Informed Vital Core
Pulse Rate Clinical Study Protocol

IVC-400-006
Rev. 1

Mindset Medical, LLC

A Multi-Center Prospective Open Label Study of a Web-based Application for Pulse Rate in Adult Patients

Original date: March 31, 2023

Principal Investigator: Daniel Lubelski, M.D.

PROTOCOL APPROVAL FORM

Protocol Number: IVC-400-006
Study Title: A Multi-Center Prospective Open Label Study of a Web-based Application for Pulse Rate in Adult Patients
Version Number: Version 1.0 dated March 31, 2023.

This study protocol was subjected to critical review. The information it contains is consistent with Mindset Medical, LLC's current knowledge of the risks and benefits of the investigational technology, as well as with the moral, ethical, and scientific principles governing clinical research as set out in the *Declaration of Helsinki*, as amended in 2000 and clarified in 2004, and the guidelines on *Good Clinical Practice*.

The study protocol has been reviewed and approved by the following:

[redacted]

Investigator's Agreement

I have read the protocol version 1.0 dated March 31, 2023 and agree to conduct the study as outlined.

The information contained in this document and all information provided to me related to this protocol are the confidential and proprietary information of Mindset Medical (Sponsor), and except as may be required by federal, state, or local laws or regulations, may not be disclosed to others without prior permission of Sponsor. However, the Principal Investigator at each site may disclose such information to supervised individuals working on the study, provided such individuals agree to be bound to maintain the confidentiality of such information.

I agree to abide by the above Confidentiality Statement.

I agree to conduct the study according to this protocol. Any changes in procedure will only be made if necessary to protect study subjects' safety, rights, or welfare.

I agree to comply with the current *International Conference on Harmonization Tripartite Guideline on Good Clinical Practice* and applicable U.S. FDA regulations including 21 CFR 50, 54, and 56.

I agree to conduct the study in person or to supervise the study.

I agree to ensure that all individuals who assist me in the conduct of the study have access to the study protocol and any amendments and am aware of their obligations under this protocol.

Printed Name of Investigator	
Signature of Investigator	
Date	

Summary of Changes

Original	Amendment Change	Reason for Change
Original release	N/A	N/A

Contents

Protocol Synopsis

Evaluating the Accuracy of a Web-Based Application - Vital Sign Measurement Platform	
Description	This multi-center prospective open label study is designed to evaluate the accuracy of Informed Vital Core Application (IVC App, IVC), a web-based application designed for measurements of vital signs including pulse rate (PR). [redacted] Mindset Medical will conduct a clinical study to evaluate the accuracy of measurement for pulse rate using the IVC App, compared to appropriate reference devices. The study will recruit subjects from clinics, hospitals, and the general public.

Study hypothesis	[redacted] PR will be collected simultaneously with the IVC App and [redacted] reference device [redacted]
Intervention model	Single Group Assignment
Masking	None (open label)
Investigational device	Informed Vital Core Application (IVC App) by Mindset Medical, LLC
Reference device	[redacted]
Primary objective	The primary objective of the study is to establish that pulse rate (PR) measured with the IVC App are accurate [redacted] with the reference [redacted]
Primary endpoint	[redacted]
Study design	The study will recruit subjects from clinics, hospitals, and the general public. [redacted]

	[redacted]
Patient population	**Inclusion Criteria** • Subjects 22 -85 years of age • Subjects willing to sign the Informed Consent Form and comply with the protocol **Exclusion Criteria** • Subjects required to wear mask or bandage that obstructs forehead, cheeks, or chin • Refusal to remove makeup, sunscreen, lotion, clothing, or items obstructing the face for the duration of measurement • Presence of facial tattoos, large birthmarks, or other skin alterations (scars, hemangiomas, vitiligo) on upper cheeks (cheekbone) or forehead of the subject • Condition that does not allow the subject to remain still for 60 seconds at a time • Subjects with cardiac arrhythmia • Any known medical condition which may result in an inaccurate measurement using the reference device • Subjects with the inability to complete an ECG
Sample size	[redacted]
Study visits	Screening/Baseline
Study duration	One day

This multi-center prospective open label study is designed to evaluate the accuracy of Informed Vital Core Application (IVC App), a web-based application designed for measurements of vital signs including pulse rate. It is hypothesized that the accuracy of the IVC App is non-inferior to the FDA-cleared/approved vital sign monitoring device (reference device).

Study Objectives

The primary objective of the study is to establish that pulse rate (PR) measured with the IVC App are accurate [redacted] measured with the reference [redacted].

Study Hypothesis

[redacted]

Study Endpoints

Primary Endpoint

[redacted]

Background

Vital sign measurement is a core process in delivering healthcare. Pulse rate is one of the most frequently measured vital signs in inpatient as well as outpatient encounters. Currently, pulse rate may have to be measured several times in a day.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Mindset Medical will conduct a clinical study to evaluate the accuracy of measurement for pulse rate using the IVC App, compared to appropriate reference devices. The study will recruit subjects from clinics, hospitals, and the general public.

Study Design

This is a multi-center prospective open label study where the same subjects are assigned the IVC Application and the [redacted].

The study will recruit subjects from clinics, hospitals, and the general public. [redacted]

All subjects will be asked to have facial assessment conducted and undergo two PR measurements using the IVC App. [redacted].

[redacted]

The PR obtained by the IVC App will be compared to the HR obtained by the [redacted]

Subjects will visit the clinic only once for the vital signs assessments unless a technical fallback session is required.

Number of Sites

The study will be conducted in up to ten (10) investigational sites in the United States. Enrollment will be competitive and each site will not enroll more than 25% of the total patient population without the written consent of the sponsor.

Number of Subjects

[redacted]

Study Duration

Study assessment is one day.

Schedule of Assessments

Table 2- Schedule of Assessments

	Screening /Baseline Day 1
Study Visit/Day	**Visit 1**
Informed Consent	X
Eligibility	X
Demographics	X
Fitzpatrick Scale Assignment**	X
Medical History	X
Concomitant Medication	X
Adverse Event Form (If applicable)	X
Pulse Rate (IVC)*	X
[redacted]	

Eligibility

Inclusion Criteria

- Subjects 22 - 85 years of age
- Subjects willing to sign the Informed Consent Form and comply with the protocol

Exclusion Criteria

- Subjects required to wear mask or bandage that obstructs forehead, cheeks, or chin
- Refusal to remove makeup, sunscreen, lotion, clothing, or items obstructing the face for the duration of measurement
- Presence of facial tattoos, large birthmarks, or other skin alterations (scars, hemangiomas, vitiligo) on upper cheeks (cheekbone) or forehead of the subject
- Condition that does not allow the subject to remain still for 60 seconds at a time
- Subjects with cardiac arrhythmia
- Any known medical condition which may result in an inaccurate measurement using the reference device
- Subjects with the inability to complete an ECG

Subject Identification

Subjects will be enrolled per the inclusion and exclusion criteria. Written informed consent, including Health Insurance Portability and Accountability Act (HIPAA) authorization, must be obtained prior to initiation of any study-specific investigative procedures. Eligible subjects will be enrolled and given a 6-digit identification code that consists of the three-digit site code, followed by a three-digit subject ID beginning with 001 and assigned sequentially (e.g., 301 001; site 301 and the first subject screened 001).

Study Execution

Enrollment

Subjects that meet the protocol qualifications and provide written informed consent shall be offered enrollment in the study. Concomitant study enrollment may be allowed with approval of the Sponsor. Study subjects may be enrolled in this study only once. A subject will be considered enrolled when the subject has signed the Informed Consent Form (ICF).

Pre-intervention screening

Review of Eligibility Criteria

Review the list of inclusion and exclusion criteria to ensure the subject is eligible to participate.

Informed Consent

Prior to conducting any study-specific tests or procedures required in this protocol, the Investigator or designee will obtain informed consent in writing from all subjects prior to any screening or study procedures. The Investigator will follow a standard process for obtaining consent that complies with all applicable regulatory requirements.

If the ICF is amended during the study, the investigator must follow all applicable regulatory requirements pertaining to approval of the amended ICF by the IEC/IRB and use of the amended form. Ongoing subjects will be required to re-confirm consent by signing the amended form.

The original and any amended signed and dated ICFs must be retained at the study site, and a copy of the signed and dated ICFs must be given to the subject. During the study, the subject will be informed if information becomes available that may be relevant to the subject's willingness to participate in the study.

The subject will be informed of procedures to protect subject privacy. Under U.S. federal law (the Privacy Rule) any protected health information (PHI) that is created or obtained during this study cannot be used or disclosed without permission. Informed consent on data processing will be obtained in writing directly from the subject before recording of any data. Authorization to use and disclose PHI will be obtained in writing directly from the subject before recording of any data. Recorded data will be pseudonymized before transferring to authorized individuals. The investigator will maintain source documents that link unique subject numbers with subject names.

Study Procedure

- Review the subject's medical history and concomitant medications and document on the appropriate Electronic Case Report Form (eCRF).
- Assign the Fitzpatrick Scale Category. Fitzpatrick category assignment must be completed by an Investigator.
- Record the subject's demographics on the appropriate eCRF.
- [redacted]
- Record any adverse events, protocol deviations, device failures.
- Complete subject disposition eCRF.

Adverse Events

Definitions

An **Adverse Event (AE)** is any untoward event that occurs after device implantation, any condition that increases in severity or frequency after device implantation, or any medical condition present at or before implantation that worsens after device implantation. All adverse events should be reported whether or not their occurrence has a causal relationship with the administration of the study material.

A **Serious Adverse Event (SAE)** is defined as any experience that:

- Is fatal or life-threatening
- Is permanently incapacitating or disabling
- Requires or prolongs in-patient hospitalization
- Results in a congenital anomaly or birth defect
- Results in permanent disability or incapacity
- Necessitates medical or surgical intervention to preclude a permanent disability or incapacity

Adverse events are not anticipated in this clinical study, since the study involves collection of pulse rate data using a remote software application and heart rate using an ECG device for a short period of time at the clinical study sites.

An **Unanticipated Adverse Device Effect (UADE)** is "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 any nature, severity, or degree of incidence in the investigational plan or any other unanticipated serious problem associated with a device that relates to the rights, safety, and welfare of subjects.

A record of each AE, including details of the nature, onset, duration, severity, relationship to the device will be recorded. AEs, should they occur, will be summarized and presented at each annual renewal for all subjects participating in the study. SAEs and UADEs should be reported to the FDA under the MDR reporting requirements and to the manufacturer.

Required Reporting Timelines per Regulatory Guidance

Required reporting time limit for the Sponsor is the number of days between the company's first knowledge of a reportable event (i.e., the receipt of information by any employee of the company) and the date the Food and Drug Administration (FDA) must be notified. Day one begins the day after the company receives information which reasonably suggests that a reportable event has occurred. Device related death, serious injury, or malfunction must be reported to FDA within 30 calendar days (no allowances are made for weekends or holidays).

However, if the event necessitates a correction or removal action, to prevent an unreasonable risk of substantial harm to the public health, then a report must be submitted within five (5) workdays, notwithstanding days including Saturdays, Sundays, and scheduled federal holidays.

Withdrawal and Lost to Follow Up

Subjects have the right to withdraw from the study at any time for any reason. The Investigator, acting in the subject's best interests, also has the right to withdraw subjects from the study. Since this study is a one-time assessment, early withdrawal is unlikely. However, it is possible for a subject withdrawal after signing consent and prior to study procedures. In all cases, the reason(s) for withdrawal must be recorded on the eCRF.

While adverse events are not anticipated in this clinical study, if the reason for removal of a subject from the study is an adverse event, the event will be recorded on the appropriate eCRF(s) and will be reported to Mindset Medical per the AE reporting guidelines (Required Reporting Timelines per Regulatory Guidance). All efforts will be made to follow the subject until the condition resolves, or the Investigator determines that the subject's health has returned to an acceptable state.

Statistical Methods

Sample Size

Inclusion of Incompetent Subjects

Subjects who lack the capacity to provide written informed consent shall not be enrolled in this study.

Statistical Analysis

Detailed methodology for descriptive and inferential statistical analyses of the data collected in this study will be documented in the Statistical Analysis Plan (SAP). Analysis populations will be defined in the SAP and any methodology to be used for missing data. The SAP will be prepared and agreed upon by signature and date by the Sponsor prior to database lock. In addition to the SAP, other graphical representations of the results may be produced after review of the data (post hoc). Any major modifications of the definition of the endpoints or analysis will be reflected in a protocol amendment.

The SAP will define how missing data will be handled, where applicable, including the use of imputation or sensitivity analyses.

Analysis of the primary endpoint

The Intent-to-Capture (ITC) population will be defined as all consented subjects who passed screening and completed at least one data collection session without withdrawing.

The Per Protocol analysis group for the primary endpoint will consist of subjects from whom PR measurements from the IVC App and HR from the [redacted] were collected during the same window.

[redacted]

The reference device Rhythm Analysis will be performed on the ECG rhythm strip using the procedure described in the Rhythm Analysis Procedure IVC-400-006i.

Data Management

Data will be reviewed throughout the study to identify any missing data, errors in data entry, or inconsistencies in the data provided. A query process will be used to resolve any discrepancies identified during the data review process and follow a Data Management Plan (DMP) that will be prepared and agreed upon by signature and date by the Sponsor prior to database lock.

Electronic Case Report Forms (eCRFs) and Source Documentation

All data obtained during the study should be entered on the eCRFs promptly. All source documents from which eCRF entries are derived should be placed in the subject's medical records. The eCRFs for each subject may be checked against source documents at the study site by the clinical site monitor.

Access to Source Data and Monitoring

During the course of the study, a representative of the Sponsor or a designated representative, i.e., a Clinical Research Associate (CRA) or monitor, may make site visits as frequently as necessary to review protocol compliance, compare eCRFs and individual subjects' medical records, assess clinical supply inventory as appropriate, and ensure that the study is being conducted in accordance with pertinent regulatory requirements. eCRF entries will be verified with source documentation. The review of medical records will be performed in a manner to ensure that subject confidentiality is maintained.

It is the Investigator's obligation to ensure that documentation of all relevant data such as medical history, concomitant diseases, date of study enrollment, visit dates, results of examinations, administrations of medication(s), and AEs are correctly entered in the subject's file.

Checking of the eCRFs for completeness and clarity, and cross-checking with source documents in the presence of the Investigator or designee, will be required to monitor the progress of the study. Moreover, regulatory authorities, IRB/REB, and/or the Sponsor's Clinical Quality Assurance group, or designee, may wish to carry out such source data checks and/or on-site audit inspections. Direct access to source data will be required for these inspections and audits; they will be carried out giving due consideration to data protection and medical confidentiality. The Investigator agrees to give the auditor access to all relevant documents for review. The same procedure applies in the case of an inspection by the regulatory authorities. Access to the eCRF will be password controlled and will conform with 21 CFR Part 11.

After every on-site audit, the Investigator will receive an audit confirmation by the auditor. This must be filed together with the study documentation and be made available to the regulatory authorities in case of supervision. At the end of the study, audit certificates will be included in the final report.

The Sponsor or designated representatives will affirm and uphold the principle of the subject's right to protection against the invasion of privacy. Throughout the study, all data will only be identified by subject number. Anonymity of the data will be maintained in all data analyses.

Archiving Study Records

Study records are to be maintained for a period defined by the laws and regulations of the participating country. For this study, a minimum of 2 years is required after the latter of the following two dates: the date the investigation was terminated or completed or the date the records are no longer required for purposes of supporting an FDA approval application.

Copies of all case report forms completed on subjects will be retained in individual subject files by the Investigator in a secure location.

ETHICAL, LEGAL, AND ADMINISTRATIVE ASPECTS

Sponsor Responsibilities

The Sponsor or their designee will conduct a remote or in-person site visit to verify the qualification of each Investigator, inspect the site facilities, and inform the Investigator of responsibilities and the procedures for ensuring adequate and correct documentation.

Investigator Responsibilities

The Investigator is required to prepare and maintain adequate and accurate case histories designed to record all observations and other data pertinent to the study for each study subject. All information recorded on the eCRFs must be consistent with the subjects' source documentation, i.e., medical records.

Good Clinical Practice

The procedures set out in this study protocol are designated to ensure that the Sponsor and the Investigator abide by the principles of the Good Clinical Practice (GCP) guidelines of the International Conference on Harmonization (ICH) and of the Declaration of Helsinki (2000 with clarification in 2004 and as amended thereto). The study also will be carried out in keeping with local legal requirements, as appropriate.

Protocol Approval and Amendment

Before the start of the study, the study protocol and/or other relevant documents will be approved by the IRB/REB or other Competent Regulatory Authorities in accordance with local legal requirements. The Sponsor must ensure that all ethical and legal requirements have been met before the first subject is enrolled in the study.

The protocol is to be followed exactly. To alter the protocol, amendments must be written, receive approval from the appropriate personnel, and receive IRB or other Competent Regulatory Authorities approval prior to implementation, as appropriate. If preliminary or interim review indicates that modification should be made in the experimental design, study parameters, subject selection, etc., these changes will be made after appropriate amendment(s) to this protocol with the mutual approval of the Sponsor and the Investigator. Any protocol change that may significantly affect the safety of study subjects must also be submitted for review and approval by the IRB prior to implementation.

Administrative changes not affecting the subject risk/benefit may be made without the need for a formal amendment. All amendments will be distributed to all protocol recipients, with appropriate instructions.

Termination of the Study

If the Investigator or Sponsor becomes aware of conditions or events that suggest a possible study-related hazard to subjects if the study continues, they may recommend to the Sponsor that the study be terminated after appropriate consultation between the relevant parties. The decision to terminate the study remains with the Sponsor. The study may also be terminated early at the Sponsor's discretion in the absence of such a finding. All enrolled subjects to that point will be notified of the study termination and reassured regarding depersonalization of any accrued specimens.

Conditions that may warrant termination by the Sponsor may include, but are not limited to, the discovery that in the opinion of the Sponsor, the study poses an unexpected, significant, or unacceptable risk to the subjects enrolled in the study. Additionally, a decision on the part of the Sponsor to suspend or discontinue development of the investigational device may be made.

Confidentiality

All study findings and documents will be regarded as confidential. The Investigator and members of his/her staff must not disclose such information without prior written approval from the Sponsor.

The anonymity of participating study subjects must be maintained. Subjects will be identified on eCRFs and other documents submitted to the Sponsor by their subject number, not by name. Documents not to be submitted to the Sponsor that identify the subject (e.g., the signed informed consent) must be maintained in confidence by the Investigator.

Publication

At the conclusion of the study, publication of the primary study outcomes may be prepared for publication in a reputable scientific journal. The publication of the principal results from any single center or other collaborative experience within the study is not allowed until the preparation and publication of the primary study outcomes. Publication of the study results with the assent of the Sponsor and Investigators should not be delayed for more than 12 months after completion of the study.

Site Training

All Investigators and appropriate study staff will be required to participate in an on-site or web-based training (or initiation if appropriate) to provide orientation and training regarding the applicable study-specific procedures, protocol, and eCRFs.

Required Reports

Table 3- Reporting Requirements

Event	Report to	Timing of Report
Study-related AEs/SAEs/UADEs	Sponsor	Within 24 hours of the study site becoming aware of such events
Withdraw of IRB approval	Sponsor	Within 5 working days
Any deviation from the protocol to protect the life or physical well-being of a subject in an emergency situation	Sponsor and IRB	As soon as possible, but in no event later than 5 working days after the emergency occurred
Any study-specific procedure(s) being performed without prior written informed consent being obtained	Sponsor and IRB	Within 5 working days of the study-specific procedure(s) being performed

Product Complaints

Any alleged deficiency related to the identity, quality, purity, durability, reliability, safety, effectiveness, or performance of a Mindset Medical product (IVC Application) shall be reported by the site to the IRB (if required) as soon as possible and to Mindset Medical via email within 3 working days after the deficiency was identified.

The site shall record the following on the product complaint form for each complaint:

- Date of complaint
- Description of the complaint, and
- Any associated adverse event(s), if applicable.

The product, along with associated components/accessories, associated with the complaint shall be returned per Sponsor instructions as soon as possible.

Contact Information

Device Regulatory Approval/Clearance

[redacted]

Per FDA Guidance document, *Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors Significant Risk and Nonsignificant Risk Medical Device Studies*, NSR device studies do not have to have an IDE application approved by FDA. However, an IRB's NSR determination of this study is required.

Table of Common Acronyms

Table of Common Acronyms	
AE	Adverse Event
BPM	Beats per Minute
DMP	Data Management Plan
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
HIPAA	Health Information Portability and Accountability Act
HTTPS	Hypertext Transfer Protocol Secure
HR	Heart Rate
ICH-GCP	International Conference of Harmonization Good Clinical Practice
ITC	Intent to Capture
IVC	Informed Vital Core app
NSR	Non-Significant Risk
PPG	Photoplethysmography

Table of Common Acronyms	
PR	Pulse Rate
RGB	Red, Green, Blue
RMS	Root Mean Square
ROI	Region of Interest
rPPG	Remote Photoplethysmography
RSA encryption	Rivest-Shamir-Adleman encryption
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SMS	Short Message Service
URL	Uniform Resource Locator
UADE	Unanticipated Adverse Device Effect

References

FDA Guidance Document, *Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors Significant Risk and Nonsignificant Risk Medical Device Studies, January 2006*

Informed Vital Core
Clinical Study Instruction Guide:
Pulse Rate

Table of Contents

Informed Vital Core Instructions
IVC-PR-CLINICAL-STUDY
Pulse Rate PRO

1. Introduction

The instruction guide details the equipment used and the steps necessary to conduct the Informed Vital Core Pulse Rate Clinical Study IVC-400-006 comparing pulse rate (PR) measurements using the Informed Vital Core Application (IVC App) and a heart rate (HR) measured by an ECG device.

