redacted]	[redacted]	[redacted]	[redacted]
Author Signature	Date	Reviewer Signature	Date
Barbara Fink, Associate Director Clinical Affairs – Emergency Care, Clinical & Medical Affairs		Tiffani Bowers, Clinical Operations Manager, Clinical Operations – Emergency Care, Clinical & Medical Affairs	
[redacted]	[redacted]	[redacted]	[redacted]
Reviewer Signature	Date	Reviewer Signature	Date
Kevin Najarian, Global Director of Biostatistics and Data Management, Clinical & Medical Affairs		Tim Johnson, Principal Regulatory Program Manager, Emergency Care	

Investigator Agreement

As Investigator of the study entitled "Philips HeartStart Intrepid 12-lead ECG Clinical Engineering Study – The ICE study" Protocol ID: CC_TC_ECR_Intrepid 12Lead_2022_11549, I agree to conduct the trial as outlined in the protocol in accordance with and the Study's Protocol; all applicable laws and regulations; ICH Guidelines for Good Clinical Practices, Standard EN-ISO 14155: 2020 and the Declaration of Helsinki; and any conditions of approval imposed by the reviewing IRB/EC or FDA conditions of approval, and The Sponsor's guidelines include, but are not limited to:

- Provide Philips with current curriculum vitae including a statement regarding relevant experience.
- Provide accurate financial disclosure information to allow Philips to make an accurate disclosure statement as required under 21 CFR, Part 54 for the course of the investigation and for up to one year after its completion
- Provide supervision of all testing of the study device/product 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.
- Permission to 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. If this study is to be inspected by a regulatory agency, Philips is to be notified as soon as possible.
- Submission of the proposed clinical investigation including the protocol and the consent form to an IRB/EC for approval and the acquisition of written approval for each subject ensuring that the requirements for obtaining informed consent are obtained prior to the use of any test articles.
- Submission of any proposed change in or significant deviation from the protocol to the IRB using a signed formal amendment document prepared by the Sponsor. Any proposed changes or deviations from the protocol require that the informed consent also reflects such changes or deviations and that the revised informed consent be approved by an IRB.
- Documentation and explanation of individual protocol deviations and violations are captured with explanations as indicated.
- Submission of reports of Adverse Events to the Sponsor and IRB/EC as outlined in the protocol.
- Submission of timely progress reports to the IRB and Sponsor at appropriate intervals on a schedule determined by the IRB or Sponsor, as indicated.
- Record keeping: the Investigator will maintain adequate and accurate records designed to record completion of all study procedures, related observations and other key data (such as safety, compliance and product accountability) pertinent to the investigation on each subject enrolled. The investigator must maintain these records for a period as specified by Philips following completion of the study report.

I agree that all information provided to me by the Sponsor including pre-clinical data, protocols, electronic databases, CRFs, and verbal and written information will be kept strictly confidential and confined to the clinical personnel involved in conduct of the trial. It is recognized that this information may be related in confidence to the IRB. I also understand that reports or information about the trial or its progress will not be provided to anyone not involved in the trial other than the Sponsor or other legally constituted authority. I agree to:

Investigator Signature: [redacted] **Date:** [redacted]

Printed Name: [redacted]

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Study Sponsor:

Emergency Care

22100 Bothell Everett Highway, Bothell, WA 98021

Device Manufacture
Philips Goldway (Shenzhen) Industrial Inc.
Registered/Production Address: No. 2 Keji North 3rd Road
Nanshan District, Shenzhen P.R. China 518057
Tel: [redacted]
Fax: [redacted]

Participating Study Site

Florida Lung & Sleep Associates
2625 Lee Blvd., Suite 100, Lehigh Acres, FL 33971

Florida Lung & Sleep Associates
4651 Palm Beach Blvd., Suite 105, Fort Myers, FL 33905

Sponsor Contact Information

Study Monitor(s)

Tiffani Bowers
Clinical Operations Manager
Address: 6501 Living Place, Pittsburgh, PA 15206
Phone: [redacted]
Email: [redacted]

Reporting of Unanticipated Serious Adverse Events or Unanticipated Adverse Device Effects

Report the occurrence of an unanticipated serious adverse event or unanticipated adverse device effect to Philips within 24 hours of the occurrence.

Tiffani Bowers
Clinical Operations Manager
Address: 6501 Living Place, Pittsburgh, PA 15206
Phone: [redacted]
Email: [redacted]

Glossary

Abbreviation	Term	Definition
AARC	Advanced Algorithm Research Center	--
AE	Adverse Event	An AE is any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)). When an AE is deemed to be related to the study device, it is termed an adverse device event.
ADE	Adverse Device Effect	Adverse event related to the use of a medical device. *Note1: this definition includes AEs resulting from insufficient or inadequate instructions for use, deployment, implantation installation, or operation or any malfunction of the medical device* *Note2: this definition includes any event resulting from use error or from intentional misuse of the medical device*
AHA	American Heart Association	The American Heart Association is a qualified 501(c)(3) tax-exempt organization with a mission to "be a relentless force for a world of longer, healthier lives."
ALS	Advanced Life Support	Refers to a set of clinical interventions for the urgent treatment of cardiac arrest, stroke and other life-threatening medical emergencies, as well as the knowledge and skills to deploy those interventions.
BMI	Body Mass Index	Body Mass Index is a calculation using a participants height and weight.
CC	Connected Care	A Philips organization that encompasses the Emergency Care Business
CFR	Code of Federal Regulation	The codification of the general and permanent rules and regulations (sometimes called

		administrative law) published in the Federal Register by the executive departments and agencies of the federal government of the United States. The CFR is divided into 50 titles that represent broad areas subject to federal regulation.
CPR	Cardiopulmonary Resuscitation	Cardiopulmonary resuscitation (CPR) is a series of lifesaving actions that improve the chance of survival following cardiac arrest, and has integrated chest compressions and rescue breathing with the goal of optimizing circulation and oxygenation. CPR improves the victim's chance of survival by providing heart and brain circulation until further measures are taken to restore spontaneous blood circulation and breathing.
CRF	Case Report Form	A document, printed or electronic, designed to record all of the protocol-required information to be reported to the sponsor on each study subject. CRF's are a living document in the respect that new information on the subject is continually gathered throughout the study.
CVD	Cardiovascular Disease	Class of diseases that involve the heart or blood vessels. Cardiovascular disease includes coronary artery diseases (CAD) such as angina and myocardial infarction (commonly known as a heart attack).
--	Device Deficiency	Inadequacy of a medical device with respect to its identity, quality, durability, reliability, safety or performance. *Note: device deficiencies include malfunctions, use errors, and inadequate labeling.*
DXL	Philips Algorithm	12 lead diagnostic ECG algorithm used in Philips products for ECG monitoring. They are distinct from the AED mode rhythm recognition detector.
EC	Ethics Committee	An independent body (a review board or a committee, institutional, regional, national, or multi-national), consisting of medical/scientific professionals and non-medical/non-scientific

		members. Its responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in a study.
ECG	Electrocardiogram	The process of recording the electrical activity of the heart over a period of time using electrodes placed on the skin. These electrodes detect the tiny electrical changes on the skin that arise from the heart muscle's electrophysiologic pattern of depolarizing and repolarizing during each heartbeat. It is very commonly performed to detect any cardiac problems.
EC or EC Pro	Emergency Care or Emergency Care Professional	Philips Business Group, Profession covers advanced life support devices
EDC	Electronic Data Capture	Electronic recording of clinical study data typically using the internet.
EMS	Emergency Medical Services	An emergency service who treat illnesses and injuries that require an urgent medical response, providing out-of-hospital treatment and transport to definitive care.
EU	European Union	The European Union (EU) is a political and economic union of 28 member states that are located in Europe
--	Event Review Pro	Philips proprietary software for post event review of event files downloaded from Philips Defibrillators
FDA	Food and Drug Administration	The US Department of Health and Human Services consumer protection agency responsible for ensuring safety and effectiveness of all drugs, biologics, vaccines, and medical devices to be used in humans.
GCP	Good Clinical Practice	A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical studies that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of study subjects are protected.

GDPR	General Data Protection Regulation	The General Data Protection Regulation (EU) 2016/679 is a regulation in EU law on data protection and privacy for all individuals within the European Union and the European Economic Area. It also addresses the export of personal data outside the EU and EEA areas.
HHS	Health and Human Services	
HIPAA	Health Insurance Portability and Accountability Act of 1996	A US law designed to provide privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals and other health care providers.
ICH	International Conference on Harmonization	A joint initiative involving both regulators and industry representatives from Japan, EU, and US as equal partners in the scientific and technical discussions of the testing procedures, which are required to ensure and assess the safety, quality and efficacy of medicines.
IEC	Independent Ethics Committee	See Ethics Committee.
IRB	Institutional Review Board	Any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such treatment.
ISO	International Organization for Standardization	An international standard-setting body composed of representatives from various national standards organizations.
MEDDEV	Medical Devices	MEDDEV stands for Medical Devices Documents. The MEDDEV Guidance Documents are developed by various working groups on behalf of the European Commission to assist stakeholders in implementing directives related to medical devices.

MDCG	Medical Device Coordination Group	The Medical Device Coordination Group deals with key issues from the medical devices sector, from Notified Body oversight or standardization to market surveillance, passing by international matters, new technologies and clinical investigation
NBP	Non-Invasive Blood Pressure	The HeartStart Intrepid measures blood pressure for both adult and infant/child patients using the oscillometric method. Systolic, diastolic, and mean measurements are provided. Alarms are available to alert of changes in the patient's condition.
OHCA	Out of Hospital Cardiac Arrest	Sudden loss of blood flow resulting from the failure of the heart to effectively pump that occurs when an individual is out of the hospital.
--	Patient	An individual who participates in a clinical study, either as a recipient of the study product(s) or as a control. Also referred to as subject or participant.
PI	Principal Investigator	Physician responsible for the conduct and oversite of the clinical study.
P&MC	Protocol and Monitoring Committee	All performance and safety data will be reviewed by Protocol and Monitoring Committee (P&MC). The P&MC will consist of the Principal Investigator, biostatistician, principal scientist, clinical study manager and members of the project team, as needed. The P&MC will review device performance as assessed by the adjudication process, adverse events, adverse device effects, the rate of failure to detect a shockable rhythm per device specifications, the rate of failure to charge to deliver the shock, error codes, dose deliveries, etc.
QA	Quality Assurance	All the planned and systematic actions that are established to ensure that a study is performed and the data are generated, documented, and reported in compliance with

		GCP and the applicable regulatory requirement(s).
SADE	Serious Adverse Device Effect	Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death, was not previously identified in a nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects (21 CFR 812.3(s)).
SAE/SADE	Serious Adverse Event	An AE or suspected adverse reaction is considered serious if, in the view of either the investigator or Sponsor, it results in any of the following outcomes: -death, -a life-threatening AE, -inpatient hospitalization or prolongation of existing hospitalization, -a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or -a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. *Note*: *planned hospitalization for a pre-existing condition, or a procedure required by the study protocol, without serious deterioration in health is not considered a serious adverse event.*
SAS	Statistical Analysis Software	SAS (previously "Statistical Analysis System") is a software suite developed by SAS Institute for advanced analytics, multivariate analyses, business intelligence, data management, and predictive analytics.

SCA	Sudden Cardiac Arrest	A sudden loss of blood flow resulting from the failure of the heart to effectively pump.
--	Significant Risk Device	Significant risk device means an investigational device that: • Is intended as an implant and presents a potential for serious risk to the health, safety or welfare of a subject; • Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; • Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety or welfare of a subject; or • Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
SpO_2	Functional Oxygen Saturation	Pulse oximetry is a noninvasive method of continuously measuring functional oxygen saturation (SpO_2) in arterial blood. SpO_2 readings indicate the percentage of hemoglobin molecules in arterial blood which are saturated with oxygen.
SPSS	Statistical Package for the Social Sciences	SPSS (Statistical Package for the Social Sciences), also known as IBM SPSS Statistics, is a software package used for the analysis of statistical data.
ST/AR	Philips ST/AR Algorithm	ST Segment and Arrythmia Recognition algorithm ECG algorithm used in Philips products for ECG monitoring, different from the AED mode rhythm recognition detector.

TMF	Trial Master File	A file that contains all the essential documents relating to a clinical study.
USA	United States of America	A federal republic composed of 50 states, a federal district, five major self-governing territories, and various possessions.
UADE	Unanticipated Adverse Device Effect	An unanticipated adverse device event (UADE) is defined in 21 CFR Part 812.3(s) as “any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects”. Other important medical events which may not result in any of the outcomes above, but which may require intervention to prevent one of the outcomes above, may in the opinion of the investigator, be considered a UADE.
USADE	Unanticipated Serious Adverse Device Effect	See Serious Adverse Device Effect.
USAE	Unanticipated Serious Adverse Effect	See Serious Adverse Event.

1. PROTOCOL SUMMARY

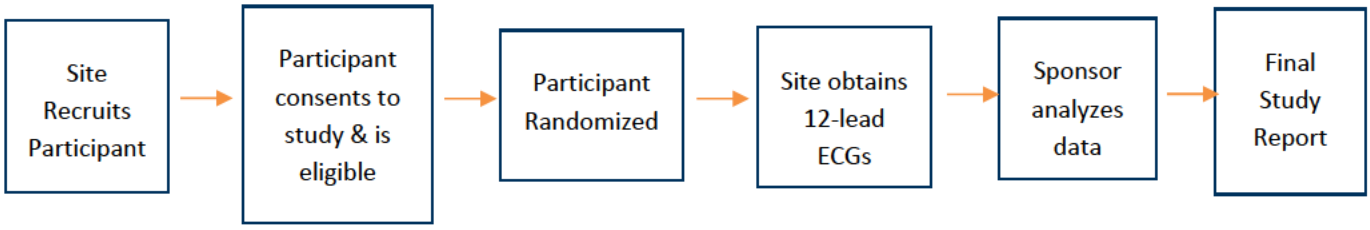
1.1 Synopsis

Study Title & ID	Philips HeartStart Intrepid 12-lead ECG Study Engineering Clinical Study – The ICE study ; CC_TC_ECR_Intrepid 12Lead_2022_11549
Test device	Philips HeartStart Intrepid Monitor/Defibrillator
Objective/s	The objective of this study is to validate the Philips DXL ECG Algorithm works as intended in the HeartStart Intrepid Monitor/Defibrillator after a software update was completed to address instances of high impedance. This study will also determine the diagnostic quality of the 12-lead ECG tracing from the HeartStart Intrepid Monitor/Defibrillator.
Study Design	This is a clinical study performed in a single center for validation purposes, with all data collection occurring within a single visit. Up to 60 (sixty) participants will be enrolled, for 56 (fifty-six) to complete data collection.
Endpoint/s	Validation • Number of failures of 'unable to obtain a 12-lead ECG' with the Philips HeartStart Intrepid Monitor/Defibrillator • Number of diagnostic quality 12-lead ECG tracings from the Philips HeartStart Intrepid Monitor/Defibrillator Safety • Frequency and severity of unexpected adverse events • Unanticipated adverse device effects (UADE)

Hypothesizes	Hypothesis 1A: We hypothesize that a 12-lead ECG will be obtained greater than 90% of the time with a target goal of 99%. H_{0A}: $\pi_A \leq 0.90$ H_{1A}: $\pi_A > 0.90$ Hypothesis 1B: We hypothesize that 12-lead ECG tracings will be of diagnostic quality greater than 90% of the time with a target goal of 99%. H_{0B}: $\pi_B \leq 0.90$ H_{1B}: $\pi_B > 0.90$ Both hypotheses must be met for overall study success.
Sample size	Up to 60 (sixty) participants will be enrolled, for 56 (fifty-six) to complete data collection.
Inclusion criteria	• Able to read, write, speak, and understand English • Age: 29 days to 89 years • Willing and able to provide informed consent and complete study procedures • Willing to have Philips representatives present during study procedures.
Exclusion criteria	• Known allergy to medical adhesives, silicone, or latex (per self-report) • Any limitation or medical condition, including but not limited to physical or cognitive disability, that would affect the participant's ability to complete study activities (per investigator) • At the time of enrollment, current enrollment in any other interventional research study • An employee, or residing family member of an employee, of a company that designs, sells, or manufactures monitor/defibrillator technology or related products (including Philips
Site(s)	Florida Lung & Sleep Associates 2625 Lee Blvd., Suite 100, Lehigh Acres, FL 33971 4651 Palm Beach Blvd., Suite 105, Fort Myers, FL 33905