2. Clinical Study Materials and Equipment

Mindset Medical (Sponsor) will provide the following materials:

- One mobile phone to run the Informed Vital Core Application, equipped with Google Voice phone number, Google Drive, and Gmail address (IVC Mobile Phone)
- Edan SE-301 ECG device with patient cable
- ECG Power Cord
- Spare disposable tab electrodes (one-time use per subject)
- Alcohol wipes
- Thumb drive
- USB-C to USB-A cable
- Make-up removal wipes
- Informed Vital Core PRO (IVC-PR-CLINICAL-STUDY)
- Phone Stand
- Phone Charger

3. Study Environment Requirements

The study environment has the following requirements:

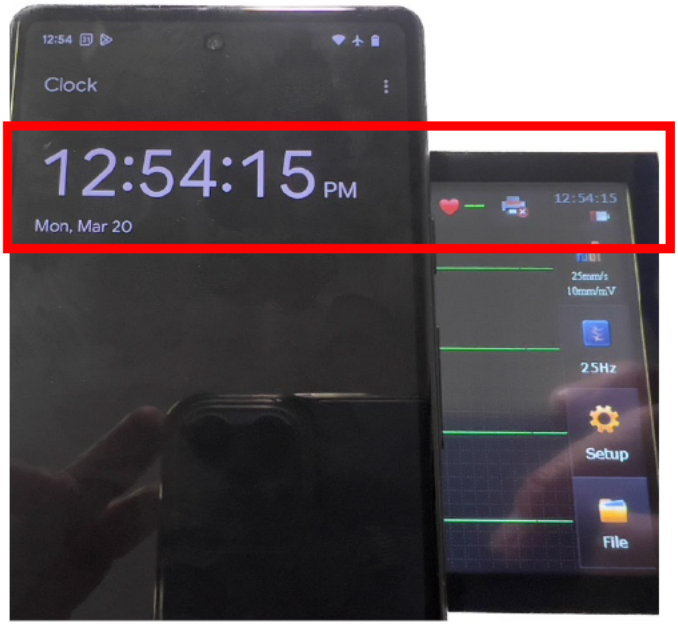
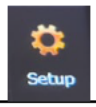
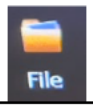
- Quiet room
- Comfortable chair
- Table at normal height (i.e., office desk or kitchen table)
- Wi-fi access
- ***Normal lighting with face being uniformly lit***
    - ***Ensure there are no shadows, dark spots, or bright spots on the subject's face***
    - ***No movement in the background behind the subjects***
    - ***No varied lighting from windows, computer screens, or TV on the subject's face or behind the subject.***

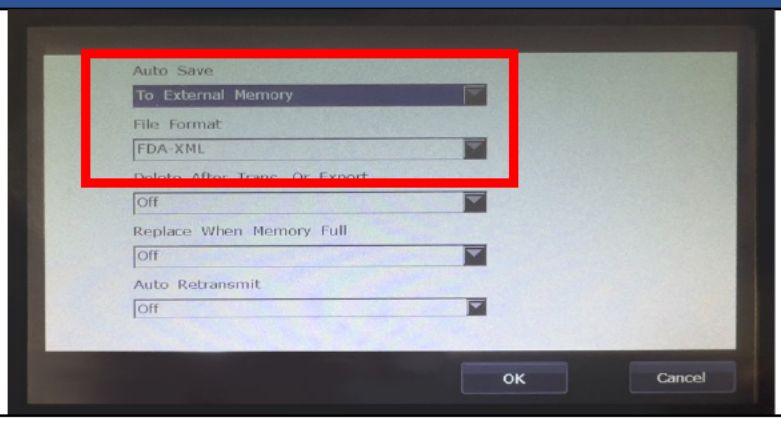
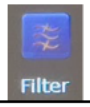
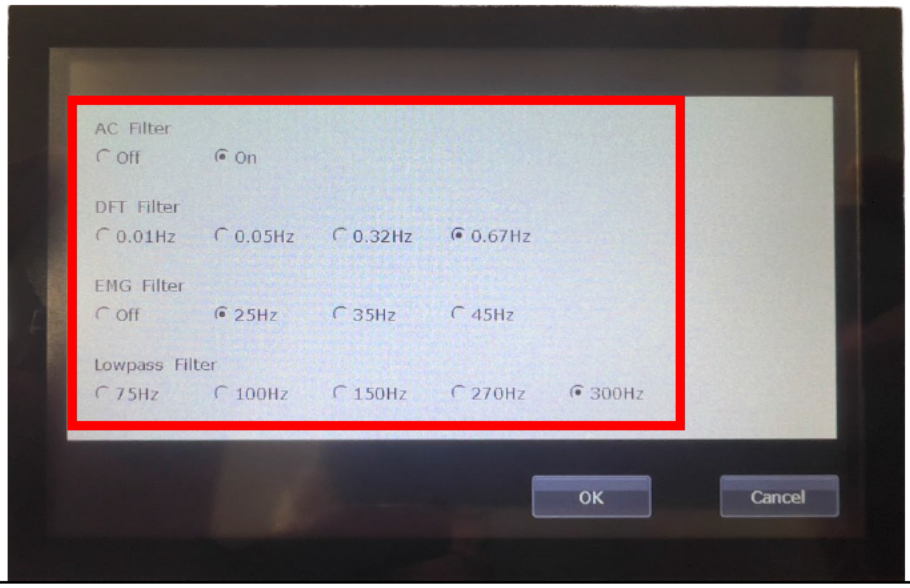
3.1. Warnings

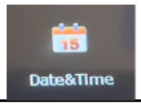
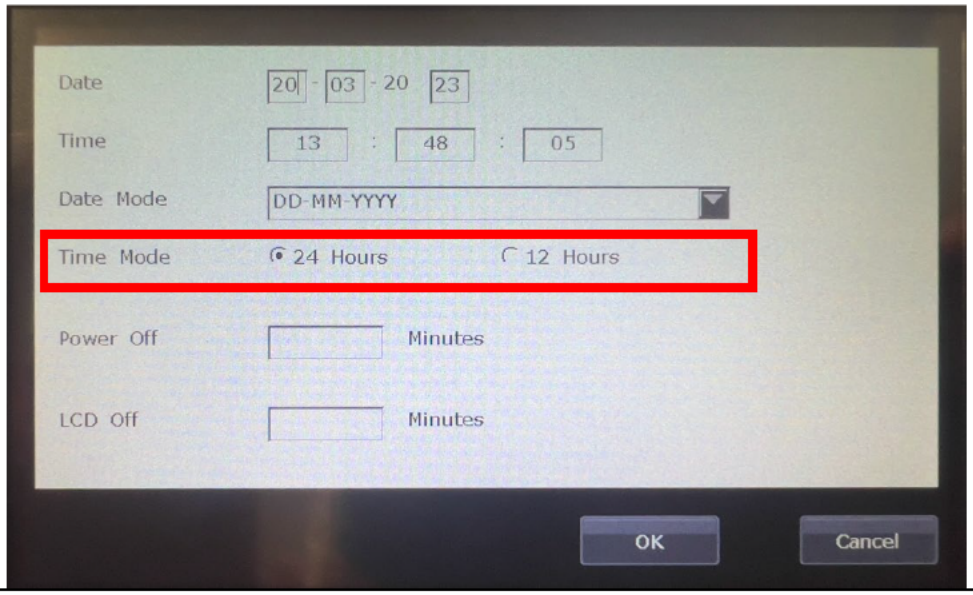
- The subject's face must be well illuminated with no shadows, including shadows cast from eyeglasses on the cheeks, no dark spots or bright spots falling across their face. Ensure the lighting direction is in front of the subject.
- Do not place subjects in front of windows or open spaces that would allow for bright light to shine from behind the subject, lowering the quality of the lighting on the face.
- Subjects should have no movement in background – no TVs, people walking behind, flashing lights or shadows, or moving fans.
- No hats, do-rags, or masks should be worn by the subject. The forehead, cheeks, and chin need to be visible.
- Heavy bangs and hair should be pulled away from the subject's face.
- Ensure the subject does not have any makeup, lotion, sunscreen, etc. on their cheeks, forehead, and chin. Clean, bare skin on the subject's face is required and makeup removal wipes may be used to remove anything on the cheeks, forehead, or chin.
- The subject must remain still during the 60-second measurement session.
    - No talking
    - No movement of the head, mouth, leg, or arms to which ECG electrodes are attached.
- Ensure that the disposable ECG tabs and electrodes are securely adhered to the subject. ***You may need to use medical tape to properly secure the electrodes to the subject and ensure the disposable tabs are not pulling away from the skin.***
    - The disposable tabs are to be used once per subject and then discarded.
    - Excessive hair may need to be shaved away from the subject's skin to ensure adherence with the disposable electrodes.

4. Verify ECG Settings

Step	Task
1.	Power on the ECG device. 
2.	Verify that the patient cable is securely fastened to the ECG device. 
3.	Verify the time settings on the ECG device and the IVC smartphone clock are within 1 second of each other. Tap the **Clock** App on the mobile-phone and compare the times on each device.

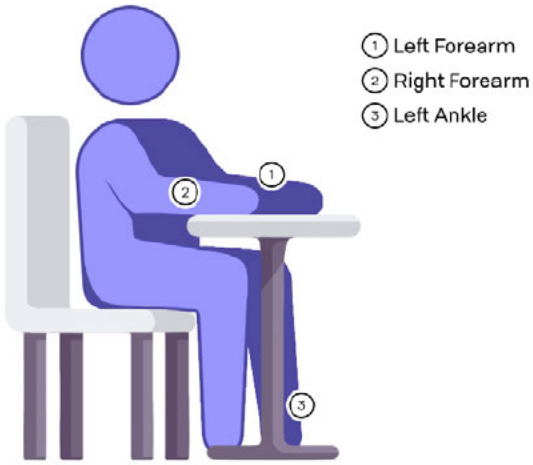
Step	Task
	 ***NOTE: Please see Appendix A for instructions to synchronize clocks.***
4.	Tap the **Setup** icon on the lower right corner of the ECG display. 
5.	Tap the **File** icon. 
6.	Verify that the options for **Auto Save** is set to "To ECG" and **File Format** is set to "FDA-XML".

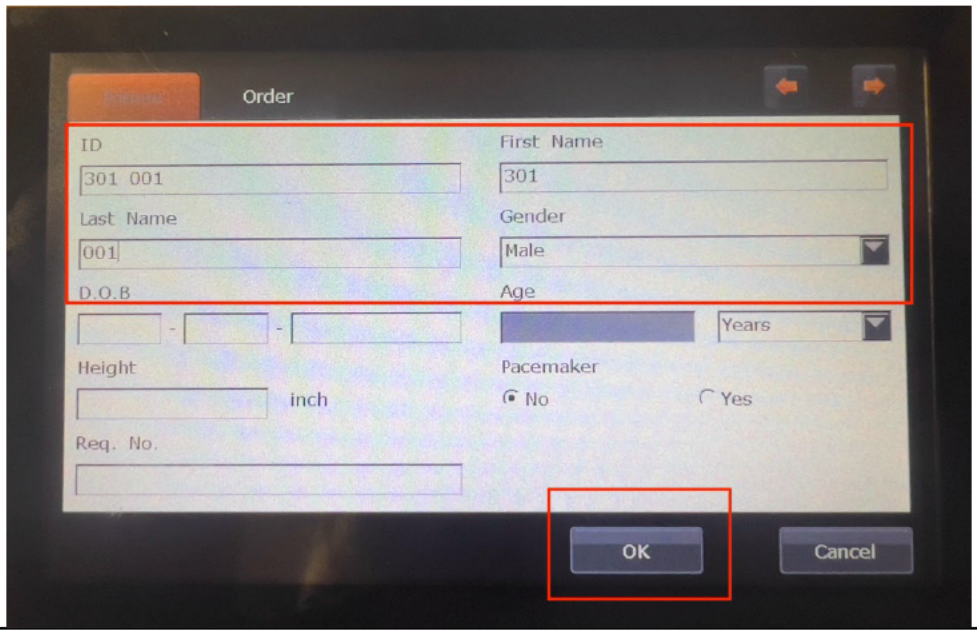
Step	Task
	
7.	Tap **OK** to return to the previous menu.
8.	Tap the **Filter** icon. 
9.	Verify the following settings: • AC Filter = ON • DFT Filer = 0.67 Hz • EMG Filter = 25 Hz • Lowpass Filter = 300 Hz 
10.	Tap **OK** to return to the previous menu.

Step	Task
11.	Tap the **Date & Time** icon. 
12.	Verify that **Time Mode** = 24 hours 

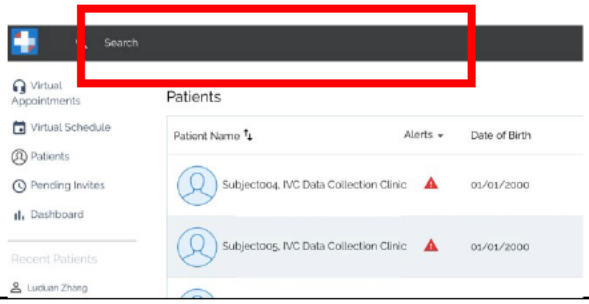
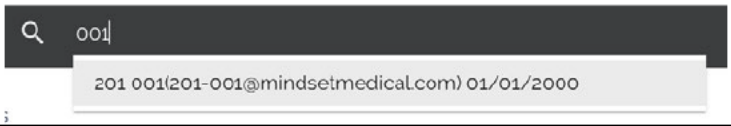
5. ECG Preparation

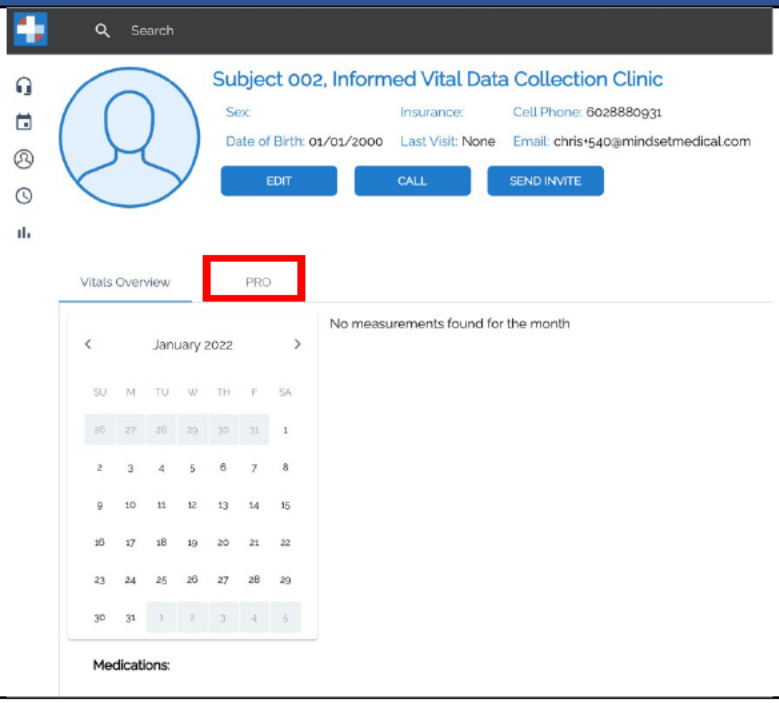
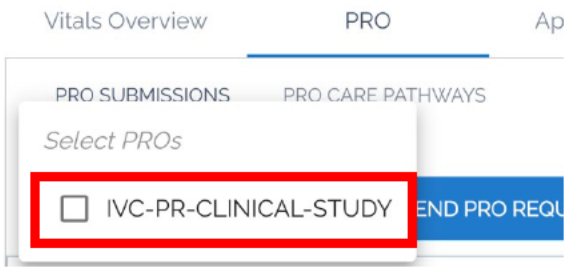
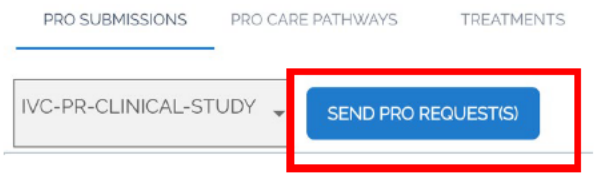
Step	Task
1.	Insert the thumb drive into a USB-A port on the rear of the ECG device. 
2.	The ECG display screen indicates the thumb drive has been inserted. 
3.	Ensure the patient cable is securely connected to the ECG device. 
4.	Make sure the subject is sitting comfortably.
5.	Ensure clothing from the subject does not interfere with electrode placement to both forearms and the left leg, just above the ankle.

Step	Task
6.	Take an alcohol swab and clean both forearms (middle) and the left leg above the ankle. Shave hair from electrode sites, if necessary. Excessive hair prevents a good connection. Dry the skin with a gauze pad to increase capillary blood flow to the tissues and to remove the dead, dry skin cells and oils.
7.	Place a disposable tab electrode on the cleaned forearms and above the left ankle. Fully attach the alligator clips to the electrodes. • **RA white** (inside right arm) • **LA black** (inside left arm) • **LL red** (above the inside left ankle)  Ensure that all alligator clips are completely attached to the respective disposable electrode tab and that all tabs are securely fixed to the respective part of the body. ***NOTE: you can use medical adhesive tape to secure the alligator clips and disposable taps if necessary.***  Right arm alligator clip  Left arm alligator clip

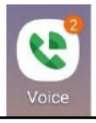
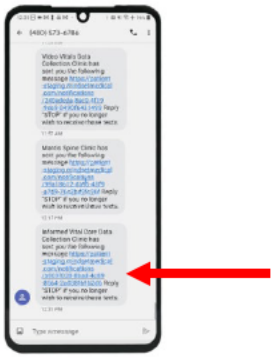
Step	Task
	 Left leg (ankle) alligator clip
8.	Tap on the **patient icon** in the top left corner of the ECG screen. 
9.	Complete the following fields: • ID = Site number- Subject Number (i.e., 301 001). Tap **Enter**. • First Name = Assigned Clinic Number (i.e., 301). Tap **Enter**. • Last Name = Subject Number (i.e., 001). Tap **Enter**. 
10.	Select **Gender** (Male/Female/Unknown).
11.	Tap **OK**.

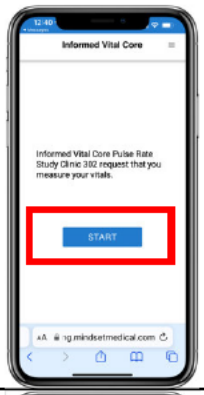
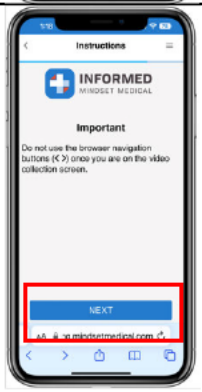
6. Sending the IVC App

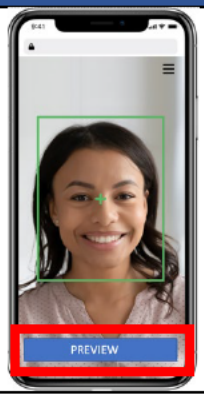
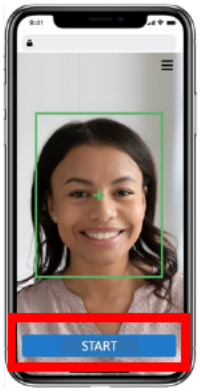
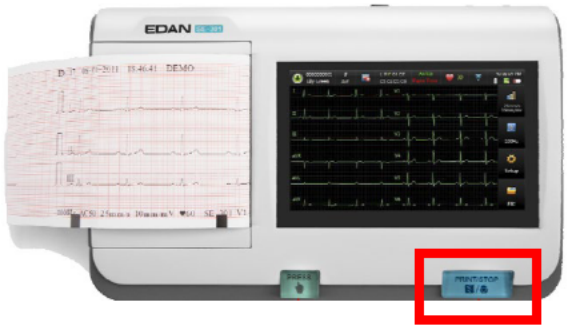
Step	Task
1.	Once the data collection coordinator has logged into the provider portal (https://provider.mindsetmedical.com), begin by selecting the clinic number (i.e., Clinic Name 301, 302, etc.) then select the subject number (e.g., 001, 002, etc.). Enter the Subject number into the **Search** field (i.e., 001). • To assist in the de-identification of patient health information, all subjects will have an email address that ties to the numerical ID in the last name (i.e., site301+001@mindsetmedical.com). • All subjects will be assigned the same phone number that is associated with the Google Voice number programmed into the phone. • All subjects will be assigned a date of birth of 01/01/2000. 
2.	Select the correct subject from the dropdown list. 
3.	Click on the **PRO** tab in the Informed Vital Core Data Collection Clinical Provider Portal.

Step	Task
	
4.	From the **Select PROs** drop down menu, select **IVC-PR-CLINICAL-STUDY**. 
5.	Click the **Send PRO Request(s)** button to send the **IVC-PR-CLINICAL-STUDY** to the mobile phone. The message will be sent to the Google Voice Messaging App on the Mobile Device. 

7. Preparing the IVC App for PR Measurement

Step	Task
1.	Ensure the subject has been sitting comfortably for 5 minutes, positioned behind a table of normal height with their back pressed against the seat rest, their feet flat on the floor, legs uncrossed, and their face uniformly lit with the light in front of the subject.
2.	Tap on the Google Voice App on the mobile phone. 
3.	Tap the link contained in the SMS Message.  ***Note: the text message may take a few minutes to be sent from the system to the phone.***
4.	When the Chrome mobile web browser is opened, tap and enter 01/01/2000 into the **DOB confirmation** field.  Tap the **Continue** button.
5.	Tap the **Start** button.

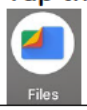
Step	Task
	
6.	 Tap the **Next** button.
7.	Make sure the subject is still and tap the **PREVIEW** button to capture an image of the subject. • Subject should remain still – no talking, head movement, fidgeting • Subject's face should be well lit with lighting in front • No movement behind the subject, TV screens, ceiling fans, or people walking • Minimize shadows including ones cast from eyeglasses on the cheeks • No hats, do-rags, masks, the forehead, cheeks, and chin need to be visible • Heavy bangs and hair should be pulled away from the face

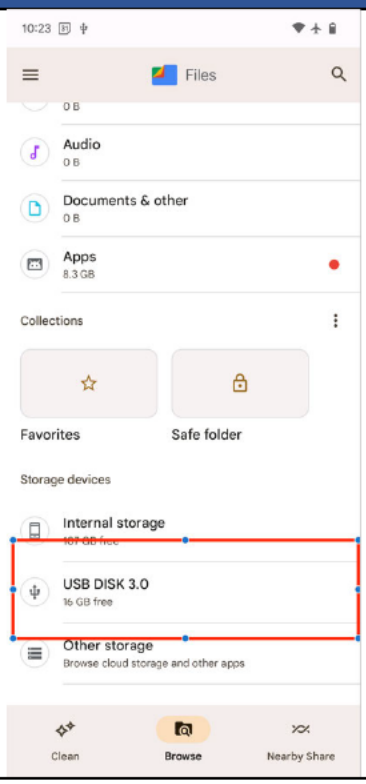
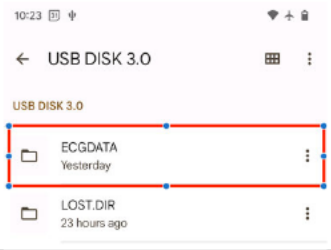
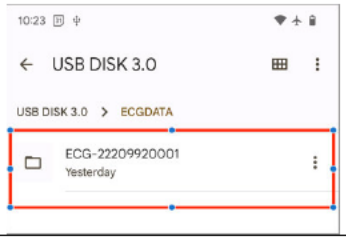
Step	Task
	
8.	Verify that the electrodes on the subject are still in place and securely attached with both arms resting on the table. Verify that the IVC App is displayed and the phone is placed in the phone stand and in front of the subject. Press the **START** button on the IVC App and the **PRINT/START** button on the ECG at the exact same time.   ***NOTE: It is important that both buttons are pressed at the same time. If they aren't, stop the session by closing the browser on the phone and stopping the ECG device, and restart (close the browser tab and return to step 2).***
9.	**AUTO Sampling** is displayed on the ECG screen while the ECG is measuring the subject's heart rate. 
10.	When the IVC App measurement session is complete, a pulse rate measurement is displayed.

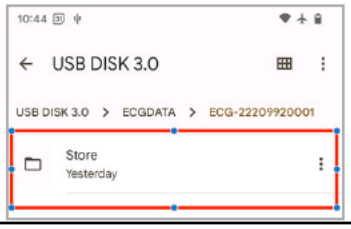
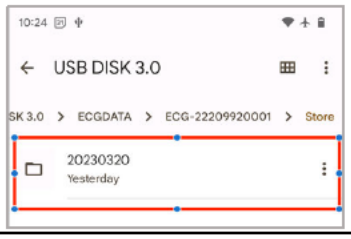
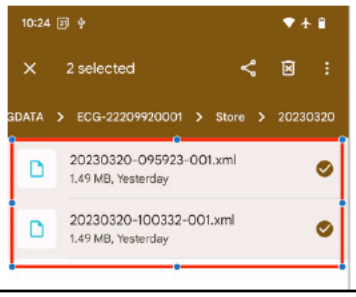
Step	Task
	 Record the subjects pulse rate in the EDC and then tap the **SUBMIT RESULTS** button.
11.	When the ECG session is complete and is being saved to the thumb drive automatically, the ECG display will show **AUTO Analyzing** and then **AUTO Sampling**. Do not remove the thumb drive while the ECG data is being saved. 
12.	Return to Section 6 (**Sending the IVC App)** and repeat Steps 4 and 5 to prepare for the second pulse rate measurement.
13.	Return to the top of Section 7 (**Preparing the IVC App for PR Measurement**) and repeat Steps 2 – 10 to capture the second IVC PR and the ECG HR.
14.	Proceed to Section 8 (**Uploading the ECG Data from the Thumb Drive**) to upload the ECG data from the thumb drive.

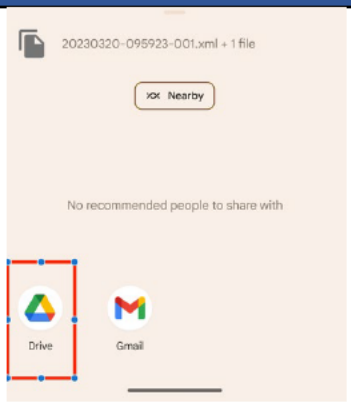
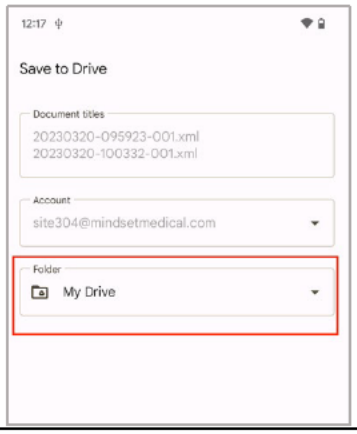
8. Uploading the ECG Data from the Thumb Drive

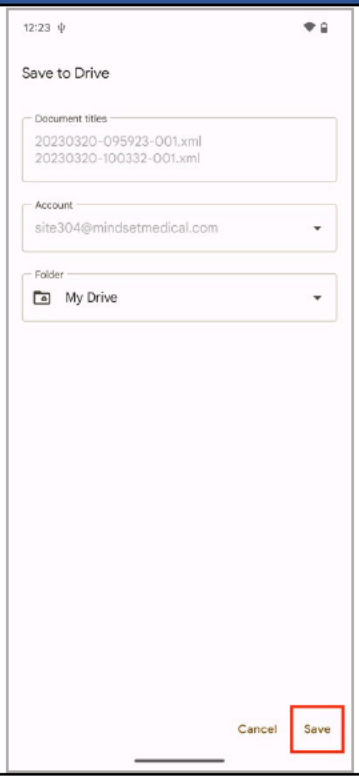
Step	Task
1.	Remove the thumb drive from the back of the ECG machine and insert the USB-A to USB-C adapter (USB-A side).
2.	Insert the USB-C side of the USB-A to USB-C adapter into the mobile phone.

Step	Task
	 USB-A to USB-C Adapter  The thumb drive will flash red when inserted correctly.
3.	Tap the **Files** icon on the mobile phone. 
4.	Scroll down and tap on **USB DISK 3.0** (site number will correspond to clinical site number).

Step	Task
	
5.	Tap on **ECCGDATA**. 
6.	Tap on ECG-XXXXXXXXX (The Xs represent the serial number of the ECG device). 
7.	Tap **Store.**

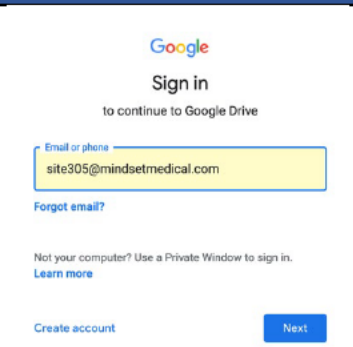
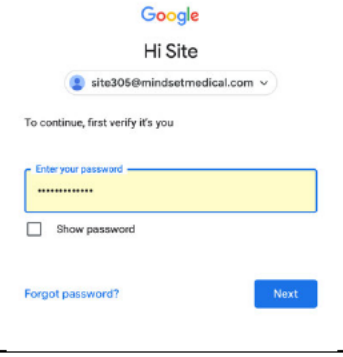
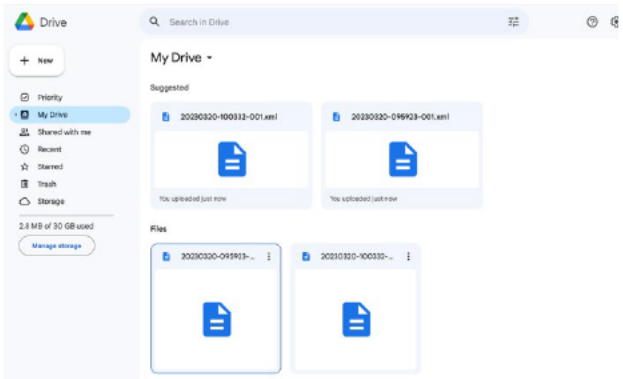
Step	Task
	
8.	Tap the folder with the current date in **YYYYMMDD** format (i.e., 20230320). 
9.	Long press the .xml file(s) to upload. Repeat this step for both files. 
10.	Tap the **share** icon. 
11.	Tap the **Google Drive** icon.

Step	Task
	
12.	Verify that the **Folder** location shows the **My Drive** folder. 
13.	Tap **Save**.

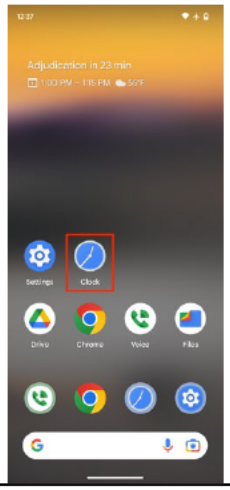
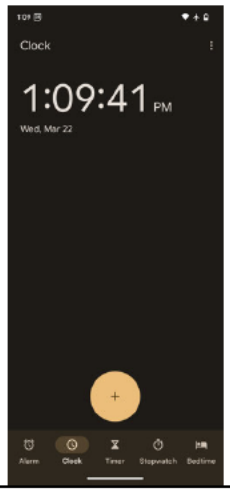
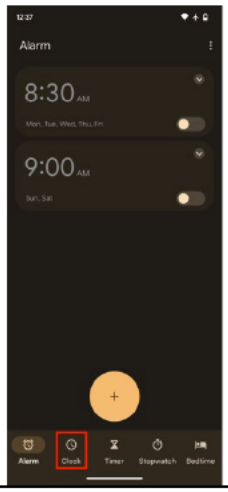
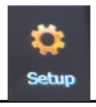
Step	Task
	

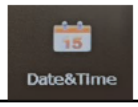
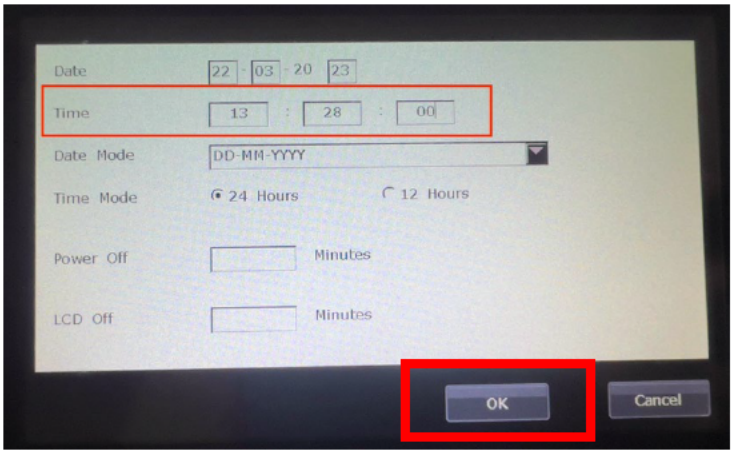
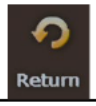
9. Verify XML Files are in Google Drive

Step	Task
1.	In a web-browser on your laptop, go to https://drive.google.com.
2.	Click on the G-Suite account associated with your clinical site (i.e., 301, 302).

Step	Task
	
3.	Enter the password. 
4.	Verify that the xml files were uploaded. 

Appendix A – Clock Synchronization between ECG and IVC App Mobile Phone

Step	Task
1.	Power on the ECG device and the IVC App mobile-phone.
2.	On the IVC App mobile-phone, tap on the **Clock** icon. 
3.	Current time is displayed (if not, tap on the **Clock** icon in the bottom left side)  
4.	On the ECG device, tap the Settings icon. 
5.	Tap the **Date & Time** icon.

Step	Task
	
10.	In the Time field, enter a time several minutes into the future, with the seconds spot completed with "00". ***Please note: Time mode should be set to 24 hours.***  Tap OK when the time on the mobile phone matches the time entered.
11.	Tap the **Return** icon to return to the main ECG screen. 

Visit

Visit Name:

Visit Date:

Informed Consent

Informed Consent date:

Protocol Version Date: Please Select

Demographics

Date of Birth:

Age: year(s)

Sex: ☐ Female ☐ Male

Ethnicity:
☐ Not Hispanic or Latino
☐ Hispanic or Latino
☐ Unknown

Race (check all that apply):
☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander
☐ White
☐ Other

Other Specify:

Visit	
Visit Name:	
Visit Date:	

Inclusion/Exclusion	
Did the subject meet all the inclusion and none of the exclusion criteria?	☐ Yes ☐ No
Inclusion Criteria	
Subjects 22 - 85 years of age:	☐ Yes ☐ No
Subjects willing to sign the Informed Consent Form and comply with the protocol:	☐ Yes ☐ No
Exclusion Criteria	
Subjects required to wear mask or bandage that obstructs forehead, cheeks, or chin:	☐ Yes ☐ No
Refusal to remove makeup, sunscreen, lotion, clothing, or items obstructing the face for the duration of readings:	☐ Yes ☐ No
Presence of facial tattoos, large birthmarks, or other skin alterations (scars, hemangiomas, vitiligo) on upper cheeks (cheekbone) or forehead of the subject:	☐ Yes ☐ No
Condition that does not allow the subject to remain still for 60 seconds at a time:	☐ Yes ☐ No
Subjects with cardiac arrhythmia:	☐ Yes ☐ No
Any known medical condition which may result in an inaccurate measurement usingthe reference device:	☐ Yes ☐ No
Subjects with the inability to complete an ECG:	☐ Yes ☐ No

Visit

Visit Name:

Visit Date:

Fitzpatrick Scale Assignment

Skin Type:

- ☐ 1 - Pale White Skin
- ☐ 2 - White Skin
- ☐ 3 - Light Brown Skin
- ☐ 4 - Moderate Brown Skin
- ☐ 5 - Dark Brown Skin
- ☐ 6 - Deeply Pigmented Dark Brown to Black Skin

Physical Traits

Is the subject wearing Glasses? ☐ Yes ☐ No

Does the subject have facial hair? ☐ Yes ☐ No

Visit

Visit Name:	
Visit Date:	

Cardiac Medical History

Coronary Artery Disease?	☐ Yes ☐ No
Congestive Heart Failure:	☐ Yes ☐ No
Peripheral Arterial Disease:	☐ Yes ☐ No
ESRD (End-Stage Renal Disease):	☐ Yes ☐ No
Hemodialysis:	☐ Yes ☐ No
Diabetes:	☐ Yes ☐ No
HTN (Hypertension):	☐ Yes ☐ No
History of Myocardial Infraction:	☐ Yes ☐ No
Valvular Heart Disease:	☐ Yes ☐ No
Cardiac Pacemaker:	☐ Yes ☐ No
Pulmonary Embolism:	☐ Yes ☐ No
Metastatic Cancer:	☐ Yes ☐ No
Peripheral Vascular Disease:	☐ Yes ☐ No
COPD (Chronic Obstructive Pulmonary Disease):	☐ Yes ☐ No
Emphysema:	☐ Yes ☐ No
History of DVT (Deep Vein Thrombosis):	☐ Yes ☐ No
Other Heart disease:	☐ Yes ☐ No
Specify:	

Visit

Visit Name:	
Visit Date:	

Medical History

Any chronic conditions?	☐ Yes ☐ No
Diagnosis:	
Start Date:	
Ongoing:	☐ Yes ☐ No
End Date:	
Diagnosis:	
Start Date:	
Ongoing:	☐ Yes ☐ No
End Date:	
Diagnosis:	
Start Date:	
Ongoing:	☐ Yes ☐ No
End Date:	
Diagnosis:	
Start Date:	
Ongoing:	☐ Yes ☐ No
End Date:	

Diagnosis:	
Start Date:	
Ongoing:	☐ Yes ☐ No
End Date:	
Diagnosis:	
Start Date:	
Ongoing:	☐ Yes ☐ No
End Date:	
Diagnosis:	
Start Date:	
Ongoing:	☐ Yes ☐ No
End Date:	
Diagnosis:	
Start Date:	
Ongoing:	☐ Yes ☐ No
End Date:	
Diagnosis:	
Start Date:	

Ongoing:	☐ Yes ☐ No
End Date:	
Diagnosis:	
Start Date:	
Ongoing:	☐ Yes ☐ No
End Date:	

Visit

Visit Name:

Visit Date:

Pulse Rate

Informed Vital Core Pulse Rate 1

Was pulse rate taken by IVC? ☐ Yes ☐ No

Reason Not Done:

Date Performed:

Informed Vital Core Pulse Rate 1: *bpm*

Informed Vital Core Pulse Rate 2

Was pulse rate taken by IVC? ☐ Yes ☐ No

Reason Not Done:

Date Performed:

Informed Vital Core Pulse Rate 2: *bpm*

Visit

Visit Name:	
Visit Date:	

Electrocardiogram

ECG 1

Was ECG performed?	☐ Yes ☐ No
Reason Not Performed:	
Date Performed:	
Have you uploaded the ECG Strip?	☐ Yes ☐ No
Reason ECG Not Uploaded:	

ECG 2

Was ECG performed?	☐ Yes ☐ No
Reason Not Performed:	
Date Performed:	
Have you uploaded the ECG Strip?	☐ Yes ☐ No
Reason ECG Not Uploaded:	

Visit

Visit Name:

Visit Date:

Electrocardiogram

ECG 1

Was Rhythm strip received? ☐ Yes ☐ No

Date Analyzed:

☐ Not able to Analyze

Reason not able to Analyze:

ECG Pulse Rate: *bpm*

ECG 2

Was Rhythm strip received? ☐ Yes ☐ No

Date Analyzed:

☐ Not able to Analyze

Reason not able to Analyze:

ECG Pulse Rate: *bpm*

Adverse Events

Adverse Event:	
Start Date:	
Ongoing?	☐ Yes ☐ No
End Date:	
Severity:	Please Select
Serious:	☐ Yes ☐ No

Serious Adverse Event

Life threatening:	☐ Yes ☐ No
Significant Disability:	☐ Yes ☐ No
Hospitalization:	☐ Yes ☐ No
Date of Admission:	
Date of Discharge:	
Congenital Anomaly or Birth Defect:	☐ Yes ☐ No
Other Medically Important Event:	☐ Yes ☐ No
Death:	☐ Yes ☐ No
Date of Death:	
Relationship to Study Procedure:	Please Select
Action Taken with Study Procedure:	Please Select
Other Action Taken:	
Any Unanticipated Adverse Device Effect:	☐ Yes ☐ No
Outcome:	Please Select
Caused Study Discontinuation:	☐ Yes ☐ No

Concomitant Medication

Medication:	Please Select
Other Medication Specify:	
Indication:	Please Select
Indication Specify:	
Start Date:	
End Date:	
Ongoing:	☐ Yes ☐ No
Dose:	
Dose Unit:	Please Select
Frequency:	Please Select
Route:	Please Select

Technical Fallback

How many technical fall backs were performed?	Please Select
Technical Fallback session 1	
Technical Fallback Session 1 Reason:	Please Select
Date of Fallback Session:	
Specify, Details 1:	
Technical Fallback session 2	
Technical Fallback Session 2 Reason:	Please Select
Date of Fallback Session:	
Specify, Details 2:	
Technical Fallback session 3	
Technical Fallback Session 3 Reason:	Please Select
Date of Fallback Session:	
Specify, Details 3:	

Device Failure

Date of Failure:	
Time of Failure:	
Notes:	

Protocol Deviation

Date of Deviation:	
Type of Deviation:	Please Select
Other, Specify:	
Brief Description of Deviation:	

End of Study

Completion or Discontinuation Date:	
Status:	Please Select
Comments:	

Investigator Signature

I have reviewed the case report form pages and confirm that, to the best of my knowledge, they accurately reflect the study information obtained for this subject.