Study Visit Summary	Participants will come into the study site for one visit. At this visit, they will review and sign the informed consent form. Participant demographic data will be captured and inclusion/exclusion will be confirmed. Once participants are found to be eligible, skin assessments will be completed and any cardiac history will be captured. Participants will then be prepared for the monitoring and 12-lead ECG. Ten ECG electrodes will be placed on the chest, shoulders, and abdomen. The SpO_2 sensor will be placed on the finger, and a blood pressure cuff will be placed around the participants bicep. The Intrepid Monitor/Defibrillator will be utilized to capture three 12-lead ECGs and monitor the participant for up to 15 minutes. Once the readings are complete all the equipment will be removed, and the participant will be free to leave the laboratory.
Anticipated Enrollment Duration	The total enrollment duration for an individual participant will not exceed one day.
Anticipated Study Duration	It is estimated that the entire study duration will not exceed one month.

1.2 Schema



1.3 Schedule of Activities

Procedures	Performed by	Visit 1
Informed Consent	PI or designee	X
Demographics	PI or designee	X
Inclusion/Exclusion	Study coordinator	X
Skin pigmentation assessment	Study coordinator	X
Enrollment	PI or designee	X
Data Collection & Monitoring	Study coordinator	X
AE Monitoring	PI	X
Participant Compensation & Study Dismissal	PI or designee	X

2. INTRODUCTION

2.1 Rationale

The Philips DXL ECG Algorithm, developed by Philips Advanced Algorithm Research Center (AARC), uses sophisticated analytical methods for interpreting cardiac data. In the HeartStart Intrepid Monitor/Defibrillator, the DXL ECG Algorithm analyzes 12 leads of simultaneously acquired ECG waveforms to provide an interpretation of rhythm and morphology across a wide variety of patient populations.

The purpose of this study is to validate the Philips DXL ECG Algorithm works as intended in The HeartStart Intrepid Monitor/Defibrillator after a software update was completed to address instances of high impedance. This study will also review diagnostic quality of the 12-lead ECG tracing from the HeartStart Intrepid Monitor/Defibrillator.

The study will monitor for any adverse events and unanticipated device effects. To ensure safety participants will be monitored using pulse oximetry (SpO_2) and Non-invasive blood pressure (NBP).

2.2 Background

Electrocardiography is now more than 100 years old and has become an essential diagnostic tool that is continually being refined and further developed (Fye, 1994). Early single-channel analog machines, first with photo galvanometers and then later with direct writing galvanometers, have evolved into multi-channel simultaneous digital acquisition systems with a variety of storage and report possibilities. Digital systems enable computerized measurement and interpretation of the acquired signals.

Development of computer-assisted ECG analysis began in the 1960s. Initially used in research facilities, computer interpretation has become an accepted tool to aid physicians in arriving at a final interpretation based on clinical data and a review of the findings.

The adult ECG Criteria Program began in 1971 as a combined development effort between engineers and a worldwide panel of cardiologists. Extensive pediatric analysis was added in 1990. Since then, the Philips algorithm has undergone several modifications and enhancements to not only take advantage of new computer technology and advanced developments in electrocardiography, but also to incorporate revised guidelines proposed by international committees.

The Philips DXL ECG Algorithm provides an analysis of the amplitudes, durations, and morphologies of the ECG waveforms and the associated rhythm. ECG waveform analysis is

based on standard criteria for interpretation of these parameters, calculations of the electrical axis, and the relationship between leads.

The algorithm is highly age and gender specific. Patient age and gender are used throughout the program to define normal limits for heart rate, axis deviation, time intervals, and voltage values for interpretation accuracy in tachycardia, bradycardia, prolongation or shortening of PR and QT intervals, hypertrophy, early repolarization, ischemia, and myocardial infarction.

Adult criteria apply if the patient age entered is 16 years old or older, or if no age is specified. Pediatric criteria apply if the patient age entered is younger than 16 years of age. Twelve different age ranges are used for the pediatric criteria to account for the rapid changes that occur in the first few days to months of life.

While increasingly detailed and well developed, no automated analysis is completely reliable, and computerized ECG analysis should always be reviewed by a qualified physician.

This study will utilize ECG monitoring via a 12-lead ECG, SpO_2 and NBP. The 2015 European Resuscitation Council Guidelines for Advanced Life Support highlights the value of other defibrillation topics (cardioversion, pacing) and physiological monitoring (ECG, end-tidal CO_2, SpO_2, non-invasive blood pressure) to guide ALS interventions and provide the best cardiac arrest care pre-hospital and in-hospital settings (Soar, 2015).

- ECG monitoring: Monitoring heart rhythm through pads, paddles or ECG electrodes is a standard part of ALS. Motion artifacts prevent reliable heart rhythm assessment during chest compressions forcing rescuers to stop chest compressions to assess the rhythm and preventing early recognition of recurrent VF/pVT.
- SpO_2: Pulse oximetry is a common standard of care to establish base line oxygenation and assessing oxygenation while receiving supplemental oxygen. Pulse oximetry is a key element to the initial assessment and treatment of a patient with an arrhythmia, normal readings range from 94% to 100%.
- Non-invasive blood pressure: Blood pressure is a key element to the initial assessment and treatment of a patient with an arrhythmia.

In the Philips HeartStart Intrepid Monitor/Defibrillator the 12-lead ECG is an optional function accessed while in monitor mode. 12-Lead function allows the preview, acquisition printing, copying, and storage of 12-Lead ECGs. In addition, the 12-Lead function provides computerized ECG analysis using one of two configuration options (under 16 years old and over 16 years old) of the DXL Algorithm. A report with measurements and interpretive statements from the analysis is displayed, stored and printed, as configured.

The study will also utilize SpO_2 and NBP monitoring. Monitoring SpO_2 Pulse oximetry is a Noninvasive method of continuously measuring functional oxygen saturation (SpO_2 in arterial blood. SpO_2 readings indicate the percentage of hemoglobin molecules in arterial blood which are saturated with oxygen. SpO_2 can be monitored in all HeartStart Intrepid clinical modes and

on both adult and infant/child patients. NBP is measured with a blood pressure monitor, a sphygmomanometer, or blood pressure gauge. The meter uses an inflatable cuff to collapse the artery and then release it under the cuff. This measures the pressure at which blood flow is starting and at which pressure blood flow is unimpeded. The HeartStart Intrepid uses a mechanical manometer to measure automatically on a pre-set schedule or manually on demand. For the purposes of this study, they will be taken every five (5) minutes for three (3) readings (0 minutes, 5 minutes and 10 minutes).

3. STUDY OBJECTIVES

The objective of this study is to validate the Philips DXL ECG Algorithm works as intended in the HeartStart Intrepid Monitor/Defibrillator after a software update was completed to address instances of high impedance. This study will also determine the diagnostic quality of the 12-lead ECG tracing from the HeartStart Intrepid Monitor/Defibrillator.

3.1 Endpoints

3.1.1 Primary Endpoints

Validation

- Number of failures of 'unable to obtain a 12-lead ECG' with the Philips HeartStart Intrepid Monitor/Defibrillator
- Number of diagnostic quality 12-lead ECG tracings from the Philips HeartStart Intrepid Monitor/Defibrillator

Safety

- Frequency and severity of unexpected adverse events
- Unanticipated adverse device effects (UADE)

3.2 Hypotheses

Hypothesis 1A: We hypothesize that a 12-lead ECG will be obtained greater than 90% of the time with a target goal of 99%.