Investigator's Signature:	
Date of Signature:	
Time of Signature:	

ADVARRA™

About Advarra's IRB Roster/ Membership List

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- No fewer than 5 voting members and no more than 9 voting members
- At least 1 scientific member for meetings reviewing US based research, and 2 scientific members for meetings reviewing Canadian research
- At least 1 non-scientific member
- Both men and women
- At least 1 person who is not otherwise affiliated with Advarra
    - These individuals may be referred to as "unaffiliated" or "community" members
    - These members are identified in the list below with the letter "N" in the "Affiliated?" column

Additional Information about IRB Review of Canadian Research

In addition to the requirements above, meetings where Canadian research is reviewed will include:

- At least 1 member knowledgeable in ethics
- At least 1 member knowledgeable in Canadian laws relevant to the biomedical research to be approved

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- Advarra's voluntary Federal wide Assurance (FWA) has been approved by OHRP.
    - IRB Organization (IORG) Number: 0000635
    - FWA Number: 00023875
    - IRB Registration Number: 00000971
- Advarra is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP)

Name	Credentials	Role	Primary Expertise	Affiliated?	Chair?	Reviews CAN Research?	CAN: Knowledgeable in ethics and/or law?
Altier, Sarah	EdD	Non-Scientist	Educator	N		N	
Ambrosini, Daniel	BA, LLB, MSc, PhD	Other Scientist	Psychiatry/ Legal	N		Y	Ethics, Law
Aramburu Alegria, Christine	PhD, RN	Other Scientist	Nursing/ Social Psychology/ Transgender Issues	N		N	

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Astein, Diego	MD	Physician Scientist	Radiology	Y	Chair	Y	Ethics
Baird, Kristin	MD	Physician Scientist	Oncology/ Pediatrician/ Hematology	N		N	
Benedict, Wendy	BA	Non-Scientist	Social Worker	N		N	
Bergstrom, Steven	MD	Physician Scientist	Oncology/ Pediatrician/ Hematology	N		N	
Berlin, Suzanne	DO	Physician Scientist	Oncology/ Women's Cancers	N		N	
Bernstein, Erica	PharmD, BCPS	Other Scientist	Pharmacology	N		N	
Berry, Donna	PhD, RN, AOCN, FAAN	Other Scientist	Nursing/ Oncology	N		N	
Block, Michelle	MS, BS, RAC, CIP	Non-Scientist	Regulatory/DoD Regulated Research	Y		Y	
Blum, Robert	PharmD	Other Scientist	Pharmacology	N	Chair	N	
Booker, Burthia	PhD	Other Scientist	Biomedical Sciences	N		N	
Borgatta, Lynn	MD, MPH	Physician Scientist	Obstetrics/ Gynecology	N		Y	
Bottorff, Michael	PharmD	Other Scientist	Pharmacology	N		N	
Braun, Peter	MD	Physician Scientist	Internal Medicine/ Infectious Disease	N		N	
Brock, Jennifer	RN	Other Scientist	Nursing/ Oncology	N		N	
Brown, Janice	RPh, MLS	Non-Scientist	Educator/ Librarian	N		N	
Brzozowski, Jane	MS, BS	Non-Scientist	Patient Advocacy	N		N	
Burkey, Madison	BSN, RN, OCN	Other Scientist	Nursing/ Oncology	Y		Y	
Byers, Derek	MD, PhD, FCCP	Physician Scientist	Internal Medicine/ Immunology	N		N	
Campbell, Laura	MD	Physician Scientist	Oncology/ Hematology/ Pediatrics/ Bioethics	N		N	
Carr, Raymond	RPh	Other Scientist	Pharmacist	N		N	
Casabar, Ed	PharmD, BCPS, AQ-ID	Other Scientist	Pharmacology	N		N	

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Cavagnaro, Joy	PhD, DABT, RAC	Other Scientist	Toxicology/ Regulatory Affairs Consultant	N		N	
Chukwu, Bernadette	PharmD	Other Scientist	Pharmacovigilance/ Drug Safety	Y		N	
Cooper, Kindra	JD	Non-Scientist	Legal	N		N	
Cooper, Phyllis	RN, BSN, OCN, CCRP	Other Scientist	Nursing/ Oncology	N		N	
Cosentino, Lidia	PhD	Other Scientist	Biology/ Protocol development	N		Y	
Cram, Gary	AS	Non-Scientist	Ethics	N		N	
Cullity, Connie	MD, MPH	Physician Scientist	FDA Regulations	Y		N	
Cummings, Theresa	RN, MS	Other Scientist	Nursing/ Public Health	N		N	
Davidson, Barbara	MS, RN, MSN, CCRC	Other Scientist	Community Health Nursing	Y		Y	
Davidson, Susan	MD	Physician Scientist	Infectious Disease/ Homeostasis	N		N	
Davis, Hannah	BS, MS	Other Scientist	Biology / Biomedical	Y		N	
Desai, Pankaj	PhD	Other Scientist	Biopharmaceutics/ Pharmacokinetics	N		N	
Dorsch, Kimberly	BS	Other Scientist	Stem Cell/ Tissue Research	N		N	
Drada, Denisse		Non-Scientist	Regulatory	Y		Y	
Duhon, Bryson	PharmD, BCPS	Other Scientist	Pharmacology	N		N	
Dyson, Maynard	MD, MA, CIP	Physician Scientist	Pediatrician/ Pulmonology	N		N	
Ebert, Susan	MS, CIP	Non-Scientist	Regulatory	Y	Sr. Chair Dir.	N	
Fernicola, Daniel	MD, FACC	Physician Scientist	Cardiology	N		N	
Ferrell, David	ThB, BA, MA	Non-Scientist	Religion / Ethics	N		Y	Ethics
Fittizzi, Cheryl	RN, CIM, CIP	Other Scientist	Nursing/ Emergency Trauma/ Public Health	N		N	
Fitzgerald, Michael	PhD	Other Scientist	Social Psychology	N		N	

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Fleck, David	PhD	Other Scientist	Psychiatry/ Behavioral Neuroscience	N		N	
Flowers, Janelle	MEd	Non-Scientist	Guidance Counselor	N		N	
Foster, Joyce	MS	Non-Scientist	Family Therapy	N		N	
Garrick, Tania	RN, BScN, MA	Other Scientist	Nursing	N		Y	
Gelinas, Luke	PhD, MAR, AB	Non-Scientist	Ethics	Y	Sr. Chair Dir.	Y	Ethics
Georgiadis, Nina	MD	Physician Scientist	Neonatal Intensive Care	N		Y	
Gill, Cyrus	RN, MS, CCRA	Other Scientist	Nursing/ Phase I	N		N	
Ginnings, Susan	RPh	Other Scientist	Pharmacist	N		N	
Gold, Herschel	BA, LLB	Non-scientist	Legal	N		Y	Ethics, Law
Goldman, Ran	MD, MHA, FRCPC	Physician Scientist	Pediatrician	N	Chair	Y	Ethics
Gonzales, Yury	MD, FACP	Physician Scientist	Internal Medicine	N		Y	
Gordner, Linda	BA	Non-Scientist	Special Education	N		Y	
Gottke, Melissa	BA	Non-Scientist	Regulatory	Y		Y	
Gray, Vernon	PhD	Non-Scientist	County Government Administrator	N		N	
Grimes, Brittany	MS	Non-Scientist	Regulatory	Y		Y	
Groisman, Iris	PhD	Other Scientist	Biochemistry/ Radiobiology/ Pharmacogenetics	N		Y	Ethics
Group, Melinda	BS, RPh	Other Scientist	Pharmacist/ Hospital Research	N		N	
Groza, Florina	MSc	Other Scientist	Biochemistry	Y		Y	
Haffizulla, Farzanna	MD, FACP, FAMWA	Physician Scientist	Internal Medicine	N		N	
Hensler, Carolyn	BS	Non-Scientist	Regulatory	N		N	
Henson, Tricia	BA, RN	Other Scientist	Nursing Sciences	Y		Y	
Hewes, Julia	MPH, BSN, RN, OCN	Other Scientist	Nursing/ Oncology	N		N	

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Hierholzer, Robert	MD	Physician Scientist	Psychiatrist	N		N	
Higley, Amanda	PhD, CIP	Other Scientist	Psychology	Y	Chair	N	
Hill, Margaret	RN, MS	Other Scientist	Nursing/ Oncology/ Clinical Trials Research	N		N	
Hiller, David	BSN, RN, AEMT, CIP	Other Scientist	Regulatory Critical Care Nursing	Y	Chair	N	
Horton, Alicia	JD, MPH	Non-Scientist	Legal/ Public Health	N		N	
Hoshower, Jason	BS, CIP	Non-Scientist	Regulatory	Y		Y	
Houser, Patricia	MD	Physician Scientist	Family Medicine	N		N	
Hsiao, Karin	BS, MS, MBA	Other Scientist	Biomedical Engineering/ Device	N		N	
Jacobsen, Eric	MD	Physician Scientist	Oncology/ Lymphoma	N		N	
Johnson, Dena	BS, MEd, CCRP, CIP	Non-Scientist	Regulatory	Y	Chair	N	
Jordan, William	DO	Physician Scientist	Oncology/ Medical	N		N	
Kaul, Neha	MA, MS, BSc	Other Scientist	Social and Behavioral Research; Regulatory; Bioethics/Ethics; Molecular Biology	Y		N	
Keely, Levering	BSN, MPA	Other Scientist	Nursing/ Device specialist	N		N	
Kim, James	MD, MBA	Physician Scientist	General Practice/ Non-Cancer Pain Management	N		Y	
Kirk, Julia	BA, CIP	Non-Scientist	Regulatory	Y		Y	
Klaff, Ali	BSCIP	Non-Scientist	Regulatory	Y		Y	
Knopman, David	MD	Physician Scientist	Alzheimer/ Neurology	N		N	
Kopec, Frederick	JD	Non-Scientist	Legal	N	Chair	N	
Kronish, Daniel	MD	Physician Scientist	Oncology/ Pediatrician	Y	Chair	Y	

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Kuebler, Philip	MD, PhD, BS	Physician Scientist	Internal Medicine/ Oncology/ Hematology	N		N	
Kuzmanovic, Dario	BA, MHSc, CRA, CHRC	Non-Scientist	Bioethics	N		Y	Ethics, Law
Kysela, Kathleen	CIP	Non-Scientist	Regulatory	Y		Y	
LaCount, Peter	MHS, MEd	Non-Scientist	Compliance Director	N		N	
Lawrence, Janice	PhD, MA, BA, BPE	Other Scientist	Physical Ed/ Life Coach	N		Y	
Leduc, Lucie	LLM	Non-Scientist	Legal/ Ethics	N		Y	Ethics, Law
Leo, Jessica	AA, CIP	Non-Scientist	Regulatory	Y		Y	
Letko, Erik	MD	Physician Scientist	Ophthalmology/ Surgery	N		N	
Lettman, Robert	BA, MBA, JD, PA	Non-Scientist	Legal	N		N	
Lind, Alecia	BS, CIP	Non-Scientist	Regulatory	Y		Y	
Longstaff, Holly	PhD	Non-Scientist	Ethics	N		Y	Ethics
Lopez, Bennie	MBA	Non-Scientist	Educator	N		N	
Lossada, Mery	MD, PA	Physician Scientist	Psychiatry/ Neurology	N		N	
Maloof, Damiana	MSN, RN, OCN	Other Scientist	Nursing/ Oncology	N		N	
Martin, Christopher	PharmD, MS	Other Scientist	Pharmacology	N	Chair	N	
McPhillips, Joseph	PhD	Other Scientist	Clinical Research Consultant	N		N	
Mensah, Sharon	MS	Other Scientist	Biological Sciences/ Clinical Research	N		N	
Mihalov, Linda	MD, FACOG	Physician Scientist	Oncology/ Gynecology	N		N	
Mitchell, Cameron	BA	Non-Scientist	Regulatory	Y		Y	
Morse, Linda	RN, MSN, OCN	Other Scientist	Nursing/ Oncology	N		N	
Mueller, Lava	MEd, MDiv	Non-scientist	Chaplain	N		N	
Munk, Gary	PhD, MS, BS	Other Scientist	Virology/ Biosafety	N		N	
Nattrass, Susan	OC, PhD, CBDT	Other Scientist	Osteoporosis and Women's Health	N		Y	
Neff, Robert	BS	Non-Scientist	Mobile Medical	N		N	
Nolan, Joseph	PhD, MS, MA, BA, BS	Other Scientist	Statistics	N		N	

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Noss, Michael	MD	Physician Scientist	Family Medicine	N		N	
O'Connell, Mary		Non-Scientist	Regulatory	N		N	
Odor, Erin	MA, CIP	Non-Scientist	Regulatory	Y	Chair	N	
O'Leary, Maura	MD	Physician Scientist	Oncology/ Pediatrician/ Hematology	N		N	
Oliver, Ayesha	BS	Non-Scientist	Regulatory	Y		Y	
Ott, Carl	MD, MPH	Physician Scientist	Internal Medicine	N		N	
Parker, R. Lamar	MD, FACOG, CPI	Physician Scientist	Obstetrics/ Gynecology	N		N	
Patrick, Kyle	DO	Physician Scientist	Medical Research	N		N	
Pettey, Cheri	MA, BA	Non-Scientist	Bioethics/ Philosophy	Y	Chair	N	
Pfeiffer, Matthew	PhD	Other Scientist	Pharmacology/ Toxicology	N		N	
Popovici-Toma, Dan	MD	Physician Scientist	Medical Advisor	N		Y	Ethics
Povar, Gail	MD, MPH, FACP	Physician Scientist	Internal Medicine	N	Chair	N	
Psenicka, Eva	BSc	Non-Scientist	Physiology/ Regulatory	N		Y	
Ramjiawan, Bram	PhD	Other Scientist	Pharmacology	N		Y	
Randolph, Robert	DMin	Non-Scientist	Chaplain	N		N	
Razzetti, Albert	MD	Physician Scientist	Internal Medicine/ Pulmonology	N		N	
Reddish, Mitchell	PhD	Non-Scientist	Professor/ Religious Studies/ Ethicist	N		N	
Renner, Laura	BA	Non-Scientist	Regulatory	Y		N	
Rewers, Mae, Edna	MS, JD, MBA	Non-Scientist	Legal/ Healthcare/ Research Compliance	N		N	
Reynolds, Deborah	RN, OCN	Other Scientist	Nursing/ Oncology	N		N	
Robinson, Deana	MPH, BS, LPN, CPhT	Other Scientist	Clinical Research LPN	Y		Y	

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Robinson, Richard	MD	Physician Scientist	Medical Oncology/ Internal Medicine	N		N	
Romain, Michael	MD	Physician Scientist	Internal Medicine	N		N	
Romanchuk, Robert	BSHS, CIP, CCRCP	Other Scientist	Clinical Research Administration/ Respiratory Therapy	N		Y	
Rush, Jason	BS, CIP	Non-Scientist	Regulatory	Y		N	
Ruwart, Mary	PhD, BS	Other Scientist	Biophysics/ Biochemistry	N		N	
Ryan, Laurajo	PharmD, MSc, BCPS	Other Scientist	Pharmacology	N		N	
Sadorra, Carol	PhD	Non-Scientist	Regulatory	Y		Y	
Salama, Suzette	BPharm, MSc, PhD	Other Scientist	Ethicist/ Pharmacology	N		Y	Ethics, Law
Saylor, Brenda	RN, BSN, ARM	Other Scientist	Community Health Nursing	Y		Y	
Selsky, Clifford	PhD, MD	Physician Scientist	Pediatrics, Hematology Oncology	N		N	
Sever, John	MD, PhD	Physician Scientist	Pediatrician/ Infectious Diseases	N		N	
Shachar, Carmel	JD, MPH	Non-Scientist	Legal	N		N	
Shafer, Michaela	PhD, RN	Other Scientist	Biomedical Research/ Nursing	N		N	
Sheedy, Carmen	BA	Non-Scientist	Regulatory	Y		Y	
Shulman, Mitchell	MDCM, FRCPC, CSPQ	Physician Scientist	Emergency Medicine	N		Y	
Siegmann, Glenn	MS, RPh	Other Scientist	Pharmacist	N		N	
Singh, Sukhbir	MD, MBA	Physician Scientist	Psychiatry Research	Y	Chair	N	
Skroback, Judith	BM	Other Scientist	Devices	Y		Y	
Somerstein, Shari	RPh	Other Scientist	Pharmacist	N		N	
Sommer, Dane	DMin, MDiv, BCC	Non-Scientist	Ministry	N		N	
Spaulding, Trevor	BA, CIP	Non-Scientist	Regulatory	Y		Y	
Stoltz, Randall	MD, CPI	Physician Scientist	Phase I Research/ Cardiovascular	N		N	

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Stone, Kurt	DD	Non-Scientist	Ministry	N		N	
Strull, William	MD	Physician Scientist	Internal Medicine	N		N	
Taucher, Kate	PharmD, MHA, BCOP	Other Scientist	Pharmacology	N		N	
Teal, Marilyn	PharmD, BS	Other Scientist	Pharmacology	N		Y	Ethics
Tillman, Beverly	RN, MSN	Other Scientist	Public Health	N		N	
Tkaczuk, Katherine	MD	Physician Scientist	Oncology/ Hematology	N		N	
Vanderwel, Marianne	MEng, MSc	Other Scientist	Quality Assurance/ Research Ethics	N		Y	Ethics, Law
Vernon, Kim	JD	Non-Scientist	Legal/ Prisoner Advocate	N		N	
Walker, Christina	MD	Physician Scientist	Family Medicine	N		N	
Way, Cynthia	CIP	Non-Scientist	Regulatory/ Phase I Research	N		N	
Wells, Christine	MD	Physician Scientist	Neurology/ Patient Advocate	N		Y	Ethics
Westby, Christian	PhD	Other Scientist	Physiology	Y	Chair	N	
Wood, Leslie	BA	Non-scientist	Communications	N		Y	Ethics
Wright-Moore, Conschetta	RN, MPH	Other Scientist	Nursing/ Clinical Research	Y		Y	

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Changes from All Member Roster Dated 03/01/2023

Member Name	Change	Date Change Made
Lauren Hartsmith	Removed	04/01/2023
Laura Campbell	Added	04/11/2023
Robert Romanchuk	Changed to Unaffiliated; removed Chair indication	05/15/2023
Neha Kaul	Added	05/17/2023
Mary Ruwart	Removed Chair indication	05/19/2023

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- Advarra's voluntary Federal wide Assurance (FWA) has been approved by OHRP.
    - IRB Organization (IORG) Number: 0000635
    - FWA Number: 00023875
    - IRB Registration Number: 00000971
- Advarra is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP)

Name	Credentials	Role	Primary Expertise	Affiliated?	Chair?	Reviews CAN Research?	CAN: Knowledgeable in ethics and/or law?
Altier, Sarah	EdD	Non-Scientist	Educator	N		N	
Ambrosini, Daniel	BA, LLB, MSc, PhD	Other Scientist	Psychiatry/ Legal	N		Y	Ethics, Law
Aramburu Alegria, Christine	PhD, RN	Other Scientist	Nursing/ Social Psychology/ Transgender Issues	N		N	

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Baird, Kristin	MD	Physician Scientist	Oncology/ Pediatrician/ Hematology	N		N	
Benedict, Wendy	BA	Non-Scientist	Social Worker	N		N	
Bergstrom, Steven	MD	Physician Scientist	Oncology/ Pediatrician/ Hematology	N		N	
Berlin, Suzanne	DO	Physician Scientist	Oncology/ Women's Cancers	N		N	
Bernstein, Erica	PharmD, BCPS	Other Scientist	Pharmacology	N		N	
Berry, Donna	PhD, RN, AOCN, FAAN	Other Scientist	Nursing/ Oncology	N		N	
Block, Michelle	MS, BS, RAC, CIP	Non-Scientist	Regulatory/DoD Regulated Research	Y		Y	
Blum, Robert	PharmD	Other Scientist	Pharmacology	N	Chair	N	
Booker, Burthia	PhD	Other Scientist	Biomedical Sciences	N		N	
Borgatta, Lynn	MD, MPH	Physician Scientist	Obstetrics/ Gynecology	N		Y	
Bottorff, Michael	PharmD	Other Scientist	Pharmacology	N		N	
Braun, Peter	MD	Physician Scientist	Internal Medicine/ Infectious Disease	N		N	
Brock, Jennifer	RN	Other Scientist	Nursing/ Oncology	N		N	
Brown, Janice	RPh, MLS	Non-Scientist	Educator/ Librarian	N		N	
Brzozowski, Jane	MS, BS	Non-Scientist	Patient Advocacy	N		N	
Burkey, Madison	BSN, RN, OCN	Other Scientist	Nursing/ Oncology	Y		Y	
Byers, Derek	MD, PhD, FCCP	Physician Scientist	Internal Medicine/ Immunology	N		N	
Carr, Raymond	RPh	Other Scientist	Pharmacist	N		N	
Casabar, Ed	PharmD, BCPS, AQ-ID	Other Scientist	Pharmacology	N		N	
Cavagnaro, Joy	PhD, DABT, RAC	Other Scientist	Toxicology/ Regulatory Affairs Consultant	N		N	

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Chukwu, Bernadette	PharmD	Other Scientist	Pharmacovigilance/ Drug Safety	Y		N	
Cooper, Kindra	JD	Non-Scientist	Legal	N		N	
Cooper, Phyllis	RN, BSN, OCN, CCRP	Other Scientist	Nursing/ Oncology	N		N	
Cosentino, Lidia	PhD	Other Scientist	Biology/ Protocol development	N		Y	
Cram, Gary	AS	Non-Scientist	Ethics	N		N	
Cullity, Connie	MD, MPH	Physician Scientist	FDA Regulations	Y		N	
Cummings, Theresa	RN, MS	Other Scientist	Nursing/ Public Health	N		N	
Davidson, Barbara	MS, RN, MSN, CCRC	Other Scientist	Community Health Nursing	Y		Y	
Davidson, Susan	MD	Physician Scientist	Infectious Disease/ Homeostasis	N		N	
Davis, Hannah	BS, MS	Other Scientist	Biology / Biomedical	Y		N	
Desai, Pankaj	PhD	Other Scientist	Biopharmaceutics/ Pharmacokinetics	N		N	
Dorsch, Kimberly	BS	Other Scientist	Stem Cell/ Tissue Research	N		N	
Drada, Denisse		Non-Scientist	Regulatory	Y		Y	
Duhon, Bryson	PharmD, BCPS	Other Scientist	Pharmacology	N		N	
Dyson, Maynard	MD, MA, CIP	Physician Scientist	Pediatrician/ Pulmonology	N		N	
Ebert, Susan	MS, CIP	Non-Scientist	Regulatory	Y	Sr. Chair Dir.	N	
Fernicola, Daniel	MD, FACC	Physician Scientist	Cardiology	N		N	
Ferrell, David	ThB, BA, MA	Non-Scientist	Religion / Ethics	N		Y	Ethics
Fittizzi, Cheryl	RN, CIM, CIP	Other Scientist	Nursing/ Emergency Trauma/ Public Health	N		N	
Fitzgerald, Michael	PhD	Other Scientist	Social Psychology	N		N	
Fleck, David	PhD	Other Scientist	Psychiatry/ Behavioral Neuroscience	N		N	

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Name	Credentials	Role	Primary Expertise	Affiliated?	Chair?	Reviews CAN Research?	CAN: Knowledgeable in ethics and/or law?
Flowers, Janelle	MEd	Non-Scientist	Guidance Counselor	N		N	
Foster, Joyce	MS	Non-Scientist	Family Therapy	N		N	
Garrick, Tania	RN, BScN, MA	Other Scientist	Nursing	N		Y	
Gelinas, Luke	PhD, MAR, AB	Non-Scientist	Ethics	Y	Sr. Chair Dir.	Y	Ethics
Georgiadis, Nina	MD	Physician Scientist	Neonatal Intensive Care	N		Y	
Gill, Cyrus	RN, MS, CCRA	Other Scientist	Nursing/ Phase I	N		N	
Ginnings, Susan	RPh	Other Scientist	Pharmacist	N		N	
Gold, Herschel	BA, LLB	Non-scientist	Legal	N		Y	Ethics, Law
Goldman, Ran	MD, MHA, FRCPC	Physician Scientist	Pediatrician	N	Chair	Y	Ethics
Gonzales, Yury	MD, FACP	Physician Scientist	Internal Medicine	N		Y	
Gordner, Linda	BA	Non-Scientist	Special Education	N		Y	
Gottke, Melissa	BA	Non-Scientist	Regulatory	Y		Y	
Gray, Vernon	PhD	Non-Scientist	County Government Administrator	N		N	
Grimes, Brittany	MS	Non-Scientist	Regulatory	Y		Y	
Groisman, Iris	PhD	Other Scientist	Biochemistry/ Radiobiology/ Pharmacogenetics	N		Y	Ethics
Group, Melinda	BS, RPh	Other Scientist	Pharmacist/ Hospital Research	N		N	
Groza, Florina	MSc	Other Scientist	Biochemistry	Y		Y	
Haffizulla, Farzanna	MD, FACP, FAMWA	Physician Scientist	Internal Medicine	N		N	
Hartsmith, Lauren	JD, CIP	Non-Scientist	Legal	Y		N	
Hensler, Carolyn	BS	Non-Scientist	Regulatory	N		N	
Henson, Tricia	BA, RN	Other Scientist	Nursing Sciences	Y		Y	
Hewes, Julia	MPH, BSN, RN, OCN	Other Scientist	Nursing/ Oncology	N		N	
Hierholzer, Robert	MD	Physician Scientist	Psychiatrist	N		N	

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Higley, Amanda	PhD, CIP	Other Scientist	Psychology	Y	Chair	N	
Hill, Margaret	RN, MS	Other Scientist	Nursing/ Oncology/ Clinical Trials Research	N		N	
Hiller, David	BSN, RN, AEMT, CIP	Other Scientist	Regulatory Critical Care Nursing	Y	Chair	N	
Horton, Alicia	JD, MPH	Non-Scientist	Legal/ Public Health	N		N	
Hoshower, Jason	BS, CIP	Non-Scientist	Regulatory	Y		Y	
Houser, Patricia	MD	Physician Scientist	Family Medicine	N		N	
Hsiao, Karin	BS, MS, MBA	Other Scientist	Biomedical Engineering/ Device	N		N	
Jacobsen, Eric	MD	Physician Scientist	Oncology/ Lymphoma	N		N	
Johnson, Dena	BS, MEd, CCRP, CIP	Non-Scientist	Regulatory	Y	Chair	N	
Jordan, William	DO	Physician Scientist	Oncology/ Medical	N		N	
Keely, Levering	BSN, MPA	Other Scientist	Nursing/ Device specialist	N		N	
Kim, James	MD, MBA	Physician Scientist	General Practice/ Non-Cancer Pain Management	N		Y	
Kirk, Julia	BA, CIP	Non-Scientist	Regulatory	Y		Y	
Klaff, Ali	BSCIP	Non-Scientist	Regulatory	Y		Y	
Knopman, David	MD	Physician Scientist	Alzheimer/ Neurology	N		N	
Kopec, Frederick	JD	Non-Scientist	Legal	N	Chair	N	
Kronish, Daniel	MD	Physician Scientist	Oncology/ Pediatrician	Y	Chair	Y	
Kuebler, Philip	MD, PhD, BS	Physician Scientist	Internal Medicine/ Oncology/ Hematology	N		N	
Kuzmanovic, Dario	BA, MHSc, CRA, CHRC	Non-Scientist	Bioethics	N		Y	Ethics, Law
Kysela, Kathleen	CIP	Non-Scientist	Regulatory	Y		Y	
LaCount, Peter	MHS, MEd	Non-Scientist	Compliance Director	N		N	

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Lawrence, Janice	PhD, MA, BA, BPE	Other Scientist	Physical Ed/ Life Coach	N		Y	
Leduc, Lucie	LLM	Non-Scientist	Legal/ Ethics	N		Y	Ethics, Law
Leo, Jessica	AA, CIP	Non-Scientist	Regulatory	Y		Y	
Letko, Erik	MD	Physician Scientist	Ophthalmology/ Surgery	N		N	
Lettman, Robert	BA, MBA, JD, PA	Non-Scientist	Legal	N		N	
Lind, Alecia	BS, CIP	Non-Scientist	Regulatory	Y		Y	
Longstaff, Holly	PhD	Non-Scientist	Ethics	N		Y	Ethics
Lopez, Bennie	MBA	Non-Scientist	Educator	N		N	
Lossada, Mery	MD, PA	Physician Scientist	Psychiatry/ Neurology	N		N	
Maloof, Damiana	MSN, RN, OCN	Other Scientist	Nursing/ Oncology	N		N	
Martin, Christopher	PharmD, MS	Other Scientist	Pharmacology	N	Chair	N	
McPhillips, Joseph	PhD	Other Scientist	Clinical Research Consultant	N		N	
Mensah, Sharon	MS	Other Scientist	Biological Sciences/ Clinical Research	N		N	
Mihalov, Linda	MD, FACOG	Physician Scientist	Oncology/ Gynecology	N		N	
Mitchell, Cameron	BA	Non-Scientist	Regulatory	Y		Y	
Morse, Linda	RN, MSN, OCN	Other Scientist	Nursing/ Oncology	N		N	
Mueller, Lava	MEd, MDiv	Non-scientist	Chaplain	N		N	
Munk, Gary	PhD, MS, BS	Other Scientist	Virology/ Biosafety	N		N	
Nattrass, Susan	OC, PhD, CBDT	Other Scientist	Osteoporosis and Women's Health	N		Y	
Neff, Robert	BS	Non-Scientist	Mobile Medical	N		N	
Nolan, Joseph	PhD, MS, MA, BA, BS	Other Scientist	Statistics	N		N	
Noss, Michael	MD	Physician Scientist	Family Medicine	N		N	
O'Connell, Mary		Non-Scientist	Regulatory	N		N	
Odor, Erin	MA, CIP	Non-Scientist	Regulatory	Y	Chair	N	
O'Leary, Maura	MD	Physician Scientist	Oncology/ Pediatrician/ Hematology	N		N	

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Oliver, Ayesha	BS	Non-Scientist	Regulatory	Y		Y	
Ott, Carl	MD, MPH	Physician Scientist	Internal Medicine	N		N	
Parker, R. Lamar	MD, FACOG, CPI	Physician Scientist	Obstetrics/ Gynecology	N		N	
Patrick, Kyle	DO	Physician Scientist	Medical Research	N		N	
Pettey, Cheri	MA, BA	Non-Scientist	Bioethics/ Philosophy	Y	Chair	N	
Pfeiffer, Matthew	PhD	Other Scientist	Pharmacology/ Toxicology	N		N	
Popovici-Toma, Dan	MD	Physician Scientist	Medical Advisor	N		Y	Ethics
Povar, Gail	MD, MPH, FACP	Physician Scientist	Internal Medicine	N	Chair	N	
Psenicka, Eva	BSc	Non-Scientist	Physiology/ Regulatory	N		Y	
Ramjiawan, Bram	PhD	Other Scientist	Pharmacology	N		Y	
Randolph, Robert	DMin	Non-Scientist	Chaplain	N		N	
Razzetti, Albert	MD	Physician Scientist	Internal Medicine/ Pulmonology	N		N	
Reddish, Mitchell	PhD	Non-Scientist	Professor/ Religious Studies/ Ethicist	N		N	
Renner, Laura	BA	Non-Scientist	Regulatory	Y		N	
Rewers, Mae, Edna	MS, JD, MBA	Non-Scientist	Legal/ Healthcare/ Research Compliance	N		N	
Reynolds, Deborah	RN, OCN	Other Scientist	Nursing/ Oncology	N		N	
Robinson, Deana	MPH, BS, LPN, CPhT	Other Scientist	Clinical Research LPN	Y		Y	
Robinson, Richard	MD	Physician Scientist	Medical Oncology/ Internal Medicine	N		N	
Romain, Michael	MD	Physician Scientist	Internal Medicine	N		N	
Romanchuk, Robert	BS, HS, CIP, CCRCP, CCRC	Other Scientist	Clinical Research Administration/ Respiratory Therapy	Y	Chair	Y	

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Rush, Jason	BS, CIP	Non-Scientist	Regulatory	Y		N	
Ruwart, Mary	PhD, BS	Other Scientist	Biophysics/ Biochemistry	N	Chair	N	
Ryan, Laurajo	PharmD, MSc, BCPS	Other Scientist	Pharmacology	N		N	
Sadorra, Carol	PhD	Non-Scientist	Regulatory	Y		Y	
Salama, Suzette	BPharm, MSc, PhD	Other Scientist	Ethicist/ Pharmacology	N		Y	Ethics, Law
Saylor, Brenda	RN, BSN, ARM	Other Scientist	Community Health Nursing	Y		Y	
Selsky, Clifford	PhD, MD	Physician Scientist	Pediatrics, Hematology Oncology	N		N	
Sever, John	MD, PhD	Physician Scientist	Pediatrician/ Infectious Diseases	N		N	
Shachar, Carmel	JD, MPH	Non-Scientist	Legal	N		N	
Shafer, Michaela	PhD, RN	Other Scientist	Biomedical Research/ Nursing	N		N	
Sheedy, Carmen	BA	Non-Scientist	Regulatory	Y		Y	
Shulman, Mitchell	MDCM, FRCPC, CSPQ	Physician Scientist	Emergency Medicine	N		Y	
Siegmann, Glenn	MS, RPh	Other Scientist	Pharmacist	N		N	
Singh, Sukhbir	MD, MBA	Physician Scientist	Psychiatry Research	Y	Chair	N	
Skroback, Judith	BM	Other Scientist	Devices	Y		Y	
Somerstein, Shari	RPh	Other Scientist	Pharmacist	N		N	
Sommer, Dane	DMin, MDiv, BCC	Non-Scientist	Ministry	N		N	
Spaulding, Trevor	BA, CIP	Non-Scientist	Regulatory	Y		Y	
Stoltz, Randall	MD, CPI	Physician Scientist	Phase I Research/ Cardiovascular	N		N	
Stone, Kurt	DD	Non-Scientist	Ministry	N		N	
Strull, William	MD	Physician Scientist	Internal Medicine	N		N	
Taucher, Kate	PharmD, MHA, BCOP	Other Scientist	Pharmacology	N		N	
Teal, Marilyn	PharmD, BS	Other Scientist	Pharmacology	N		Y	Ethics
Tillman, Beverly	RN, MSN	Other Scientist	Public Health	N		N	

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Tkaczuk, Katherine	MD	Physician Scientist	Oncology/ Hematology	N		N	
Vanderwel, Marianne	MEng, MSc	Other Scientist	Quality Assurance/ Research Ethics	N		Y	Ethics, Law
Vernon, Kim	JD	Non-Scientist	Legal/ Prisoner Advocate	N		N	
Walker, Christina	MD	Physician Scientist	Family Medicine	N		N	
Way, Cynthia	CIP	Non-Scientist	Regulatory/ Phase I Research	N		N	
Wells, Christine	MD	Physician Scientist	Neurology/ Patient Advocate	N		Y	Ethics
Westby, Christian	PhD	Other Scientist	Physiology	Y	Chair	N	
Wood, Leslie	BA	Non-scientist	Communications	N		Y	Ethics
Wright-Moore, Conschetta	RN, MPH	Other Scientist	Nursing/ Clinical Research	Y		Y	

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Changes from All Member Roster Dated 12/01/2022

Member Name	Change	Date Change Made
Hannah Davis	Added	12/20/2022
Beth Overmoyer	Removed	07/01/2022
Nicole Sieffert	Removed	12/09/2022

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About Advarra's IRB Roster/ Membership List

Advarra maintains one roster and follows specific regulations and policies to determine how each individual panel that reviews research will be comprised. Each convened IRB meeting that reviews research will include:

- No fewer than 5 voting members and no more than 9 voting members
- At least 1 scientific member for meetings reviewing US based research, and 2 scientific members for meetings reviewing Canadian research
- At least 1 non-scientific member
- Both men and women
- At least 1 person who is not otherwise affiliated with Advarra
    - These individuals may be referred to as "unaffiliated" or "community" members
    - These members are identified in the list below with the letter "N" in the "Affiliated?" column

Additional Information about IRB Review of Canadian Research

In addition to the requirements above, meetings where Canadian research is reviewed will include:

- At least 1 member knowledgeable in ethics
- At least 1 member knowledgeable in Canadian laws relevant to the biomedical research to be approved

All IRB members can review US based research. Members eligible to review Canada-based research are identified below with the letter "Y" in the "Reviews CAN Research?" column. Additionally, whether these members are deemed to be knowledgeable in ethics and/or knowledgeable in Canadian laws relevant to the biomedical research to be approved will be identified in the "CAN: Knowledgeable in ethics and/or law?" column.

About the IRB

Advarra is organized and operates in compliance with the US and Canadian regulations and policies governing research with human subjects, as applicable.

- Advarra's IRB is registered with FDA and OHRP.
- Advarra's voluntary Federal wide Assurance (FWA) has been approved by OHRP.
    - IRB Organization (IORG) Number: 0000635
    - FWA Number: 00023875
    - IRB Registration Number: 00000971
- Advarra is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP)

Name	Credentials	Role	Primary Expertise	Affiliated?	Chair?	Primary(P) or Alternate(A)?	Reviews CAN Research?	CAN: Knowledgeable in ethics and/or law?
Altier, Sarah	EdD	Non-Scientist	Educator	N		A	N	
Ambrosini, Daniel	BA, LLB, MSc, PhD	Other Scientist	Psychiatry/ Legal	N		A	Y	Ethics, Law

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Aramburu Alegria, Christine	PhD, RN	Other Scientist	Nursing/ Social Psychology/ Transgender Issues	N		A	N	
Astein, Diego	MD	Physician Scientist	Radiology	Y	Chair	A	Y	Ethics
Baird, Kristin	MD	Physician Scientist	Oncology/ Pediatrician/ Hematology	N		A	N	
Barr, Hallie	PharmD, MBA, BCOP	Other Scientist	Pharmacy / Oncology	Y		A	N	
Benedict, Wendy	BA	Non-Scientist	Social Worker	N		A	N	
Bergstrom, Steven	MD	Physician Scientist	Oncology/ Pediatrician/ Hematology	N		A	N	
Berlin, Suzanne	DO	Physician Scientist	Oncology/ Women's Cancers	N		A	N	
Bernstein, Erica	PharmD, BCPS	Other Scientist	Pharmacology	N		A	N	
Berry, Donna	PhD, RN, AOCN, FAAN	Other Scientist	Nursing/ Oncology	N		A	N	
Block, Michelle	MS, BS, RAC, CIP	Non-Scientist	Regulatory/DoD Regulated Research	Y		A	Y	
Blum, Robert	PharmD	Other Scientist	Pharmacology	N	Chair	A	N	
Bode, Kate	BS	Non-Scientist	Regulatory	Y		A	N	
Booker, Burthia	PhD	Other Scientist	Biomedical Sciences	N		A	N	
Borgatta, Lynn	MD, MPH	Physician Scientist	Obstetrics/ Gynecology	N		A	Y	
Bottorff, Michael	PharmD	Other Scientist	Pharmacology	N		A	N	
Braun, Peter	MD	Physician Scientist	Internal Medicine/ Infectious Disease	N		A	N	
Brown, Janice	RPh, MLS	Non-Scientist	Educator/ Librarian	N		A	N	
Brzozowski, Jane	MS, BS	Non-Scientist	Patient Advocacy	N		A	N	
Burkey, Madison	BSN, RN, OCN	Other Scientist	Nursing/ Oncology	Y		A	Y	
Byers, Derek	MD, PhD, FCCP	Physician Scientist	Internal Medicine/ Immunology	N		A	N	

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Campbell, Laura	MD	Physician Scientist	Oncology/ Hematology/ Pediatrics/ Bioethics	N		A	N	
Carr, Raymond	RPh	Other Scientist	Pharmacist	N		A	N	
Cavagnaro, Joy	PhD, DABT, RAC	Other Scientist	Toxicology/ Regulatory Affairs Consultant	N		P	N	
Cesary, Kelly	MSN, APN, ANP-BC, AOCNP	Other Scientist	Oncology / Hematology / Nursing	N		A	N	
Chukwu, Bernadette	PharmD	Other Scientist	Pharmacovigilance/ Drug Safety	Y		A	N	
Cooper, Kindra	JD	Non-Scientist	Legal	N		A	N	
Cooper, Phyllis	RN, BSN, OCN, CCRP	Other Scientist	Nursing/ Oncology	N		A	N	
Cosentino, Lidia	PhD	Other Scientist	Biology/ Protocol development	N		A	Y	
Cram, Gary	AS	Non-Scientist	Ethics	N		A	N	
Cullity, Connie	MD, MPH	Physician Scientist	FDA Regulations	Y		A	N	
Cummings, Theresa	RN, MS	Other Scientist	Nursing/ Public Health	N		A	N	
Davidson, Barbara	MS, RN, MSN, CCRC	Other Scientist	Community Health Nursing	Y		A	Y	
Davidson, Susan	MD	Physician Scientist	Infectious Disease/ Homeostasis	N		A	N	
Davis, Hannah	BS, MS	Other Scientist	Biology / Biomedical	Y		A	N	
Desai, Pankaj	PhD	Other Scientist	Biopharmaceutics/ Pharmacokinetics	N		A	N	
Dorsch, Kimberly	BS	Other Scientist	Stem Cell/ Tissue Research	N		A	N	
Drada, Denisse		Non-Scientist	Regulatory	Y		A	Y	
Duhon, Bryson	PharmD, BCPS	Other Scientist	Pharmacology	N		A	N	
Dyson, Maynard	MD, MA, CIP	Physician Scientist	Pediatrician/ Pulmonology	N		A	N	

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Ebert, Susan	MS, CIP	Non-Scientist	Regulatory	Y	Sr. Chair Dir.	P	N	
Fernicola, Daniel	MD, FACC	Physician Scientist	Cardiology	N		A	N	
Ferrell, David	ThB, BA, MA	Non-Scientist	Religion / Ethics	N		A	Y	Ethics
Fittizzi, Cheryl	RN, CIM, CIP	Other Scientist	Nursing/ Emergency Trauma/ Public Health	N		A	N	
Fitzgerald, Michael	PhD	Other Scientist	Social Psychology	N		A	N	
Fleck, David	PhD	Other Scientist	Psychiatry/ Behavioral Neuroscience	N		A	N	
Flowers, Janelle	MEd	Non-Scientist	Guidance Counselor	N		A	N	
Foster, Joyce	MS	Non-Scientist	Family Therapy	N		A	N	
Garrick, Tania	RN, BScN, MA	Other Scientist	Nursing	N		A	Y	
Gelinas, Luke	PhD, MAR, AB	Non-Scientist	Ethics	Y	Sr. Chair Dir.	P	Y	Ethics
Georgiadis, Nina	MD	Physician Scientist	Neonatal Intensive Care	N		A	Y	
Ginnings, Susan	RPh	Other Scientist	Pharmacist	N		A	N	
Gold, Herschel	BA, LLB	Non-scientist	Legal	N		A	Y	Ethics, Law
Goldman, Ran	MD, MHA, FRCPC	Physician Scientist	Pediatrician	N	Chair	A	Y	Ethics
Gonzales, Yury	MD, FACP	Physician Scientist	Internal Medicine	N		P	Y	
Gordner, Linda	BA	Non-Scientist	Special Education	N		A	Y	
Gorman, Richard	MD	Physician Scientist	Pediatrics / Infectious Diseases	N		A	N	
Gottke, Melissa	BA	Non-Scientist	Regulatory	Y		A	Y	
Gray, Vernon	PhD	Non-Scientist	County Government Administrator	N		A	N	
Grimes, Brittany	MS	Non-Scientist	Regulatory	Y		A	Y	

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Groisman, Iris	PhD	Other Scientist	Biochemistry/ Radiobiology/ Pharmacogenetics	N		A	Y	Ethics
Group, Melinda	BS, RPh	Other Scientist	Pharmacist/ Hospital Research	N		P	N	
Groza, Florina	MSc	Other Scientist	Biochemistry	Y		A	Y	
Haffizulla, Farzanna	MD, FACP, FAMWA	Physician Scientist	Internal Medicine	N		P	N	
Hensler, Carolyn	BS	Non-Scientist	Regulatory	N		A	N	
Henson, Tricia	BA, RN	Other Scientist	Nursing Sciences	Y		A	Y	
Hewes, Julia	MPH, BSN, RN, OCN	Other Scientist	Nursing/ Oncology	N		A	N	
Hierholzer, Robert	MD	Physician Scientist	Psychiatrist	N		A	N	
Higley, Amanda	PhD, CIP	Other Scientist	Psychology	Y	Chair	A	N	
Hill, Margaret	RN, MS	Other Scientist	Nursing/ Oncology/ Clinical Trials Research	N		A	N	
Hiller, David	BSN, RN, AEMT, CIP	Other Scientist	Regulatory Critical Care Nursing	Y	Chair	A	N	
Horton, Alicia	JD, MPH	Non-Scientist	Legal/ Public Health	N		A	N	
Hoshower, Jason	BS, CIP	Non-Scientist	Regulatory	Y		A	Y	
Houser, Patricia	MD	Physician Scientist	Family Medicine	N		A	N	
Hsiao, Karin	BS, MS, MBA	Other Scientist	Biomedical Engineering/ Device	N		A	N	
Hubbard, Tyler	MA, CIP	Non-Scientist	Social and Behavioral Research / Regulatory	Y		A	N	
Jacobsen, Eric	MD	Physician Scientist	Oncology/ Lymphoma	N		A	N	
Johnson, Dena	BS, MEd, CCRP, CIP	Non-Scientist	Regulatory	Y	Chair	A	N	