$H_{0A}: \pi_A \leq 0.90$

$H_{1A}: \pi_A > 0.90$

Hypothesis 1B: We hypothesize that 12-lead ECG tracings will be of diagnostic quality greater than 90% of the time with a target goal of 99%.

H_{0B}: $\pi_B \leq 0.90$

H_{1B}: $\pi_B > 0.90$

4. BOTH HYPOTHESES MUST BE MET FOR OVERALL STUDY SUCCESS. STUDY DESIGN

4.1 Overall Design

This is a clinical study performed in a single center for validation purposes, with all data collection occurring within a single visit.

Up to 60 (sixty) participants will be enrolled, for 56 (fifty-six) to complete data collection.

4.2 Rationale for Study Design

This clinical study is designed primarily as an engineering evaluation to validate the software functionality for the HeartStart Intrepid Monitor/Defibrillator. This study is necessary to confirm the device is functioning as designed prior to release of the software.

4.3 Sample size

Up to 60 (sixty) participants will be enrolled, for 56 (fifty-six) participants to complete data collection.

4.4 Study Duration and End of Study Definition

The total enrollment duration for an individual participant will not exceed one day; it is estimated that the entire study duration will not exceed one month.

5. STUDY PARTICIPANTS

5.1 Study Sample Considerations

The software change was created to help with high impedance experienced with some patients while obtaining a 12-lead ECG. This high impedance can be a result of skin conditions (wet skin) or electrodes that have been exposed to air for extended periods of time. Extended exposure to air will dry out the electrodes prematurely and reduce their adhesive and conductive properties. The study will utilize electrodes from an unopened package, a package open for 24 hours and package open for 30 days. This will be a stratification factor for randomization.

The inclusion/exclusion do not specify any clinical conditions for enrollment, as the study does not plan to diagnose or confirm any medical conditions.

5.2 Inclusion Criteria

Inclusion criteria are as follows:

- Able to read, write, speak, and understand English
- Aged 29 days to 89 years
- Willing and able to provide informed consent and complete study procedures
- Willing to have Philips representatives present during study procedures.

5.3 Exclusion Criteria

Exclusion criteria are as follows:

- Known allergy to medical adhesives, silicone, or latex (per self-report)
- Any limitation or medical condition, including but not limited to physical or cognitive disability, that would affect the participant's ability to complete study activities (per investigator)
- At the time of enrollment, current enrollment in any other interventional research study
- An employee, or residing family member of an employee, of a company that designs, sells, or manufactures monitor/defibrillator technology or related products (including Philips)

5.4 Definitions of Enrollment and Screen Failures

Potentially eligible participants will be consented, if willing (see Section 7.1.2), and all participants who sign the consent form will be considered enrolled. Formal assessment of eligibility according to the criteria listed in Sections 5.2 and 5.3 will take place following consent, and any participants found to be ineligible at this point will be considered screen failures. The following data will be reported for screen failures:

- Sociodemographic data (age, sex, and race/ethnicity);
- Adverse events during the enrollment period;
- Reason/s for ineligibility.

Any participant that discontinues/is withdrawn from the study following randomization will be categorized as an early termination (see Section 11) rather than a screen failure, even if the discontinuation/withdrawal occurred prior to the participant beginning the study intervention.

5.5 Strategies for Recruitment and Retention

The participants will be of both sexes, with a wide body mass index (BMI) range, to support generalizability of results. Due to the small sample size, no firm parameters for these measures have been determined a priori.

This study is not limited to adult patients. It is anticipated that at least 30% of the sample will be under the age of 16.

It is anticipated that racial/ethnic minorities will represent at least 30% of the sample.

All participants will be enrolled within the US. Recruitment will be the responsibility of the site and will take place through recruitment of their internal databases. As this study involves only one visit, it is not likely that participants will drop-out or be lost to follow-up before study completion. No specific strategies for retention are required.

6. STUDY PRODUCT

6.1 Description of Intervention

The HeartStart Intrepid Monitor/Defibrillator Model 867172 is a lightweight, portable Monitor/Defibrillator with a large display. It provides four clinical modes of operation: Monitor, Manual Defibrillation/Synchronized Cardioversion, AED and Pacing. The HeartStart Intrepid is powered by a rechargeable Lithium-Ion battery, AC Power or DC power with use of a special DC

Power Module. Available battery power is determined by viewing the battery power indicators located on the front of the device, the icon on the display, or by checking the gauge on the battery itself. Additionally, AC Power may be applied as a secondary power source and for continual battery charging.

This study will only utilize some of the monitoring functionality within the device. The HeartStart Intrepid Monitor/Defibrillator uses the Philips DXL ECG Algorithm. The Philips DXL ECG Algorithm produces precise and consistent ECG measurements that are used to generate interpretive statements. The process begins with the simultaneous acquisition of the twelve conventional leads along with patient demographic information.

The HeartStart Intrepid Monitor/Defibrillator utilized in this study will have software version 1.00.46. This software has been modified from its released version to account for instances of high impedance.

During the 12-lead ECG acquisitions, patients will have their SpO_2 and blood pressure monitored.

The Philips HeartStart Intrepid Monitor /Defibrillator is currently released for sale in the European market. It will be submitted to the FDA for 510(k) clearance during the time of this study. In the United States it is considered a Class II medical device. For the purposes of this study, the device will only be able to be used for monitoring and no clinical decision will be made based on the results obtained. None of the defibrillator accessories will be available for use. The Philips HeartStart Intrepid Monitor /Defibrillator used for this study is considered an investigational medical device. The sponsor considers this study to be a minimal risk study with a non-significant risk device. As monitor/defibrillator is not implantable, not supporting or sustaining life, not curing, mitigating, or treating disease, or otherwise preventing impairment of human health, and does not otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

A 12-lead ECG will be acquired three times (3) for each participant. The 12-lead ECG does not continuously record. As the leads are connected to the electrodes, markers will be placed for the three-lead and five-lead configurations. The Philips HeartStart Intrepid Monitor /Defibrillator has a 12-lead ECG preview screen that will allow the site staff to determine if a 12-lead ECG can be acquired. Once the ‘start acquire’ button is pushed, the recording will start and approximately 10 to 12 seconds a 12-lead ECG will be recorded. If the 12-lead does not have a good signal, no recording will be able to be obtained.

Participants will be randomized to electrodes that are either from an unopened package or have had the package open for 24 hours or 30 days. The 30-day electrodes will have a window of being opened plus or minus 10 days. The length of time the package is open is proportional to the amount of conductive gel that has dried on the electrode. The longer the electrode package is open, the drier the conductive gel and the higher the impedance. The dried electrodes will be used to simulate high impedance.

6.2 Description of Other Study Products

The Philips HeartStart Monitor/Defibrillator can be used with the following accessories for this study. NOTE: None of the defibrillator accessories will be available for this study.

Model No.	Product Name/Description	UDI GTIN
M2202A	Adult radiotranslucent foam solid gel electrodes, 5 electrodes/pouch (300/case)	20884838002535
989803148821	Small Adult radiolucent foam, solid gel ECG electrode, 30 electrodes/pouch (600/case)	20884838007783
M1644A	5-lead ICU ECG set, snap, limb (AAMI)	00884838021280
M1645A	5-lead ICU ECG set, snap, limb (IEC)	00884838010833
M1602A	5-lead ICU ECG set, snap, chest (AAMI)	00884838021259
M1668A	5-lead ECG trunk cable (AAMI/IEC)	00884838010963
989803173131	5-lead ECG set, disposable, bedside (AAMI) (1 pack=20 lead sets)	20884838075690
989803174211	5-lead ECG set, disposable, bedside (IEC) (1 pack=20 lead sets)	20884838075737
M1663A	10-lead (5+5) ECG trunk cable, 2.0m (AAMI/IEC)	00884838010925
M1949A	10-lead (5+5) ECG trunk cable, 2.7m (AAMI/IEC)	00884838002463
989803176161	5-lead ruggedized ECG cable, snap, limb (AAMI)	00884838028302
989803176171	5-lead ruggedized ECG cable, snap, chest (AAMI)	00884838028319
989803176181	5-lead ruggedized ECG cable, snap, limb (IEC)	00884838028326
989803138171	75mm Chemical Thermal Paper (10 rolls)	10884838000725
989803202611	USB Data Drive	00884838087477
989803202921	Wireless Communication Module	00884838090958
989803202601	Rechargeable Lithium-Ion battery pack. Discontinue after 989803206451 release.	00884838087491

Model No.	Product Name/Description	UDI GTIN
989803206451	Rechargeable Lithium-Ion battery pack. Replace 989803202601. For Rest of World. **Not release** for India.	00884838099197
989803202931	DC Power Module	00884838093669
M3725A	Test Load, 50 Ohm, plug-style	00884838033573
989803171271	Test Plug, shorted	20884838015405
SpO_2 Sensors and Cables		
M1131A	Single-patient SpO_2 Sensor - Pediatric/Adult Finger (0.5m)	00884838010246
M1132A	Infant Single-Patient SpO_2 Sensor – Infant finger (0.9m)	00884838010284
M1133A	Neo/Infant/Adult Single-Patient SpO_2 Sensor – Adult Finger, Infant Thumb/Toe (0.9m)	00884838010215
M1134A	Adhesive-free Neo/Inf/Adult SpO_2 Sensor - Neonatal foot/hand; Infant thumb/great toe; Adult finger (0.9m)	00884838010222
M1191B	Reusable SpO_2 Sensor - Adult Finger (2m)	00884838010215
M1191BL	Reusable SpO_2 Sensor - Adult Finger (3m)	00884838010222
M1192A	Reusable SpO_2 Glove Sensor – Pediatric/Small Adult (1.5m)	00884838010246
M1196A	Reusable SpO_2 Sensor - Adult Finger (3m)	0084838001381
M1941A	SpO_2 Extension Cable, (2m)	00884838011922
M1943A	Reusable SpO_2 Sensor Adapter Cable (1m)	00884838011939
M1943AL	Reusable SpO_2 Sensor Adapter Cable (3m)	00884838011946
Non-Invasive Blood Pressure Cuffs and Air Hoses - NBP Air Hoses		
M1598B	NIBP Adult/Pediatric Air Hose (1.5 m)	00884838001695

Model No.	Product Name/Description	UDI GTIN
Non-Invasive Blood Pressure Cuffs and Air Hoses - Multi-Patient Comfort Care Cuffs - Single Hose		
M1572A	Comfort Care Cuff - Pediatric	00884838001558
M1573A	Comfort Care Cuff - Small Adult	00884838001565
M1574A	Comfort Care Cuff - Adult	00884838001572
M1574XL	Comfort Care Cuff – Adult XL	00884838050075
M1575A	Comfort Care Cuff - Large Adult	00884838001589
Non-Invasive Blood Pressure Cuffs and Air Hoses - Multi-Patient Easy Care Cuffs - Single Hose		
M4552B	Easy Care Cuff – Infant (Antimicrobial, Qty 1)	00884838002999
M4553B	Easy Care Cuff – Pediatric (Antimicrobial, Qty 1)	00884838003026
M4554B	Easy Care Cuff - Small Adult (Antimicrobial, Qty 1)	00884838003057
M4555B	Easy Care Cuff – Adult (Antimicrobial, Qty 1)	00884838003095
M4556B	Easy Care Cuff - Adult Long (Antimicrobial, Qty 1)	00884838003125
M4557B	Easy Care Cuff - Large Adult (Antimicrobial, Qty 1)	00884838003156
M4558B	Easy Care Cuff - Large Adult X-Long (Antimicrobial, Qty 1)	00884838003187

6.3 Concomitant Therapy

There are no medication/therapy restrictions in the inclusion/exclusion criteria. Participants may continue to use any current medications/therapies required.

6.4 Preparation, Handling, Storage, and Accountability

6.4.1 Acquisition and Accountability

The HeartStart Intrepid Monitor/Defibrillator and necessary accessories will be shipped to the investigator. The HeartStart Intrepid devices will be returned to the Sponsor at the end of the study. The unused accessories and re-usable used accessories will be returned to the sponsor, any used disposable accessories will be disposed of by the site after use. An inventory of devices will be maintained.

6.4.2 Formulation, Appearance, Packaging, and Labeling

The Device Label, User Manual and Operating Manual are included with the IRB submission. Some content of these documents may change before regulatory submission. The Philips HeartStart Defibrillator monitor will be labeled with "CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use."

6.4.3 Product Storage and Stability

Allow for settling time if the device has been in extreme temperatures. The time required for the device to warm from -20°C before use is 80 minutes. The time required for the device to cool from 70°C before use is 80 minutes.

6.4.4 Preparation

The Philips HeartStart Intrepid Monitor/Defibrillator will be set up by a trained Philips Employee. The staff will be trained to use the ECG monitoring, 12-lead ECG, SpO_2, NBP, and data management functions. Proper skin preparation and electrode placement are important elements in producing a high quality 12-Lead ECG. See Appendix A for the *Improving ECG Quality* Application Note.

The study staff will follow the product labeling regarding cleaning and disinfection of the Intrepid Monitor/Defibrillator and the accessories between each participant. See Appendix B for Instructions for Use. Each day prior to seeing participants, the site will ensure the device is ready for use by utilizing the 'RFU' indicator. See Appendix B for *Instructions for Use*.

At the beginning of each week of enrollment (except for the first training week) the study site will complete the operational check per the Instructions for use prior to any participant use.

6.5 Measures to Minimize Bias

6.5.1 Type of Randomization

Block randomization will be employed to ensure balance across subjects with regard to electrode age (new, 24 hours, 30 days).

6.5.2 Implementation of Randomization

The randomization schedule will be incorporated into the database. Assignment to an electrode will be apparent upon subject enrollment and entry into the database.

7. STUDY PROCEDURES

7.1 Recruitment Procedures

7.1.1 Pre-screening

Participants will be contacted by designated study staff from the site's database of patients. Potential participants may also be found by utilizing advertisements.

Phone screening

Recruitment will be the responsibility of the site. Potential participants will be screened over the phone for eligibility, and then scheduled for an enrollment visit.

Phone screening will include questions regarding age, sex, height and weight (for calculation of BMI), to facilitate the recruitment of participants of all ages with a wide BMI range.

A waiver of informed consent for screening will be submitted to the IRB for contacting these participants.

7.1.2 Consent

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be IRB-approved, and the participant will be provided ample time to review the form prior to enrollment, including the opportunity to discuss potential enrollment with family or others. For any participants under the age of 16, a parent will be asked to sign an Informed Consent Form on behalf of their child.

During the phone screening a preliminary assessment of eligibility will be performed by the investigator or designee. Once the participant arrives on site, the investigator or designee will describe the purpose of the study, all study procedures, possible risks of participation, and their rights as a research participant. Participants must be informed that participation is voluntary and

they may withdraw from the study at any time without prejudice, and the quality of their medical care will not be impacted by declining to enroll or withdrawing from the study for any reason. After an opportunity to ask questions, willing and eligible participants will be asked to sign the consent form on paper. It is anticipated that the consent process will take approximately 15 minutes to complete. Apart from preliminary eligibility assessment, no study procedures will take place prior to consent.

7.2 Study Visits

Study Visit 1

Once the participant arrives, the study will be explained in full detail. If the participant agrees, he/she will be consented into the study and the participant will be given a copy of the informed consent.

Once consent is obtained the following study related procedures will be conducted:

Demographics: gender, age, ethnicity, height and weight will be collected.

Inclusion/Exclusion Verification

Skin pigmentation assessment: Skin pigmentation will be assessed with a Mexameter probe (C&K Electronic; Köln, Germany) a small hand-held tool held over the skin of the inner arm (an area with minimal sun exposure) for a few seconds that emits three light wavelengths to calculate melanin and hemoglobin content in arbitrary units on a scale of 0-999 (within ±5%).