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Jordan, William	DO	Physician Scientist	Oncology/ Medical	N		A	N	
Kaul, Neha	MA, MS, BSc	Other Scientist	Social and Behavioral Research; Regulatory; Bioethics/Ethics; Molecular Biology	Y	Chair	A	N	
Keely, Levering	BSN, MPA	Other Scientist	Nursing/ Device specialist	N		A	N	
Kim, James	MD, MBA	Physician Scientist	General Practice/ Non-Cancer Pain Management	N		A	Y	
Kirk, Julia	BA, CIP	Non-Scientist	Regulatory	Y		A	Y	
Klaff, Ali	BSCIP	Non-Scientist	Regulatory	Y		A	Y	
Knopman, David	MD	Physician Scientist	Alzheimer/ Neurology	N		A	N	
Kopec, Frederick	JD	Non-Scientist	Legal	N	Chair	A	N	
Kronish, Daniel	MD	Physician Scientist	Oncology/ Pediatrician	Y	Chair	A	Y	
Kuebler, Philip	MD, PhD, BS	Physician Scientist	Internal Medicine/ Oncology/ Hematology	N		A	N	
Kuzmanovic, Dario	BA, MHSc, CRA, CHRC	Non-Scientist	Bioethics	N		A	Y	Ethics, Law
Kysela, Kathleen	CIP	Non-Scientist	Regulatory	Y		A	Y	
LaCount, Peter	MHS, MEd	Non-Scientist	Compliance Director	N		P	N	
Lawrence, Janice	PhD, MA, BA, BPE	Other Scientist	Physical Ed/ Life Coach	N		A	Y	
Leduc, Lucie	LLM	Non-Scientist	Legal/ Ethics	N		A	Y	Ethics, Law
Leo, Jessica	AA, CIP	Non-Scientist	Regulatory	Y		A	Y	
Letko, Erik	MD	Physician Scientist	Ophthalmology/ Surgery	N		A	N	
Lettman, Robert	BA, MBA, JD, PA	Non-Scientist	Legal	N		A	N	
Lind, Alecia	BS, CIP	Non-Scientist	Regulatory	Y		A	Y	

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Name	Credentials	Role	Primary Expertise	Affiliated?	Chair?	Primary(P) or Alternate(A)?	Reviews CAN Research?	CAN: Knowledgeable in ethics and/or law?
Longstaff, Holly	PhD	Non-Scientist	Ethics	N		A	Y	Ethics
Lopez, Bennie	MBA	Non-Scientist	Educator	N		A	N	
Lossada, Mery	MD, PA	Physician Scientist	Psychiatry/ Neurology	N		A	N	
Maloof, Damiana	MSN, RN, OCN	Other Scientist	Nursing/ Oncology	N		A	N	
Martin, Christopher	PharmD, MS	Other Scientist	Pharmacology	N	Chair	A	N	
McPhillips, Joseph	PhD	Other Scientist	Clinical Research Consultant	N		A	N	
Mensah, Sharon	MS	Other Scientist	Biological Sciences/ Clinical Research	N		A	N	
Mihalov, Linda	MD, FACOG	Physician Scientist	Oncology/ Gynecology	N		A	N	
Mitchell, Cameron	BA	Non-Scientist	Regulatory	Y	Chair	A	Y	
Morse, Linda	RN, MSN, OCN	Other Scientist	Nursing/ Oncology	N		A	N	
Mueller, Lava	MEd, MDiv	Non-scientist	Chaplain	N		A	N	
Munk, Gary	PhD, MS, BS	Other Scientist	Virology/ Biosafety	N		A	N	
Nattrass, Susan	OC, PhD, CBDT	Other Scientist	Osteoporosis and Women's Health	N		A	Y	
Neff, Robert	BS	Non-Scientist	Mobile Medical	N		A	N	
Nolan, Joseph	PhD, MS, MA, BA, BS	Other Scientist	Statistics	N		A	N	
Noss, Michael	MD	Physician Scientist	Family Medicine	N		A	N	
O'Connell, Mary		Non-Scientist	Regulatory	N		A	N	
Odor, Erin	MA, CIP	Non-Scientist	Regulatory	Y	Chair	A	N	
O'Leary, Maura	MD	Physician Scientist	Oncology/ Pediatrician/ Hematology	N		A	N	
Oliver, Ayesha	BS	Non-Scientist	Regulatory	Y		A	Y	
Ott, Carl	MD, MPH	Physician Scientist	Internal Medicine	N		A	N	
Parker, R. Lamar	MD, FACOG, CPI	Physician Scientist	Obstetrics/ Gynecology	N		A	N	

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Patrick, Kyle	DO	Physician Scientist	Medical Research	N		A	N	
Pfeiffer, Matthew	PhD	Other Scientist	Pharmacology/ Toxicology	N		A	N	
Popovici-Toma, Dan	MD	Physician Scientist	Medical Advisor	N		A	Y	Ethics
Povar, Gail	MD, MPH, FACP	Physician Scientist	Internal Medicine	N	Chair	A	N	
Psenicka, Eva	BSc	Non-Scientist	Physiology/ Regulatory	N		A	Y	
Ramjiawan, Bram	PhD	Other Scientist	Pharmacology	N		A	Y	
Randolph, Robert	DMin	Non-Scientist	Chaplain	N		A	N	
Razzetti, Albert	MD	Physician Scientist	Internal Medicine/ Pulmonology	N		A	N	
Reddish, Mitchell	PhD	Non-Scientist	Professor/ Religious Studies/ Ethicist	N		A	N	
Renner, Laura	BA	Non-Scientist	Regulatory	Y		A	N	
Rewers, Mae, Edna	MS, JD, MBA	Non-Scientist	Legal/ Healthcare/ Research Compliance	N		A	N	
Reynolds, Deborah	RN, OCN	Other Scientist	Nursing/ Oncology	N		A	N	
Robinson, Deana	MPH, BS, LPN, CPhT	Other Scientist	Clinical Research LPN	Y		A	Y	
Robinson, Richard	MD	Physician Scientist	Medical Oncology/ Internal Medicine	N		A	N	
Romain, Michael	MD	Physician Scientist	Internal Medicine	N		A	N	
Romanchuk, Robert	BSHS, CIP, CCRCP	Other Scientist	Clinical Research Administration/ Respiratory Therapy	N		A	Y	
Rush, Jason	BS, CIP	Non-Scientist	Regulatory	Y		A	N	
Ruwart, Mary	PhD, BS	Other Scientist	Biophysics/ Biochemistry	N		A	N	

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Ryan, Laurajo	PharmD, MSc, BCPS	Other Scientist	Pharmacology	N		A	N	
Sadorra, Carol	PhD	Non-Scientist	Regulatory	Y		A	Y	
Salama, Suzette	BPharm, MSc, PhD	Other Scientist	Ethicist/ Pharmacology	N		A	Y	Ethics, Law
Saylor, Brenda	RN, BSN, ARM	Other Scientist	Community Health Nursing	Y		A	Y	
Selsky, Clifford	PhD, MD	Physician Scientist	Pediatrics, Hematology Oncology	N		A	N	
Shafer, Michaela	PhD, RN	Other Scientist	Biomedical Research/ Nursing	N		A	N	
Sheedy, Carmen	BA	Non-Scientist	Regulatory	Y		A	Y	
Shulman, Mitchell	MDCM, FRCPC, CSPQ	Physician Scientist	Emergency Medicine	N		A	Y	
Siegmann, Glenn	MS, RPh	Other Scientist	Pharmacist	N		A	N	
Singh, Sukhbir	MD, MBA	Physician Scientist	Psychiatry Research	Y	Chair	A	N	
Skroback, Judith	BM	Other Scientist	Devices	Y		A	Y	
Somerstein, Shari	RPh	Other Scientist	Pharmacist	N		A	N	
Sommer, Dane	DMin, MDiv, BCC	Non-Scientist	Ministry	N		A	N	
Spaulding, Trevor	BA, CIP	Non-Scientist	Regulatory	Y		A	Y	
Stoltz, Randall	MD, CPI	Physician Scientist	Phase I Research/ Cardiovascular	N		A	N	
Stone, Kurt	DD	Non-Scientist	Ministry	N		A	N	
Strull, William	MD	Physician Scientist	Internal Medicine	N		A	N	
Taucher, Kate	PharmD, MHA, BCOP	Other Scientist	Pharmacology	N		A	N	
Teal, Marilyn	PharmD, BS	Other Scientist	Pharmacology	N		P	Y	Ethics
Tillman, Beverly	RN, MSN	Other Scientist	Public Health	N		A	N	
Tkaczuk, Katherine	MD	Physician Scientist	Oncology/ Hematology	N		A	N	

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Vanderwel, Marianne	MEng, MSc	Other Scientist	Quality Assurance/ Research Ethics	N		A	Y	Ethics, Law
Vernon, Kim	JD	Non-Scientist	Legal/ Prisoner Advocate	N		A	N	
Walker, Christina	MD	Physician Scientist	Family Medicine	N		A	N	
Way, Cynthia	CIP	Non-Scientist	Regulatory/ Phase I Research	N		A	N	
Wells, Christine	MD	Physician Scientist	Neurology/ Patient Advocate	N		A	Y	Ethics
Westby, Christian	PhD	Other Scientist	Physiology	Y	Chair	P	N	
Witkowski, Amy	CIP	Non-Scientist	IRB Professional	N		A	N	
Wood, Leslie	BA	Non-scientist	Communications	N		A	Y	Ethics
Wright-Moore, Conschetta	RN, MPH	Other Scientist	Nursing/ Clinical Research	Y		A	Y	

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Roster Changes:

Member Name	Change	Date Change Made
Cheri Pettey	Removed	11/01/2023
Cyrus Gill	Removed	11/02/2023
Jennifer Brock	Removed	11/15/2023
Kelly Cesary	Added	11/16/2023
Kate Bode	Added	11/22/2023
Cameron Mitchell	Added Chair designation	11/27/2023
Hallie Barr	Added	11/28/2023

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INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Mindset Medical, LLC / "A Multi-Center Prospective Open Label Study of a Web-based Application for Pulse Rate in Adult Patients"**
Protocol Number:	**IVC-400-006**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

KEY INFORMATION
You are invited to take part in a research study. This research study is designed to evaluate the accuracy of Informed Vital Core (IVC App, IVC), a web-based application designed for measurements of vital signs including pulse rate (PR). Your Investigator will explain the clinical study to you. Clinical studies include only people who choose to take part voluntarily, after considering all the information in this document. Please take your time to make your decisions about taking part.

Clinical studies help us improve and grow our knowledge on the safety and effectiveness of investigational devices. For this reason, the law requires that investigational devices must be clinically tested. As required by law, this clinical study has been reviewed by an Institution Review Board, (IRB) and the United States Food and Drug Administration (FDA). This clinical study will be conducted in the United Sates. The clinical study is being investigated, organized, and financed by Mindset Medical, LLC.

Your participation in this clinical study is voluntary. Therefore, you will only be included in the clinical study if you give your written consent. You may choose to not participate, or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. The Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

Please do not hesitate to discuss questions with your Investigator. Afterward, you will be given plenty of time to think about whether you wish to take part in this study before you will be asked to decide.

WHY IS THE CLINCIAL STUDY BEING CONDUCTED?
The clinical study involves research. The objective of this study is to evaluate the investigational software (IVC APP, IVC) as a simple and non-invasive way to measure vital signs. This is a research study to test a new software application detecting Pulse Rate (PR). This study will compare the PR measurement using the IVC App to the heart rate (HR) measured by an electrocardiogram (ECG) device (reference device).

It is hypothesized that the accuracy of the IVC App is non-inferior to the accuracy of an FDA-cleared/approved vital sign monitoring device (reference device). This research is to evaluate the accuracy of measurement for each Pulse Rate vital sign with the IVC App, compared to appropriate reference devices.

You are being asked to participate in this research study because you are between the ages of 22-85.

WHAT INFORMATION WILL BE COLLECTED AND USED FOR THIS STUDY?
The study staff working on the study will collect information about you. This includes your health information.

Data collected will be entered into the electronic data capture (EDC) system and used for analysis.

The following data will be collected:

- Date of Birth/Age
- Gender
- Ethnicity
- Skin Tone as rated by the Fitzpatrick Scale
- Facial variables (glasses, facial hair, facial tattoos, and/or makeup)
- Cardiac Medical History
- Chronic Medical Conditions
- Pulse Rate taken by IVC App (conducted twice)
- Heart Rate taken by ECG (conducted twice)

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do, we will not identify you. Only summarized data from the entire study will be presented.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

HOW MANY PEOPE WILL TAKE PART IN THE STUDY?
About 85 people will take part in the study.

The study will recruit volunteers from clinics, hospitals, and the general public.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?
If you decide to take part in the clinical study, you will complete the entire study today.

The duration of the study is one day.

Table 1 – Overview of study activities/visit schedules

	Screening /Baseline Day 1
Study Visit/Day	**Visit 1**
Informed Consent	X
Eligibility	X
Demographics	X
Fitzpatrick Scale Assignment**	X
Medical History	X
Concomitant Medication (medications you are taking)	X
Adverse Event Form (If applicable)	X
Pulse Rate (IVC)*	X
ECG (reference device)*	X

**The collection of pulse rate from the IVC App and HR from ECG reference device should be taken twice for all subjects.*
***Investigator to perform*

During this one visit you will be asked to read and sign this informed consent form prior to participating in any study-related activities. After you have provided your consent for study participation, you will be asked a series of questions related to your eligibility into this study, demographic, relevant medical history, and relevant medications. You will also be visually evaluated by the Investigator for your skin type, using the Fitzpatrick Classification Scale for Skin Types. One image of your face will be captured to be used by the Sponsor to evaluate lighting, environmental conditions, and your Fitzpatrick Classification Scale Skin Type. All the information will be collected and used for evaluation purposes at the end of the study and will not contain any Protected Health Information (PHI).

You will not be able to wear a mask or bandage that obstructs your forehead, cheeks, or chin. You will need to agree to remove makeup, sunscreen, lotion, clothing, or items obstructing the face for the duration of the measurement. You will also need to be able to remain still for 60 seconds at a time.

You will be attached to an ECG device using 3 disposable tab electrodes attached to the inside of your left forearm, the inside of your right forearm, and just above the inside of the left ankle

to read the ECG results. At the same time you will be asked to sit still for one minute looking at the phone in the stand while the IVC App takes measurements of your face.

You will then be asked if there were any adverse events (side effects) that you experienced while in the study.

HOW LONG WILL I BE IN THIS STUDY?
Your participation in this study is less than one hour unless there is a technical issue encountered, in which case you will be asked to come back and complete the visit if the study is still enrolling subjects.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?
There are no foreseeable risks or known side effects to this study.

There may be slight discomfort from remaining still for 1 minute.

Skin irritation is rare but could occur during an ECG from the electrodes or gel that is used.

You will have photographs of your face taken for this study. It is possible that your face may be recognizable and your identity may be known.

UNFORESEEN RISKS
Since the study is using investigational software, there may be other risks that are unknown but it is highly unlikely.

ARE THERE BENEFITES TO TAKING PART IN THE STUDY?
This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

Since the IVC App is a web-based application, it can easily be utilized at hospitals (replacing vital signs carts), physician offices, clinics, and at patient's homes without the need for a trained nurse to capture the vitals. The IVC App can easily be utilized at a patient's home without the need to purchase specialized equipment.

Traditional pulse rate devices rely on physical contact of a patient, either placed on a wrist, arm, fingertip, or some other part of the body. This IVC App does not require any physical contact of a patient, rather they will simply look directly into the camera embedded on the phone device.

ALTERNATIVES
This research study is for research purposes only. The only alternative is to not participate in this study.

COMPENSATION FOR PARTICIPATION
«Compensation»

You will be paid up to a total of $75.00 if you complete this study. If you have any questions regarding your compensation for participation, please contact the study staff.

CONFIDENTIALITY
Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

To make sure that the health information collected in this study is accurate, it will need to be checked from time to time against your medical records. Some persons may need to see these records in order to monitor the research and verify the accuracy of the study data, including:

- A limited number of representatives from the study sponsoring company (namely its monitors and auditors),
- The institutional review board – Advarra IRB (an independent committee that reviewed the aspects of this study to help protect the rights and welfare of study subjects),
- Government regulatory authorities including, the US Food and Drug Administration (FDA) and other foreign regulatory agencies.

Your study records including confidential information about you collected during the study will be kept at a secure location.

While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.

By signing this information and consent form, you consent to the collection, access, use and disclosure of your information as described above.

COMPENSATION FOR INJURY
If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are

participating in this study. If you tell the study staff that you think you have been injured, then they will help you get the care you need.

If you are injured as a result from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. By signing this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

COSTS
There will be no charge to you for your participation in this study. The study device, study-related procedures, and study visit will be provided at no charge to you or your insurance company.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600

Columbia, MD 21044

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00070500.

PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

❒**YES** (If yes, please complete the information below)
❒**NO**

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

_____

Subject's Printed Name

_____ _____

Subject's Signature Date

_____

Printed Name of the Person Conducting the Consent Discussion

_____ _____

Signature of the Person Conducting the Consent Discussion Date

CONSENT FOR OPTIONAL SUBSTUDY
You are also being asked to participate in an optional substudy.

"Informed Vital Core, Data Collection Protocol (Respiratory Rate, Pulse Oxygen Saturation, and Blood Pressure)" is the substudy.

If you leave the substudy for any reason, the Investigator may ask you to have some end-of-study tests for your safety (for example, if you have experienced any adverse or serious adverse events while participating in the substudy.

WHY IS THE CLINICAL SUBSTUDY BEING CONDUCTED?
The scope of this substudy is to gather data from an FDA approved device called the Masimo MightySat Rx Fingertip Pulse Oximeter and/or Caretaker Vital Stream continuous blood pressure device) while gathering real-time environmental images to improve the measurement of pulse rate (PR), respiratory rate (RR), blood oxygen saturation (SpO2), and blood pressure (BP) for the purpose of training the algorithms of the IVC App.

You will be asked to provide four measurements of either SpO2 or blood pressure. You may be asked to do four measurements of one or the other, or a combination of two sessions of each, etc.

You will be asked to sit for 120 seconds while the IVC App takes continuous photos of your face and/or fingertip while you wear the reference device.

WHAT INFORMATION WILL BE COLLECTED AND USED FOR THIS SUBSTUDY?
- Sex
- Race
- Ethnicity
- Skin Tone as rated by the Fitzpatrick Scale
- Age
- Height/Weight
- Facial variables (glasses, facial hear, facial tattoos, and/ or makeup)
- Permission to collect photos. You will be asked to sit for 120 seconds while the IVC APP takes continuous photos of your face and/ or fingertip.
- Pulse Rate, Respiratory rate, SpO2, and Blood Pressure

RISKS
You will have photographs of your face taken for this substudy. It is possible that your face may be recognizable and your identity may be known.

There may be other risks that are unknown.

BENEFITS
This substudy is for research purposes only. There is no direct benefit to you from your participation in the substudy. Information learned from the substudy may help other people in the future.

ALTERNATIVES
This research substudy is for research purposes only. The only alternative is to not participate in this substudy.

CONFIDENTIALITY
Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

COMPENSATION FOR INJURY
If you become ill or are injured while you are in the substudy, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this substudy. If you tell the study staff that you think you have been injured then they will help you get the care you need.

If you are injured as a result of procedures done for the purpose of this substudy, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage. By signing this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

COMPENSATION FOR PARTICIPATION
«Compensation»

You will be paid up to a total of $75.00 for 4 data collection sessions if you complete this substudy.

If you have any questions regarding your compensation for participation, please contact the study staff.

There will be no charge to you for your participation in this substudy.

You may decide not to participate in the optional substudy or you may choose to withdraw from the substudy for any reason. If you decide not to participate in the substudy, your decision will have no impact on your ability to participate in the initial study and will have no impact on any other benefits to which you would otherwise be entitled.

The Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

Please indicate your preference below:

❒**YES** _____ **(initials)** I agree to participate in the substudy described above.

❒**NO** _____ **(initials)** I do not agree to participate in the substudy described above.

_____
Subject's Printed Name

_____ _____
Subject's Signature Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the Investigator and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name
- Address
- Phone number
- Date of birth
- Medical history
- Information from your study visits, including all test results

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Mindset Medical, LLC
- Representatives of Total Clinical Trial Management (TOTAL CRO)
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study)
- The Food and Drug Administration (FDA) and other US federal and state agencies
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported
- Governmental agencies of other countries
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study
- Other research doctors and medical centers participating in this study, if applicable

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study device/Software works and is safe
- To compare the study device/Software to other devices/Software
- For other research activities related to the study device/Software

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the Investigator at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data from your doctor.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____

Printed Name of Subject

_____ _____

Signature of Subject Date

No.	Site Name	PI Name	Staff	Credentials	Phone #	Role	Address	City	State	Zip Code
301	Velocity Clinical Research	Gregg Lucksinger	Victor Haas	BS, GCP, IATA	512-506-8287	Coordinator	1900 Cypress Creek, Suite 200	Cedar Park	Texas	78613
301	Velocity Clinical Research	Gregg Lucksinger	Valencia Smith	MA, GCP, IATA	512-506-8287	Coordinator	1900 Cypress Creek, Suite 200	Cedar Park	Texas	78613
301	Velocity Clinical Research	Gregg Lucksinger	Amy Vester	BS, GCP, IATA, BLS	512-506-8287	Coordinator	1900 Cypress Creek, Suite 200	Cedar Park	Texas	78613
301	Velocity Clinical Research	Gregg Lucksinger	Angel Cervantes	GCP, IATA	512-506-8287	Coordinator	1900 Cypress Creek, Suite 200	Cedar Park	Texas	78613
301	Velocity Clinical Research	Gregg Lucksinger	Tambra Dora	Certified Medical Assistant, Phlebotomy, CPR, GCP,	512-506-8287	Coordinator	1900 Cypress Creek, Suite 200	Cedar Park	Texas	78613
301	Velocity Clinical Research	Gregg Lucksinger	Therese Spalding	RN, IATA, BLS, GCP, CPR	512-506-8287	Coordinator	1900 Cypress Creek, Suite 200	Cedar Park	Texas	78613
301	Velocity Clinical Research	Gregg Lucksinger	Yasmin Mota	NRCMA, CPR, BCLS, IATA, GCP	512-506-8287	Coordinator	1900 Cypress Creek, Suite 200	Cedar Park	Texas	78613
302	Velocity Clinical Research	Marian Shaw	Kate Lyon	CPR, GCP	208-377-8653	Coordinator	2950 E. Magic View Dr., Suite 182	Meridian	Idaho	83642
302	Velocity Clinical Research	Marian Shaw	Paula Dockstader	CPhT, CPR, GCP	208-377-8653	Coordinator	2950 E. Magic View Dr., Suite 182	Meridian	Idaho	83642
302	Velocity Clinical Research	Marian Shaw	Audra Weslowski	GCP, IATA	208-377-8653	Coordinator	2950 E. Magic View Dr., Suite 182	Meridian	Idaho	83642
302	Velocity Clinical Research	Marian Shaw	Erika Calhoun	AS, GCP	208-377-8653	Coordinator	2950 E. Magic View Dr., Suite 182	Meridian	Idaho	83642
302	Velocity Clinical Research	Marian Shaw	Westin Payne	BA, GCP	208-377-8653	Coordinator	2950 E. Magic View Dr., Suite 182	Meridian	Idaho	83642
302	Velocity Clinical Research	Marian Shaw	Cecelia Pena	BS, IATA, GCP	208-377-8653	Coordinator	2950 E. Magic View Dr., Suite 182	Meridian	Idaho	83642
302	Velocity Clinical Research	Marian Shaw	Ronnie Moore	AS, GCP	208-377-8653	Research Assistant	2950 E. Magic View Dr., Suite 182	Meridian	Idaho	83642
302	Velocity Clinical Research	Marian Shaw	Tyler Scoggins	BA, GCP	208-377-8653	Research Assistant	2950 E. Magic View Dr., Suite 182	Meridian	Idaho	83642
304	Velocity Clinical Research	Margaret Rhee	Alanna Billups	BA, CITI Protection of Human Services, CITI GCP for	216-682-0320	Coordinator	3619 Park East Dr., Suite 300	Cleveland	Ohio	44122
304	Velocity Clinical Research	Margaret Rhee	Maggie Jedlinsky	MSW, BSW (Bach. of Social Work), ACRP GCP cert.	216-682-0320	Coordinator	3619 Park East Dr., Suite 300	Cleveland	Ohio	44122
304	Velocity Clinical Research	Margaret Rhee	Cameron Robinson	BS, ACRP GCP	216-682-0320	Coordinator	3619 Park East Dr., Suite 300	Cleveland	Ohio	44122
304	Velocity Clinical Research	Margaret Rhee	Casssie Uminski	Community College, Health Carreers Program	216-682-0320	Data Entry Coordinator	3619 Park East Dr., Suite 300	Cleveland	Ohio	44122
304	Velocity Clinical Research	Margaret Rhee	Jane Boggan	CITI GCP (health info privacy/security for clinical),	216-682-0320	Data Entry Coordinator	3619 Park East Dr., Suite 300	Cleveland	Ohio	44122
304	Velocity Clinical Research	Margaret Rhee	Lisle Merriman	BA, CITI human subjects research GCP & HIPS, GCP for	216-682-0320	Data Entry Coordinator	3619 Park East Dr., Suite 300	Cleveland	Ohio	44122
305	Velocity Clinical Research	Greg Feldman, MD, CPI	Keith Cullum	Associate degree (x2), BLS, IATA, ACRP intro to GCP	803-766-2680	Site Operations Manager	1655 Bernardin Ave. Suite 300	Columbia	South Carolina	29204
305	Velocity Clinical Research	Greg Feldman, MD, CPI	Laura Weier	BS	803-766-2680	Coordinator	1655 Bernardin Ave. Suite 300	Columbia	South Carolina	29204
305	Velocity Clinical Research	Greg Feldman, MD, CPI	Brandon Harp	MHA, BS (x2)	803-766-2680	Coordinator	1655 Bernardin Ave. Suite 300	Columbia	South Carolina	29204
305	Velocity Clinical Research	Greg Feldman, MD, CPI	Sharon Williams	Phlebotomy certification	803-766-2680	Research Assistant	1655 Bernardin Ave. Suite 300	Columbia	South Carolina	29204
305	Velocity Clinical Research	Greg Feldman, MD, CPI	Catherine Mann	Technical college (3 areas), CPR, ACRP GCP Simulation,	803-766-2680	Research Assistant	1655 Bernardin Ave. Suite 300	Columbia	South Carolina	29204
305	Velocity Clinical Research	Greg Feldman, MD, CPI	DeAnn Tucker	BBA, Associate of Arts, foster care courses	803-766-2680	Regualtory Coordinator	1655 Bernardin Ave. Suite 300	Columbia	South Carolina	29204
306	Velocity Clinical Research	Lawrence J. Sindel, MD	Jessica Miller, RN	RN	251-263-5669	Coordinator	3715 Dauphin St, Bldg 2, Ste 503B	Mobile	Alabama	36608
306	Velocity Clinical Research	Lawrence J. Sindel, MD	Myia McMillian, B.S., Assistant CRC	BS, Assistant CRC,	251-263-5669	Coordinator	3715 Dauphin St, Bldg 2, Ste 503B	Mobile	Alabama	36608
306	Velocity Clinical Research	Lawrence J. Sindel, MD	Laura Hill	BS, CCRC	251-263-5669	Coordinator	3715 Dauphin St, Bldg 2, Ste 503B	Mobile	Alabama	36608
306	Velocity Clinical Research	Lawrence J. Sindel, MD	Mike Weichman	N/A	251-263-5669	Research Assistant	3715 Dauphin St, Bldg 2, Ste 503B	Mobile	Alabama	36608
306	Velocity Clinical Research	Lawrence J. Sindel, MD	Robyn Robertson	Administrative Clinical Assistant, CITI GCP, IATA, OSHA E	251-263-5669	Regulatory Coordinator	3715 Dauphin St, Bldg 2, Ste 503B	Mobile	Alabama	36608
306	Velocity Clinical Research	Lawrence J. Sindel, MD	Danny Kakish	GCP	251-263-5669	Coordinator	3715 Dauphin St, Bldg 2, Ste 503B	Mobile	Alabama	36608
307	Velocity Clinical Research	J. Scott Overcash, MD	Lakeyla Bates	BA, AA, ACPR Intro to GCP, CITI IRB Chair, ACRP	619-567-1550	Senior Regulatory Specialist	5565 Grossmont Center Dr, Bldg 2, Suite 1	La Mesa	California	91942
307	Velocity Clinical Research	J. Scott Overcash, MD	Angela Anorve	BS, ACRP GCP, OSHA Bloodborne Pathogen	(619) 567-1550	Coordinator	5565 Grossmont Center Dr, Bldg 2, Suite 1	La Mesa	California	91942
307	Velocity Clinical Research	J. Scott Overcash, MD	Ashliegh Lindsay	CPT I, Phlebotomy program, college (current), CA	(619) 567-1550	Coordinator	5565 Grossmont Center Dr, Bldg 2, Suite 1	La Mesa	California	91942
307	Velocity Clinical Research	J. Scott Overcash, MD	Audrey Sanchez	Clinical Research Coordinator, BA,	(619) 567-1550	Coordinator	5565 Grossmont Center Dr, Bldg 2, Suite 1	La Mesa	California	91942
307	Velocity Clinical Research	J. Scott Overcash, MD	Hunter Asmann	BBA (bachelor's of business administration), GCP for	(619) 567-1550	Coordinator	5565 Grossmont Center Dr, Bldg 2, Suite 1	La Mesa	California	91942
307	Velocity Clinical Research	J. Scott Overcash, MD	Keji Kubari	BS	(619) 567-1550	Coordinator	5565 Grossmont Center Dr, Bldg 2, Suite 1	La Mesa	California	91942
307	Velocity Clinical Research	J. Scott Overcash, MD	Kevin Fong	BA, Teaching english as a foregin language, GCP (intro	(619) 567-1550	Data Entry Coordinator	5565 Grossmont Center Dr, Bldg 2, Suite 1	La Mesa	California	91942
307	Velocity Clinical Research	J. Scott Overcash, MD	Stephanie Esquer-Soto	Phlebotomy, Certified Phlebotomy Tech	(619) 567-1550	Data Entry Coordinator	5565 Grossmont Center Dr, Bldg 2, Suite 1	La Mesa	California	91942
307	Velocity Clinical Research	J. Scott Overcash, MD	Sylvia Lindholm	CPR, CITI HIPS, NIH Protecting Human Research Particip	(619) 567-1550	Coordinator	5565 Grossmont Center Dr, Bldg 2, Suite 1	La Mesa	California	91942
307	Velocity Clinical Research	J. Scott Overcash, MD	Pat Kappen, CCRP	CCRP, Edu. in Clinical Trials Design/Management, Certif	(619) 567-1550	Regulatory Coordinator	5565 Grossmont Center Dr, Bldg 2, Suite 1	La Mesa	California	91942

Listing 16.2.1.1
Subject Disposition
All-Enrolled Population

Subject ID	Date of Informed Consent	Completion or Discontinuation Date	Status	Reason for Discontinuation	ITC Population	PP Population	Reason ITC subject is excluded from PP population
301-001	02JUN2023	02JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
301-002	02JUN2023	02JUN2023	COMPLETED		Yes	Yes	
301-003	09JUN2023	09JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
301-004	12JUN2023	12JUN2023	COMPLETED		Yes	Yes	
301-005	13JUN2023	13JUN2023	COMPLETED		Yes	Yes	
301-006	13JUN2023	13JUN2023	COMPLETED		Yes	Yes	
301-007	14JUN2023	14JUN2023	DISCONTINUED	SCREEN FAILURE	No	No	
301-008	14JUN2023	14JUN2023	COMPLETED		Yes	Yes	
301-009	15JUN2023	15JUN2023	COMPLETED		Yes	Yes	
301-010	16JUN2023	16JUN2023	COMPLETED		Yes	Yes	
301-011	16JUN2023	16JUN2023	COMPLETED		Yes	Yes	
301-012	16JUN2023	16JUN2023	COMPLETED		Yes	Yes	
301-013	20JUN2023	20JUN2023	COMPLETED		Yes	Yes	
301-014	20JUN2023	20JUN2023	COMPLETED		Yes	Yes	
301-015	21JUN2023	21JUN2023	COMPLETED		Yes	Yes	
301-016	21JUN2023	21JUN2023	COMPLETED		Yes	Yes	
301-017	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
301-018	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
301-019	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	

ITC = Intent-to-Capture, PP = Per-Protocol

Listing 16.2.1.1
Subject Disposition
All-Enrolled Population

Subject ID	Date of Informed Consent	Completion or Discontinuation Date	Status	Reason for Discontinuation	ITC Population	PP Population	Reason ITC subject is excluded from PP population
301-020	23JUN2023	23JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
301-021	26JUN2023	26JUN2023	COMPLETED		Yes	Yes	
301-022	27JUN2023	27JUN2023	COMPLETED		Yes	Yes	
302-001	02JUN2023	02JUN2023	COMPLETED		Yes	Yes	
302-002	05JUN2023	05JUN2023	COMPLETED		Yes	Yes	
302-003	06JUN2023	06JUN2023	COMPLETED		Yes	Yes	
302-004	07JUN2023	07JUN2023	COMPLETED		Yes	Yes	
302-005	07JUN2023	07JUN2023	COMPLETED		Yes	Yes	
302-006	13JUN2023	13JUN2023	COMPLETED		Yes	Yes	
302-007	14JUN2023	14JUN2023	COMPLETED		Yes	Yes	
302-008	14JUN2023	14JUN2023	COMPLETED		Yes	Yes	
302-009	15JUN2023	15JUN2023	COMPLETED		Yes	Yes	
302-010	15JUN2023	15JUN2023	COMPLETED		Yes	Yes	
302-011	16JUN2023	16JUN2023	COMPLETED		Yes	Yes	
302-012	16JUN2023	16JUN2023	COMPLETED		Yes	Yes	
302-013	20JUN2023	20JUN2023	COMPLETED		Yes	Yes	
302-014	21JUN2023	21JUN2023	COMPLETED		Yes	Yes	
302-015	21JUN2023	21JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
302-016	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
302-017	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	

ITC = Intent-to-Capture, PP = Per-Protocol

Listing 16.2.1.1
Subject Disposition
All-Enrolled Population

Subject ID	Date of Informed Consent	Completion or Discontinuation Date	Status	Reason for Discontinuation	ITC Population	PP Population	Reason ITC subject is excluded from PP population
302-018	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
302-019	23JUN2023	23JUN2023	COMPLETED		Yes	Yes	
302-020	27JUN2023	27JUN2023	COMPLETED		Yes	Yes	
302-021	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
304-001	20JUN2023	20JUN2023	COMPLETED		Yes	Yes	
304-002	20JUN2023	20JUN2023	DISCONTINUED	PROTOCOL DEVIATION	No	No	Rhythm strip not uploaded
304-003	21JUN2023	21JUN2023	COMPLETED		Yes	Yes	
304-004	21JUN2023	21JUN2023	COMPLETED		Yes	Yes	
304-005	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
304-006	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
304-007	27JUN2023	27JUN2023	COMPLETED		Yes	Yes	
304-008	27JUN2023	27JUN2023	COMPLETED		Yes	Yes	
304-009	27JUN2023	27JUN2023	COMPLETED		Yes	Yes	
304-010	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
304-011	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
304-012	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
304-013	29JUN2023	29JUN2023	COMPLETED		Yes	Yes	
305-001	06JUN2023	06JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
305-002	06JUN2023	06JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
305-003	08JUN2023	08JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded

ITC = Intent-to-Capture, PP = Per-Protocol

Listing 16.2.1.1
Subject Disposition
All-Enrolled Population

Subject ID	Date of Informed Consent	Completion or Discontinuation Date	Status	Reason for Discontinuation	ITC Population	PP Population	Reason ITC subject is excluded from PP population
305-004	09JUN2023	09JUN2023	COMPLETED		Yes	Yes	
305-005	23JUN2023	23JUN2023	COMPLETED		Yes	Yes	
305-006	23JUN2023	23JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
305-007	26JUN2023	26JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
305-008	26JUN2023	26JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
305-009	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
305-010	29JUN2023	29JUN2023	COMPLETED		Yes	Yes	
305-011	29JUN2023	29JUN2023	DISCONTINUED	OTHER	No	No	Study closed prior to assessment.
305-012	29JUN2023	29JUN2023	COMPLETED		Yes	Yes	
306-001	22JUN2023	22JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
306-002	22JUN2023	22JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
306-003	26JUN2023	26JUN2023	COMPLETED		Yes	Yes	
306-004	26JUN2023	26JUN2023	COMPLETED		Yes	No	The reference device does not collect data
306-005	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
306-006	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
306-007	29JUN2023	29JUN2023	COMPLETED		Yes	Yes	
307-001	14JUN2023	14JUN2023	COMPLETED		Yes	Yes	
307-002	14JUN2023	14JUN2023	COMPLETED		Yes	Yes	
307-003	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
307-004	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	

ITC = Intent-to-Capture, PP = Per-Protocol

Listing 16.2.1.1
Subject Disposition
All-Enrolled Population

Subject ID	Date of Informed Consent	Completion or Discontinuation Date	Status	Reason for Discontinuation	ITC Population	PP Population	Reason ITC subject is excluded from PP population
307-005	22JUN2023	22JUN2023	COMPLETED		Yes	No	The reference device does not collect data
307-006	23JUN2023	23JUN2023	COMPLETED		Yes	Yes	
307-007	23JUN2023	23JUN2023	DISCONTINUED	SCREEN FAILURE	No	No	
307-008	23JUN2023	23JUN2023	COMPLETED		Yes	Yes	
307-009	26JUN2023	26JUN2023	COMPLETED		Yes	Yes	
307-010	26JUN2023	26JUN2023	COMPLETED		Yes	No	Thumb drive not recognized by pixel phone. USB was sent back to sponsor for review on 7/20/23
307-011	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	

ITC = Intent-to-Capture, PP = Per-Protocol

Protocol Number: IVC-400-006

Informed Vital Core Application (IVC App)
Statistical Analysis Plan

A Multi-Center Prospective Open Label Study of a Web-based Application for Pulse Rate in Adult Patients

Mindset Medical, LLC
Version 3
Date: June 22, 2023

Signature Table

Name	Signature	Date
Elaine Thompson Study Biostatistician/ Biostatistician Review		
Dan Lubelski, M.D. Medical Reviewer		
Kereshmeh Shahriari Regulatory Reviewer		

Summary of Changes

Original	Amendment Change	Reason for Change
Original release	N/A	
Version 2	Throughout – updated protocol version and date, updated study design, Fitzpatrick numbers, UADE language, and total sessions collected to two.	Update to Clinical Protocol.
	Throughout - updated reference device from Kardia to Edan. Updated language from PR to HR throughout the document in sections that reference the Edan ECG. Removed reference to Bluetooth.	Change in reference device.
	Product description updated to current language.	Specified language
	Throughout – confidentiality notice added to footer, added summary of changes table, minor edits to improve clarify and consistency.	Document Versioning
	Removed duplicative information that is in the Clinical Protocol.	Organization
	Updated ITC group description for new 12 RR-interval analysis and to add clarification of the disposition of subjects who withdraw during collection.	Clarity
	Removed all non-applicable sections.	
	Clarified descriptive statistics.	
	Moved power analysis to the end, added reference.	
	Added health condition and conmeds coding.	

Original	Amendment Change	Reason for Change
Version 3	Section 6.2 updated the Fitzpatrick 5 or 6 group to 15% of the Per Protocol group and included language for targeted enrollment if needed.	Specified language

Contents

List Of Abbreviations

The following abbreviations and special terms are used in this Statistical Analysis Plan.

Abbreviation or special term	Explanation
AE	Adverse Event
ARMS	Average Root Mean Square
BMI	Body Mass Index
BP	Blood Pressure
BPM	Beats per Minute
CI	Confidence Interval
CSR	Clinical Study Report
ECG	Electrocardiogram
eCRF	electronic Case Report Form
EDC	Electronic Data Capture
FDA	Food and Drug Administration
HR	Heart Rate
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IRB	Institutional Review Board
ITC	Intent-to-Capture
IVC App	Informed Vital Core Application
MedDRA	Medical Dictionary for Regulatory Activities
PP	Per Protocol
PR	Pulse Rate
PT	Preferred Term
PPG	Photoplethysmography
RGB	Red, Green, and Blue
RMS	Root Mean Square
rPPG	Remote Photoplethysmography
RR	The time elapsed between two successive R waves of the QRS signal on the electrocardiogram (and its reciprocal, the HR).
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
UADE	Unanticipated Adverse Device Effect

1.0 Introduction

This documentation describes the planned data analyses for clinical study IVC-400-006 sponsored by Mindset Medical, LLC.

This SAP supersedes the statistical considerations identified in the protocol; where considerations are substantially different, and these differences will be identified. If additional analyses are required to supplement objectives described in the SAP, they may be performed and will be identified in the Clinical Study Report (CSR) or through an SAP addendum (as warranted).

Analyses described in the current SAP version is based on the protocol version 1 IVC-400-006 dated March 31, 2023.

2.0 Study Objectives and Endpoints

2.1 Study Objective

The primary objective of the study is to establish that pulse rate (PR) measured with the IVC App are accurate to within +/- 3 BPM ARMS (average root mean square) of Heart Rate (HR) measured with the reference ECG device.

2.1.1 Primary Endpoint

The primary endpoint is a non-inferiority comparison to an FDA approved reference device to establish that PR measured with the IVC App are accurate to an ARMS of +/- 3 BPM. In accordance with ISO 80601-2-61:2017(E) accuracy will be calculated as the RMS difference between the IVC App and the heart rate measured by the ECG reference device.

3.0 Study Hypothesis

The IVC App can measure pulse rate between 50 and 130 BPM to an accuracy of +/-3 BPM average RMS. The hypothesis will be tested in a non-inferiority design. PR will be collected simultaneously with the IVC App and HR with an ECG reference device, and the ARMS and its 95% confidence interval calculated. If the upper limit of the 95% confidence interval of the ARMS is < 3.0, the IVC App will be determined to be non-inferior and the hypothesis that it is accurate to an ARMS of +/- 3.0 accepted.

4.0 Statistical and Analytical Procedures

4.1 Analysis Populations and Collection Groups

The following populations will be considered for the study:

4.1.1 All-Enrolled Population

The All-Enrolled population will be defined as all subjects who signed the ICF. The number of screen failures and the reasons for failure will be tabulated and reported. Subjects who consent but withdraw before data collection will be tabulated and reported.

4.1.2 Intent-to-Capture Population (ITC)

The Intent-to-Capture (ITC) population will be defined as all consented subjects who passed screening and completed at least one data collection session without withdrawing.

4.1.3 Per-Protocol Population (PP)

In order to compare devices, subjects must have a simultaneous PR measurement from the IVC App and an HR measurement from the reference ECG device. Therefore, the Per Protocol analysis group for the primary endpoint will consist of subjects from whom PR measurement from the IVC App and a successful HR data collection from the ECG reference device were collected during the same window.

In preliminary testing of the ECG reference device, not all collections produced a rhythm strip suitable for analysis. The ECG data are processed after the subject's participation in the study ends, so there is no way to detect an unusable ECG collection during the study. In order to increase the likelihood of collecting usable ECG data, two sessions will be collected from each subject.

Subjects will be asked to collect up to 3 additional sessions as technical fallbacks if a collection failure occurs from the reference device or if conditions at the study site interfere with the functionality of the IVC App. Examples of technical difficulties include, but are not limited to, frozen or stuttering video during data capture, failure of the reference device to produce a rhythm strip, connection issues with the reference device, interruptions during data collection that require the subject to leave the camera frame, or upload failures.

4.1.4 Successful Data Collection

ECG rhythm analysis will be performed and calculated using a synchronized moving average across 12-RR intervals as described in IVC-400-006i – Informed Vital Core Heart Rate Rhythm Analysis Procedure. A successful data collection is defined as a session that produces a measurement from the IVC App and the ECG reference device where the moving average of the HR measurement from the reference device does not vary by more than 15 BPM during the 1 minute of measurement. A 15 BPM threshold is applied to the ECG data because variability in contact with the electrodes, subject movement, or atypical ECG waveforms can result in processing artifacts that appear as unrealistically large jumps or fluctuations in HR during the session. In instances where the reference HR is found to vary by more than 15 BPM, the second data collection session will be used for analysis.