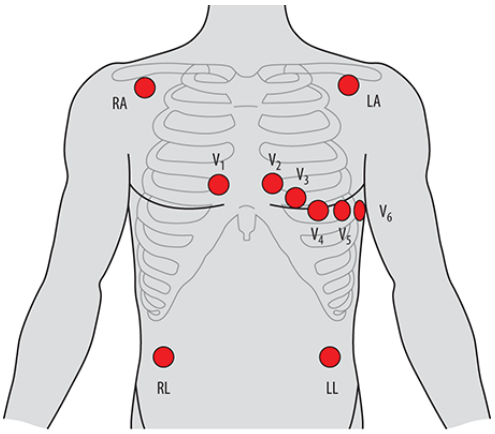
Skin assessment: The participants skin will be assessed with palpation to assess temperature, moisture, and texture.

Medical History: Participants will be asked if they have any relevant cardiac history (for example, a pacemaker).

Enrollment into study: Once the above procedures are complete. Participants will be randomly assigned (like the flip of a coin) to a set of ECG electrodes: brand new, package open for 24 hours and package open for 30 days

12-lead ECG: Participants will have 10 electrodes placed on their body by a trained member of the study staff. The electrodes will be placed similar to those used for out of hospital 12-lead ECGs. One electrode is placed on the right shoulder, left shoulder, right waist, and left waist. Six V/C electrodes are placed on the chest. The right waist electrode is the reference electrode, as shown in the figure below. The study team shall use the 'Improving ECG quality' application note for obtaining a good quality ECG. Once the skin is prepped, all of the electrodes will be placed on the patient. The cables will be connected to the electrodes in the following order 3 leads, 5 leads, and chest leads. Once the 5 leads are place and prior to the acquisition of the 12-lead

ECG, the 12-lead ECG preview screen will be made available, the study staff will then place the remaining electrodes and determine if a 12-lead ECG can be obtained. If the 12-lead ECG cannot be obtained and the participant has been randomized to either the 1 day or 30 day electrodes, the electrodes will be swapped for electrodes from an unopened package. If the 12-lead ECG cannot be obtained after the electrodes have been changed, this will be considered a 'Fail.'



Source: Derek R. Cooney: *Cooney's EMS Medicine*: www.accessemergencymedicine.com

After the ECG electrodes are placed, the patient will have their SpO_2 and noninvasive blood pressure monitored as detailed in the instructions for use. The blood pressure cuff will be placed on the opposite arm from the SpO_2 sensor.

Once all electrodes and monitoring functionality is placed, the patient will be given time to relax. Once relaxed, the participant will be asked to lay quietly for up to 15 minutes while the device collects the ECG and other vitals are monitored. See the table below for frequency. After the readings are completed, all equipment will be removed and the participant will be free to leave the laboratory.

Data Acquisition frequency.

Monitoring Functionality	Data Acquisition by device
Non-Invasive Blood Pressure	Minute 0, Minute 5, and Minute 10
12-Lead ECG	Immediately after the NBP cuff deflates (approximately minute 1, minute 6 and minute 11)
SpO_2	Continuously (1 minute intervals)

It is anticipated for the first 1 to 3 participants, that a Philips Engineer and members of the Philips Clinical Team will be on-site to observe the study. The Philips Engineer will be able to troubleshoot any of the issues experienced with the capture of the 12-lead ECG on the HeartStart Intrepid.

At the end of each day the device data will be downloaded utilizing the USB drive. This data will be uploaded into the corresponding participant file for analysis. Printed copies of the 12-lead ECG will be stored in the participant file. Once the study is complete, the original paper files will be sent to the sponsor. Copies of the originals will be maintained at the site.

7.3 Adverse Event Surveillance

Safety monitoring will take place throughout the study. Events that are reported by participants without prompting will also be captured and followed.

All study procedures will take place during the initial visit, under the supervision of the Principal Investigator. The Principal Investigator is a physician and all visits will take place at a clinical facility, allowing for clinical intervention if needed. The risks associated with the study are immediate; that is, it is considered highly unlikely that a related adverse event will take place after the completion of a study visit.

7.4 Data Processing and Scoring

Electrocardiograms from all ECG monitoring events are to be presented to the independent reviewer. Participant Number, age and gender are pre-printed on the ECG. The reviewer will make an assessment of each ECG and document the results in the case report form.

ECGs will be examined in each of the following criteria. We have assumed that the HeartStart Intrepid Monitor/Defibrillator runs at a paper speed of 25 mm/s, that is, each second is represented by five large squares.

a. 1mV calibration, any lead, as the number of large squares
   - A number OR not readable.
b. Heart rate, as displayed on the ECG
   - A whole number, as beats per minute, OR missing.
c. Heart rate, as the number of large squares in an RR interval
   - A number OR not readable.
     Enter one small square as 0.2 large square.
     Enter a minimum and a maximum if the rhythm is irregular.
d. Cardiac axis: not readable OR normal OR abnormal.
e. Rhythm: not readable OR normal OR abnormal.
f. P wave, any lead: not readable OR normal OR abnormal.
g. PR interval, any lead: not readable OR normal OR abnormal.
h. QRS complex, any lead: not readable OR normal OR abnormal.
i. ST segment, any lead: not readable OR normal OR abnormal.
j. T wave, any lead: not readable OR normal OR abnormal.
k. QT interval, any lead: not readable OR normal OR abnormal.
l. U wave, any lead: not readable OR normal OR abnormal.

m. Overall impression — ONE OF not interpretable OR normal OR abnormal, but no action required OR abnormal and requires immediate action.

An ECG from the printed patient record is considered to be of diagnostic quality when every part of the waveform in every lead is readable.

SpO_2 data and NBP data will be utilized to troubleshoot any 12-lead ECG tracings that are not readable or abnormal.

7.5 Participant Compensation

Participants who complete the study will be reimbursed $100 in the form of a gift card for their time and participation in the study. Pro-rated compensation will be provided to individuals whose participation is terminated early for any reason. In that scenario, participants will be reimbursed according to the following schedule:

- Participant signs consent, but is found to be not eligible $25

8. ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

8.1 Adverse Events and Serious Adverse Events

8.1.1 Definition of Adverse Events

An AE is any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related (21 CFR 312.32 (a)). When an AE is deemed to be related to the study device, it is termed an adverse device event.

1.1.1. Definition of Serious Adverse Events

An AE or suspected adverse reaction is considered serious if, in the view of either the investigator or Sponsor, it results in any of the following outcomes: death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. When a serious AE is deemed to be related to the study device, it is termed a serious adverse device event (SADE).

8.2 Unanticipated Adverse Device Event

An unanticipated adverse device event (UADE) is defined in 21 CFR Part 812.3(s) as “any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects”.

Other important medical events which may not result in any of the outcomes above, but which may require intervention to prevent one of the outcomes above, may in the opinion of the investigator, be considered a UADE.

8.3 Classification of an Adverse Event or Adverse Device Event

1.1.2. Severity of Event

All AEs will be assessed by the study clinician using a protocol defined grading system as follows:

- Mild – Events require minimal or no treatment and do not interfere with the participant’s daily activities.
- Moderate – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- Severe – Events interrupt a participant’s usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term “severe” does not necessarily equate to “serious”.

8.3.1 Relationship to the Study or Device

All AEs will have their relationship to study procedures and the study device assessed by the clinician who examines and evaluates the participant based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below.

- Definitely Related – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event occurs in a plausible time relationship to study intervention administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study intervention should be clinically plausible.
- Probably Related – There is evidence to suggest a causal relationship, and the influence of other factors is unlikely. The clinical event occurs within a reasonable time after

administration of the study intervention, is unlikely to be attributed to concurrent disease or other drugs or chemicals.

- Potentially Related – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after the application of the electrodes). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). Although an AE may rate only as "possibly related" soon after discovery, it can be flagged as requiring more information and later be upgraded to "probably related" or "definitely related", as appropriate.
- Unlikely to be related – A clinical event whose temporal relationship to study intervention administration makes a causal relationship improbable (e.g., the event did not occur within a reasonable time after administration of the study intervention) and in which other drugs or chemicals or underlying disease provides plausible explanations (e.g., the participant's clinical condition, other concomitant treatments).
- Not Related – The AE is completely independent of study intervention administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by the clinician).

8.3.2 Expectedness

The Principal Investigator will be responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

8.4 Adverse Event Assessment and Follow-Up

All AEs including local and systemic reactions not meeting the criteria for a serious adverse event (SAE) will be captured on the appropriate (e)CRF. Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

An incidental finding is an anatomical deviation which is found as a result of the 12-lead ECG acquisition with respect to the medical condition of the participant of which they were previously unaware. This study is not for diagnostic purposes, so if incidental health findings are discovered as part of a study the subject will be informed and advised to consult their physician. Further evaluation of such findings shall not be under the purview of the study and the investigators shall not be obliged to bear any further costs. In case of significant incidental finding the study site will have the Principal Investigator repeat the 12-lead ECG with a released device. Any incidental finding and communication to the participant will be noted in the AE form.

8.5 Serious Adverse Event or Serious Adverse Device Event Reporting

The study investigator shall complete a SAE or UADE Form and submit to the Sponsor and to the reviewing IRB as soon as possible, but in no event later than 24 hours (for a SAE) or 10 working days (for a UADE) after the investigator first learns of the effect. The Sponsor is responsible for conducting an evaluation of the SAE/UADE and shall report the results of such evaluation to the Food and Drug Administration (FDA) and to the review IRB or 10 working days (for a UADE) after the Sponsor first receives notice of the effect. Thereafter, the Sponsor shall submit such additional reports concerning the effect as FDA requests.

8.6 Device Deficiency

All device deficiencies, use or user errors, and equipment failures will be documented. Use or user errors will be captured as part of the source documentation. Device deficiencies and equipment failures will be kept on a separate log. The serial numbers and type of deficiency/failure will be captured. Unanticipated device deficiencies that lead or may lead to an SAE will be reported to the Sponsor within 24 hours of learning of the event.

8.7 Unanticipated Problems

8.7.1 Definition of Unanticipated Problems

An unanticipated problem (UP) is any incident, experience, or outcome that for which the nature, severity, or frequency is unexpected for the subject population or research activities as described in the current IRB approved protocol, supporting documents, and the consent form.

8.7.2 Unanticipated Problem Reporting

The Principal Investigator will submit to the Sponsor and to the reviewing IRB a report of any UADE occurring during an investigation as soon as possible, but in no event later than 10 working

days after the investigator first learns of the effect (21 CFR 812.150(a)(1)). Under 812.46(b), the Sponsor shall report the results of such evaluation to the FDA and to all reviewing IRB's and participating investigators within 10 working days after the Sponsor first receives notice of the effect. Thereafter the Sponsor shall submit such additional reports concerning the effect as FDA requests (21 CFR 812.150(b)(1)).

9. RISK BENEFIT ASSESSMENT

9.1 Known Potential Risks

A. Loss of confidentiality/privacy is a risk in all studies collecting personal and/or sensitive data.

B. The only anticipated adverse event (AE) related to the 12-lead ECG is skin irritation or discomfort associated with the electrodes. It is possible the 12-lead ECG may uncover a medical condition in which the participant was previously unaware. This is considered an incidental finding. Refer to Section 8.4 for handling

C. During blood pressure monitoring, some participants may feel some discomfort as the blood pressure cuff loosens and tightens during the assessment.

D. There are no associated adverse events with pulse oximetry monitoring.

9.2 Risk Mitigation

A. Efforts to protect participant confidentiality are described in section 11.2.4. Privacy breaches will be reported to the relevant participant/s and will be treated as an unanticipated problem despite being listed here (see Sections 8.7 and 11.2.4)

B. Participants reporting a history of allergic reactions to medical adhesives will not be recruited.

Participants will be monitored by study staff during the study procedure, if at any point the participant wants to stop, the study will be stopped, and the participant may withdraw from the study.

9.3 Known Potential Benefits

Participation in this study will not result in direct benefit to the participant.

9.4 Assessment of Potential Risks and Benefits

It is the opinion of the Sponsor and the Principal Investigator that the benefits of this protocol outweigh the risks.

10. STATISTICAL CONSIDERATIONS

The statistical analysis plan has been incorporated into this protocol. It is not a stand-alone document.

10.1 Sample Size Determination

Each hypothesized endpoint estimates a target proportion of 99% with an expectation to be statistically better than 90%. Using a one-sided exact test, with 80% power and alpha of 0.025, a sample size of 56 evaluable subjects is required.

Both hypothesized endpoints must be met for study success, therefore alpha level adjustments are not necessary to address familywise error.

10.2 General Considerations

Continuous data will be presented by mean, standard deviation, median, minimum and maximum observation, and 95% confidence interval. Categorical data will be presented as frequencies, percentages, and the 95% Clopper-Pearson confidence interval. Significance tests will be conducted at a two-sided significance level (alpha) of 0.05, or a one-sided significance level of 0.025.

10.3 Participant Disposition

Participant disposition, including the total number of participants enrolled, randomized, and completed, along with reasons for early terminations, will be compiled.

10.4 Analyses

10.4.1 Demographics and Baseline Characteristics

Participant demographics (age, sex, race/ethnicity) and descriptive characteristics will be summarized for all participants enrolled and for evaluable participants.

10.4.2 Analysis of the Primary Endpoints

Endpoint 1A: Obtaining the 12-lead ECG

Endpoint 1B: Diagnostic quality of the 12-lead ECG tracings

A one-sided exact binomial test will be used to assess each of the primary endpoints. Both endpoints must be met for study success.

10.4.3 Adjustment for Multiplicity

Both hypothesized endpoints must be met for study success, therefore alpha level adjustments are not necessary to address familywise error.

10.4.4 Exploratory Analyses

Exploratory analyses are not planned.

10.4.5 Sensitivity Analyses

Sensitivity analyses are not planned.

10.4.6 Safety Analyses

Adverse events will be collected and summarized using descriptive statistics.

10.5 Planned Interim Analyses

No interim analyses will be undertaken. After the first 3 (three) participants, if a 12-lead ECG was not able to be obtained, the study will be paused and the software will be re-evaluated. In addition, the first 3 ECGs will be reviewed for diagnostic quality. If they are not found to be of adequate quality, the study will be paused and the software will be re-evaluated.

10.6 Study Termination

There are no statistical criteria for terminating the study. The study may be paused to re-evaluate the software if the first three participants have ECG tracings were not able to be obtained by the device or if they were not found to be of adequate quality (as assessed in section 7.4).

10.7 Missing Data

Missing data will not be imputed.

10.8 Deviations from the Statistical Analysis Plan

Any deviations from the original statistical plan will be noted in the clinical study report.

11. OPERATIONAL CONSIDERATIONS

11.1 Early Termination of Participation

11.1.1 Discontinuation (active drop-out)

A participant may opt to discontinue participation at any time, and they are not required to provide a reason. If a reason is provided, it will be recorded. If a participant wishes to withdraw their own data from the dataset, this request should be made in writing, and the requirement for this request should be communicated to the participant.

11.1.2 Withdrawal (by investigator)

An investigator may withdraw a participant from the study for the following reasons:

- If any AE, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant;
- If the participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

The reason for participant withdrawal from the study will be recorded. AE surveillance (see Section 7.3) will continue until resolution. Withdrawal of a participant for a reason other than what is listed here will be considered a major protocol deviation (see Section 11.5.2).

11.1.3 Impact of Early Termination on Recruitment and Enrollment

Recruitment and enrollment will continue until 60 participants complete all study procedures.

11.2 Regulatory and Ethical Considerations

11.2.1 Institutional Review Board

The IRB for this study is:

Allendale Investigational Review Board (AIRB)
30 Neck Road
Old Lyme, CT 06371
Office: [redacted]

11.2.2 Informed Consent Procedure and Documentation

The procedure for seeking informed consent is described in Section 7.1.2. A copy of the signed consent form will be provided to each participant for their records. The informed consent process will be conducted and documented in the source document (including signature and date), prior to undergoing any study procedures other than those described in Section 7.1.1 required for preliminary eligibility assessment.

11.2.3 Study Discontinuation and Closure

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. If the study is suspended or terminated, the Sponsor will be responsible for informing the IRB, and the investigator at each site will be responsible for informing all participants and providing guidance as to the remainder of the study procedures if necessary.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of excessive risk to participants;
- Insufficient compliance to protocol requirements;
- Data that are not sufficiently complete and/or evaluable;
- Demonstration of efficacy that would warrant stopping (if described in Section 10.6);
- Determination of futility (if described in Section 10.6).

It may be possible for the study to resume once concerns about safety, protocol compliance, or data quality are addressed satisfactorily and approved by the Sponsor, IRB, and any other regulatory bodies.

11.2.4 Confidentiality and Privacy

Participant confidentiality and privacy will be held strictly in trust by the participating investigators, their staff, and the Sponsor. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to descriptive and clinical information relating to participants. The study protocol, documentation, data, and all other information generated will therefore be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the Sponsor.

The study monitor, other authorized representatives of the Sponsor, representatives of the IRB, and other regulatory agencies, may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. Each participating site will permit access to such records.

Each study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, institutional policies, or Sponsor requirements. All other research data will be coded with a unique identifier and provided to the Sponsor. 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), medical history, and concomitant medications review. All research activities will be conducted in as private a setting as possible. The privacy of each subject and confidentiality of data shall be preserved in reports and when publishing any data.

Data management procedures are described in Section 11.4.3.

11.2.5 Future Use of Stored Specimens and Data

All study data received from participating sites will be stored and may be used by the Sponsor for future analyses. This possibility will be captured in the consent form

11.3 Study Oversight

11.3.1 Safety Oversight

Adverse event surveillance procedures are described in Section 7.3, and definitions and reporting procedures are described in Section 8. Subsequent to monitoring of site records and reports, Philips will review and classify adverse events and ensure ongoing safety evaluation of the clinical study as described in ISO 14155 *Safety Evaluation and Reporting*.

11.3.2 Monitoring

Monitoring visits (on site or remote) will be performed by authorized Sponsor representative/s periodically. The site staff will ensure that the monitor is supplied with original study participant records and other documentation as requested. The monitor will verify that 100% of the study participants were appropriately consented using the IRB-approved consent form. The monitor will verify treatment assignment or randomization was completed accurately, and will review all adverse events, unanticipated problems, device deficiencies, and protocol deviations. The monitor will also document review and reconciliation of investigational product/s if needed. Monitoring reports, discrepancies, and resolution will be documented in the trial master file.

11.3.3 Vulnerable Populations

According to ISO 14155, a vulnerable subject is an individual whose willingness to volunteer in a clinical study could be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of retaliatory response from senior members of a hierarchy in case of refusal to participate.

This may include those individuals with lack of or loss of autonomy due to immaturity, mentally disabled individuals, persons of nursing homes, children, impoverished persons, subjects in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, those incapable of giving informed consent, university students, subordinate hospital/laboratory personnel, sponsor employees, members of the armed forces, persons kept in detention, etc.

- Participants under the legal age to give consent will be enrolled in the study
- All participants under the legal age to give consent will have the study and any risks and/or benefit explained. Following this discussion, the child/adolescent will be asked to sign an Assent in the presence of a parent or guardian complete
- Allendale IRB will review all versions of Assent to ensure safeguards and language is appropriately expressed
- As this study is a non-interventional, non-diagnostic effort, it is not anticipated any additional medical care will be provided. However, if there is an incidental finding the participant will be informed and advised to consult their physician

11.4 Quality Assurance and Quality Control

11.4.1 Training

The investigator and all research staff will be trained to the study protocol, devices, trial master file documents, monitoring plan, CRFs and/or eCRFs, data entry, and all additional Sponsor expectations, as applicable. In addition, training related to data privacy, data protection laws, HIPAA, and redacting any patient identifiers in data required for transmission to the Sponsor will be documented. Once complete, training and delegations will be documented for all personnel.

11.4.2 Data Collection and Handling

Data collection and handling is the responsibility of the staff at the site under the supervision of the site investigator. Only staff that have been delegated by the investigator are authorized to enter or make changes to data in the CRFs. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

11.4.3 Data Management

All data will be entered into DataTrak, a 21 CFR Part 11-compliant data capture system provided by the Sponsor. The data will be housed within a secure server (based in Virginia, USA) and accessible only to the sponsor, study personnel, and investigators. Access to the EDC system will be secured through logins managed by a system administrator and appropriated training will be provided. The EDC system provides the capability to perform data management activities within a consistent, auditable, and integrated electronic environment (data security, data entry, data validation). Data entries and modifications will be recorded via an audit trail. If the data manager or study monitors identify data errors or inconsistencies, they will generate queries that will be sent to the Principal Investigators and study staff. After queries are resolved, the database will be locked, and the data will be imported into a statistical software and analyzed by biostatisticians.

11.4.4 Data Retention Period

Hard copies of all study documentation will be kept on site for at least two years after study completion. The Sponsor will maintain study records indefinitely in a secure location.

11.5 Protocol Deviations

A protocol deviation is any departure from the IRB-approved protocol, made with or without prior IRB approval.

11.5.1 Emergency Deviations

An emergency deviation is any departure from the approved procedures that is undertaken to protect the life or physical wellbeing of a participant. In such cases, there is not enough time to seek IRB approval for the deviation. All emergency deviations should be reported as a UP+AE (see Section 8).

11.5.2 Major Protocol Deviations

A major protocol deviation is any event which leads to the following:

- Participant withdrawal (by the investigator) for a reason other than what is listed in Section 11.1.2;
- Absence of a valid primary endpoint for a given participant. This protocol includes multiple primary endpoints (see Section 3.1.1), both/all of which need be missing to be considered a major protocol deviation;
- Enrolment of an ineligible participant;

- Enrolment of more than the IRB-approved sample size specified in Sections 4.3 and 10.1.

All major protocol deviations require prior approval as a planned protocol deviation by the IRB. A planned deviation occurs when the investigator prospectively and intentionally plans to deviate from study procedures. Most, but not all, planned protocol deviations are one-off requests that apply to a single participant.

11.5.3 Minor Protocol Deviations

Minor protocol deviations are those that do not impact the scientific soundness of the study or the rights, safety, or welfare of participants.

11.5.4 Reporting Protocol Deviations

By definition, emergency deviations are considered to be UPs, and will be reported as such. Major protocol deviations that did not receive approval as planned protocol deviations will be reported within 24 hours of the learned event per Allendale IRB's policy. Minor protocol deviations will be collated and reported to the IRB, DSMB, and FDA at each annual review. Reporting procedures will follow those described for AEs and UPs.

11.6 Publication and Data Sharing

11.7 Study Registration

This study meets the definition of an Applicable Clinical Trial per 42 CFR Part 11 and will be registered on ClinicalTrials.Gov. The possibility of study registration will be included in the consent form.

11.8 Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest (apart from that related to Philips) of persons who have a role in the design, conduct, analysis, publication, or any aspect of this study will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

REFERENCES

Fye, W. (1994). “A History of the Origin, Evolution, and Impact of Electrocardiography. *American Journal of Cardiology*, 73:937-949.

Soar, J. J. (2015). European Resuscitation Council Guidelines for Resuscitation 2015: Section 3. Adult Advanced Life Support. *Resuscitation* , 95.

LIST OF APPENDICES

Appendix A: Application Note

Improving ECG

Appendix B: Instructions for Use

Appendix B:

Internal Review Signatures

[redacted]	[redacted]	[redacted]	[redacted]
Reviewer Signature	Date	Reviewer Signature	Date
Dawn Jorgenson, Principal Scientist, Research & Development, Emergency Care & Resuscitation		Marc Rubinstein, MD Medical Affairs Director,, Connected Care	
[redacted]	[redacted]	[redacted]	[redacted]
Reviewer Signature	Date	Reviewer Signature	Date
Edward Kompare, Senior Medical Solutions Specialist, Medical Affairs, Emergency Care & Resuscitation		Sen Zhang, Project Manager, Emergency Care - Professional	
[redacted]	[redacted]	[redacted]	[redacted]
Reviewer Signature	Date	Reviewer Signature	Date
Rui Jin, Advanced Electrical Engineer, Emergency Care & Resuscitation		Vicky Wang, Senior Regulatory Affairs Engineer, Emergency Care - Professional	