The second session will not be treated as a fallback for the IVC App. The study is designed to represent a patient encounter with the IVC App. Under the intended use, if the IVC App cannot collect video from which a PR can be determined after prompts to stop moving or improve lighting, patients are instructed to retry up to twice. If the HR collection with the ECG reference device is successful but the IVC App does not produce a PR, the subject will be excluded from the PP analysis group and considered to be an IVC App collection failure.

All subjects in the ITC group who were not included in the PP group will be listed with the reason they were excluded from the analysis. Subjects will be excluded if the reference device does not collect data, the ECG

from both reference device collections is not suitable for rhythm analysis as defined above, or the IVC App does not report a PR during the first session where the ECG collection is successful.

A subject could withdraw before all data collection attempts and technical fallbacks are completed. If the subject has a successful collection, they will still be included in the PP group. Otherwise, they will be excluded from the PP group. If they completed an IVC App collection without a reference HR, that collection will be included when calculating the IVC App success rate as described in section 5.3.2.

4.1.5 Data Collection Groups

Simultaneous data collection from the ECG reference device and IVC App device will be performed on all subjects so there is only one data collection group.

4.2 Analysis Variables

4.2.1 Subject's Disposition and Analysis Sets

Disposition will be summarized descriptively with counts and percentages using the All-Enrolled population for both devices (IVC App and reference device) data collection and all Intent to Collect and all Per Protocol subjects. The number and percentage of subjects who prematurely discontinued from the study along with reasons for study discontinuation will be summarized as well.

A subject's eligibility with inclusion/exclusion criteria failed/met will be listed, along with the list of protocol deviations.

4.2.2 Demographics and Baseline Characteristics

Demographic data and baseline characteristics will include:

- Sex
- Ethnicity
- Race
- Fitzpatrick scale- Fitzpatrick scale skin tones will be grouped into light (Fitzpatrick 1 and 2), medium (Fitzpatrick 3 and 4) and dark (Fitzpatrick 5 and 6).
- Age (years)
- Height (cm)
- Weight (kg)
- BMI (kg/m^2)

Demographics and baseline characteristics will be tabulated and summarized as described in section 5.2.2.

The summary results will be based on the ITC population.

4.2.3 Health Conditions and Concomitant Medications

Self-reported health conditions will be coded using MedDRA, tabulated and reported.

Concomitant medications will be coded with WHODrug, tabulated, and reported.

The summary results will be based on the ITC population.

4.2.4 Endpoint Variables

The endpoint variables are the IVC App PR and ECG reference device HR.

Summary statistics of the HR and PR measured for each device within the PP group will be tabulated and reported as described in section 5.2.2.

Subjects in the PP group will be tabulated by IVC App PR in groups of 10 bpm and the number of subjects and percentages in each pulse rate group reported.

4.2.5 Subgroup Analysis

No subgroup analyses will be performed, since the study is not powered or sized for subgroup analysis.

4.2.6 Adverse Events (AE)

While adverse events are not anticipated in this clinical study, if the reason for removal of a subject from the study is an adverse event, the event will be recorded on the appropriate eCRF(s) and will be reported to Mindset Medical per the AE reporting guidelines (Required Reporting Timelines per Regulatory Guidance). All efforts will be made to follow the subject until the condition resolves, or the Investigator determines that the subject's health has returned to an acceptable state.

All verbatim AE terms will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) of the latest version and summarized by system organ class (SOC) and preferred term (PT).

An Unanticipated Adverse Device Effect (UADE) is "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 any nature, severity, or degree of incidence in the investigational plan or any other unanticipated serious problem associated with a device that relates to the rights, safety, and welfare of subjects.

All Life-Threatening AEs will be considered as Severe.

All AEs will be classified in one of two types of relation to device:

- Not Related
- Related (Definitely Related and Possibly Related)

AEs in the ITC population will be tabulated and summarized by type, severity, and MedDRA codes as described in section 5.2.2.

5.0 Statistical Methods

5.1 Software

The primary endpoint analyses will be performed using CRAN R Version 4.3.0 or higher using the boot package version 1.3-28.1 or above. Tables and listings will be produced using R and SAS version 9.4 (SAS Institute Inc.)

5.2 General Considerations

5.2.1 Listings

All study data will be included in the study data listings. Both the captured data and the MedDRA and WHODrug codes will be provided. Listings will be displayed by subject in chronological order, if not stated otherwise.

Study data will be provided in electronic format, either as SAS XPT V5 files or CSV files.

5.2.2 Descriptive Statistics and Summary Tables

The total number of subjects in the study group (N) under the stated population will be displayed in the header of summary tables.

For age, height, weight, and BMI, the mean, standard deviation, minimum and maximum will be presented along with the n size from which the statistics were calculated.

PR and HR data will be presented as median, lower, and upper quartiles, min, max, and n size because they were not normally distributed in product development data (5.1.4).

For categorical variables, count, and percentage of subjects/counts in each device group and/or category will be presented. Percentages will be based on number of subjects with non-missing values, if not specified otherwise.

5.3 Endpoint Data Analysis Methods

5.3.1 Primary Endpoint

For the primary endpoint analysis, the ARMS will be calculated as the square root of the mean difference between the devices, as described in ISO 80601-2-61:2017(E). All PP subjects will be included in the primary endpoint analysis. The 95% CI for the primary endpoint analysis will be determined by jackknifing 100,000 samples with replacement and calculating a 95% CI from the distribution of ARMS among the jackknifed samples. If the ARMS and its upper 95% confidence interval are below the target of 3.0, the device will be determined to be non-inferior.

A Bland-Altman plot will be constructed from the differences vs. the average measured PRs and HRs for all PP subjects to assist in visualizing the differences between devices and the full range of PR and HR measurements. Since the differences were not normally distributed due to the "white coat" effect on PR in the product development data, upper and lower 95th percentiles will be drawn on the graph to aid in visualization rather than two standard deviations. Visible outliers with greater than +/- 6.0 BPM difference from the reference device will be tabulated. A threshold of +/- 6.0 BPM will be considered outlying because under a labelled ARMS of +/- 3.0, 95% of the differences should fall in the range of +/- 6.0 BPM against the reference.

5.3.2 IVC App PR Reporting Rate

The overall PR reporting rate of the IVC App will be calculated from the ITC population. All subjects with an IVC App PR from the first non-fallback session will be counted as IVC App collections. The total count of subjects with IVC App collections will be divided by the count of subjects in the ITC group to calculate the overall PR reporting rate for the IVC App.

A second rate will be calculated as above, only excluding subjects who had no IVC App sessions collected due to repeated technical failures. The second rate reflects the proportion of subjects who were able to use the IVC App and is more reflective of proportion of sessions where a reliable PR can be determined from the analyzed video frames. The number of subjects excluded due to technical failures will also be reported.

6.0 BACKGROUND, SAMPLE SIZE

6.1 Power Analysis Methodology

Power analysis and enrollment percentages for the PR measures were based on data collected from 571 consented subjects who attempted one or more simultaneous data collections from a Masimo MightySat fingertip PPG device (reference device) and the IVC App. The data collection rate across the 571 subjects was used to determine how many subjects to enroll in order to meet the target n size for the non-inferiority analysis. Collection success defined as a successful data collection from the IVC App was 80.5% (95% CI of 79% - 82%).

The measured PRs from both the reference device and the IVC App had a high kurtosis, as did the differences between devices. Data were also not Box-Cox normal, so they were treated as nonparametric. Deviation from a normal distribution has previously been observed in measured PR during studies and is attributed to a "white coat" phenomenon, with people who have higher 24-hour resting heart rates showing a more pronounced increase (1).

Under the assumption that the IVC App is non-inferior to the reference device, at 90% power the upper bound of the bootstrapped 95% CI should fall below 3.0, 90% of the time. Subsampling the differences between the devices at systematically varied n sizes and calculating an ARMS and its 95% CI on each subsample gives a distribution of 95% confidence intervals for each n size. The distribution of confidence

intervals is used to determine power at that n size. Since the distribution of differences was nonparametric, 95% CI distributions were bagged (bootstrap aggregated). The bagging procedure was performed as follows:

1. A cohort of 475 or 484 subjects with one paired PR measurement each was established as described later.
2. Random subsamples with replacement were selected from the cohort at n sizes from 20 to 100 in intervals of 5. For each n size, 4,000 subsamples were generated.
3. The 95% confidence interval on the Arms was bootstrapped on each subsample by jackknifing with replacement 2,000 times.
4. The 95% confidence interval upper bounds were aggregated for each n size to produce a distribution of upper 95% confidence intervals.
5. 90th and 95th percentiles were calculated to find the power at each n size.

6.2 Power Analysis for Sample Size

A total of 85 subjects (n = 85) will be enrolled.

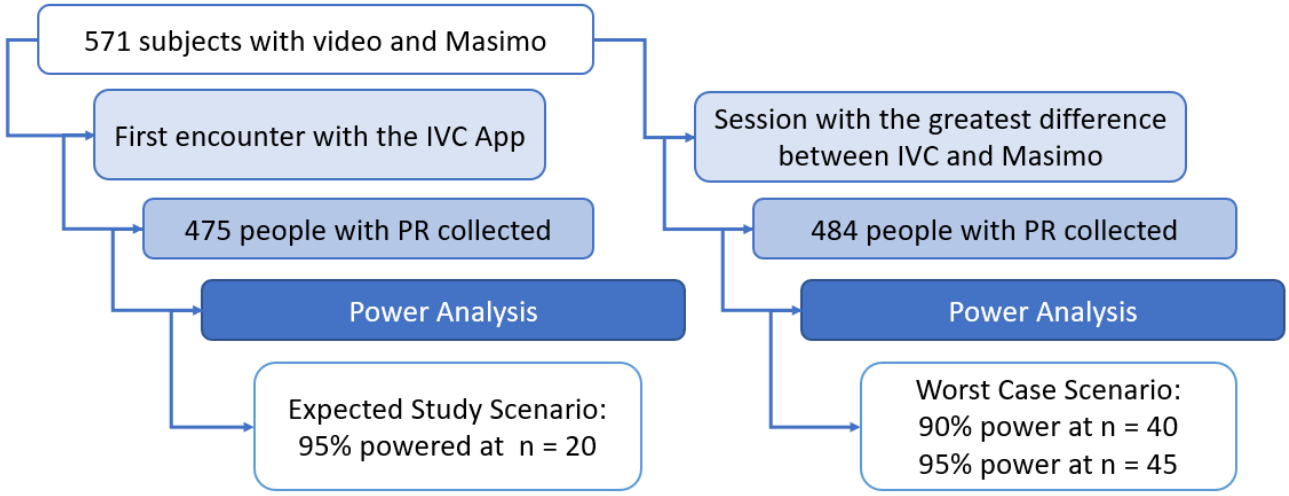


Figure 1. Power analysis workflow. The first sessions were selected as representative of the study design for the initial power analysis (left). A second set of sessions with the largest difference from the reference device were used in a conservative scenario (right).

A total of 475 subjects out of the 571 in the product development cohort had data collected the IVC App in from the first PR collection and were included in the initial power analysis. Only the first PR sessions were used in order to accurately model the clinical study design, where subjects will have only one IVC App collection. The overall ARMS was 0.9 BPM. The bagging procedure was performed on n sizes ranging from 20 to 100 subjects (Figure 2). At all n sizes in the analysis, the 95th percentile of the confidence intervals was below the target ARMS of 3.0. Thus, n sizes of 20 or greater are powered at 95%.

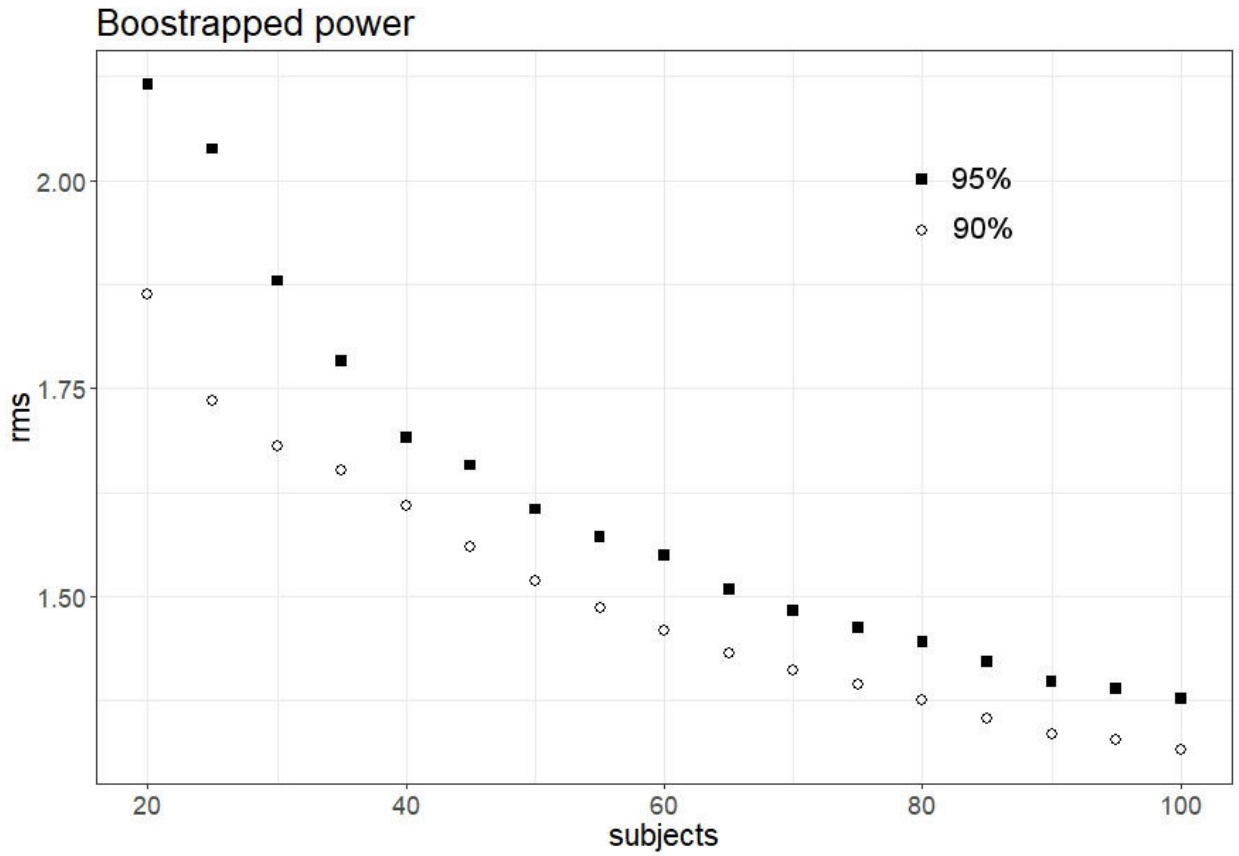


Figure 2. Bagging results for sample sizes ranging from 20 to 100. The filled-in squares show the 95th percentile and the open circles show the 90th percentile of the upper bound of the confidence intervals. The x-axis shows the sample size of the subsamples and the y-axis is the RMS. All 95th percentiles are below the target ARMS of 3.0.

As well as the first IVC App collection attempt used in the power analysis above, some of the subjects provided additional data collection sessions under varied conditions for product development. To perform a more conservative power analysis, the session with the largest absolute difference from the reference device was selected for each subject. The same bagging analysis over 484 “worst case” collections with an ARMS of 1.5 BPM showed 90% power with 40 subjects and 95% power with 45 subjects. The conservative power analysis was used to establish a PP group goal of 55 subjects to ensure that power is at or above 95%. Additionally, a sample size greater than 50 subjects ensures that the sample is likely to be representative of the IVC App performance under the Central Limit Theorem. Since the IVC App is designed to report only reliable results and inform the user that a PR could not be collected otherwise, not all sessions result in a successful PR measurement. As mentioned above, the PR collection rate for the IVC app was 80%, so the study will be overenrolled to reach the target PP group size. A total of 85 subjects will be enrolled, allowing for screening failures, withdrawals, technical failures, and sessions where the IVC App does not report a PR.

In order to ensure a diverse PP group, the enrollment target for the PP group is 15% in the dark (Fitzpatrick 5-6) skin tone group. Initially enrollment will be random, but targeted enrollment may be used to meet skin tone goals if the dark skin tone PP group is projected to fall below the 15% goal.

6.3 Safety Analysis

No safety analysis is planned. The IVC App is a remote device so no device related AEs are anticipated.

6.4 Exploratory Analyses

All exploratory analyses will be based on ITC and PP populations.

7.0 References

1) Paolo Palatini, Edoardo Casiglia, Paolo Pauletto, Jan Staessen, Niko Kaciroti and Stevo Julius. Relationship of Tachycardia With High Blood Pressure and Metabolic Abnormalities. A Study With Mixture Analysis in Three Populations. Hypertension 30:1267–1273 (1997). https://doi.org/10.1161/01.HYP.30.5.1267

Informed Vital Core
Rhythm Strip Analysis Procedure for IVC-400-006

IVC-400-006i
Rev. 1

Mindset Medical, LLC

Table of Contents

Contents

1. Introduction

Mindset Medical is the developer of the new, prescription use, Informed Vital Core Application (IVC App). The IVC App is intended to measure the vital signs including the pulse rate (PR). The IVC App will be available by prescription use, intended for use in hospitals, clinics, long-term care, and home and is designed to be used as a web-based application.

This procedure uses the rhythm strip from the Edan SE-301 ECG device to determine the heart rate measured by the ECG device during the Informed Vital Core Pulse Rate Clinical Study. The terms heart rate analysis and rhythm strip analysis may be used interchangeably in this document, as they are both defined as the procedure by which the Edan SE-301 ECG-produced rhythm strip is analyzed to determine a heart rate.

2. Scope

The scope of this document is limited to determining the heart rate obtained by the Edan SE-301 ECG device used in IVC-400-006 Pulse Rate Clinical Study. This document does not include the procedure for heart rate determination or analysis produced by the IVC App.

3. References

Document Number	Description
IVC-400-006	Informed Vital Core – Clinical Study Protocol
IVC-400-006g	Informed Vital Core – Clinical Study Site Instruction Guide: Pulse Rate

4. Procedure

Heart rate (HR) is calculated using lead-I from a 6-lead ECG taken with the Edan SE-301 (ECG). The ECG unit is configured to conduct a 60 second ECG recording conducted simultaneously with an IVC App PR measurement session. The results of the ECG recording are stored in a standardized XML format and are referred to as the ECG XML Rhythm Strip file(s) (or rhythm strip(s)). Simple averaging over the course of the session is not precise due to natural heart rate variability. In order to achieve high enough precision to validate the accuracy of the IVC App, the inter-session heart rate must match the measurement times reported by the ECG device.

A Python script (or script) reads the ECG XML Rhythm Strip files, aligns the data collection windows, and performs the heart rate analysis; calculating a heart rate that is accurately synchronized to the IVC App data collection window. The heart rates produced from the rhythm strip by the Python script will be used as the reference for the primary endpoint analysis.

The Python script has been validated on stable releases of standard publicly available libraries and runs in a virtual environment configured from a requirements text file that lists the specific packages and versions (Xie, et. al., 2023). Heart rate analysis is performed using the WFDB package described in Waveform Database Software Package (WFDB) for Python (version 4.1.0). The SHA # will be documented on the Rhythm Strip Analysis Report (RSAR). Validation of the procedure in Section 4.1 and 4.2 will be outlined in Appendix B.

4.1. General Procedure for Collecting ECG Rhythm Strip XML File

1. After the ECG measurement has been collected from the subject per the clinical study protocol, the clinical site staff will upload the ECG Rhythm Strip XML File to a shared drive per the IVC-400-006g Pulse Rate Clinical Study Site Instruction Guide.
2. The subject ID will be on the ECG Rhythm Strip XML file and the file will be copied by Mindset Medical staff to a file folder on SharePoint.
3. The Rhythm Strip Analysis Report will be stored on SharePoint.
4. The ECG Rhythm Strip XML files and Heart Rate Analysis Reports will be stored per 21 CFR 812.140 (b), (d), and (e) when the trial is complete.

4.2. Rhythm Strip Analysis of Electrocardiogram Signal for Reference Heart Rate

Steps involved for the Mindset Medical staff in generating the reference heart rate are listed below:

1. Access the ECG Rhythm Strip XML file from the SharePoint folder.
2. Download the metadata file produced by the IVC App.
3. Run the Python Script on the XML file and the IVC App metadata file. The script can be run from the command line in a Python virtual environment that enforces the version control with arguments that point to the ECG XML Rhythm Strip file and the IVC App metadata file. The Python script performs the following steps:
    a. Read the ECG Rhythms Strip XML file and return the lead-I signal in millivolts at a 1 kHz sample rate.
    b. Adjust for the 2.3 second buffer delay added by the Edan SE-301 to synchronize timing with the reference device clock.
    c. Apply the WFDB XQRS peak detection algorithm.
    d. Plot and save the ECG signal with peak markers for visual validation.
    e. Compute the moving average heart rate (HR-MA) by using a sliding window of 12 RR-intervals. Boundary values are imputed using expanding windows.
    f. Sample the HR-MA at the solution times reported by IVC App metadata and average.

4. Visual validation of the Rhythm Strip Analysis Report is performed by two Mindset Medical reviewers. The first review is the primary reviewer and the second reviewer will perform a quality control review.
    a. Discrepancies identified will be documented and reviewed by management for inclusion or exclusion in the final analysis.
5. The result is a single integer value for reference heart rate that is entered into the study electronic data capture system.

Note: The script will warn if there is a timing discrepancy or if the reference range violates the study protocol which can be included in the notes field.

5. References

Xie, C., McCullum, L., Johnson, A., Pollard, T., Gow, B., & Moody, B. (2023). Waveform Database Software Package (WFDB) for Python (version 4.1.0). *PhysioNet*. https://doi.org/10.13026/9njx-6322

Appendix A – Readme

- Create venv with Python 3.9.16
- pip install -r requirements.txt
- Run using command below

python edan_se301_ra.py file_name_ecg file_name_ivc timezone_name

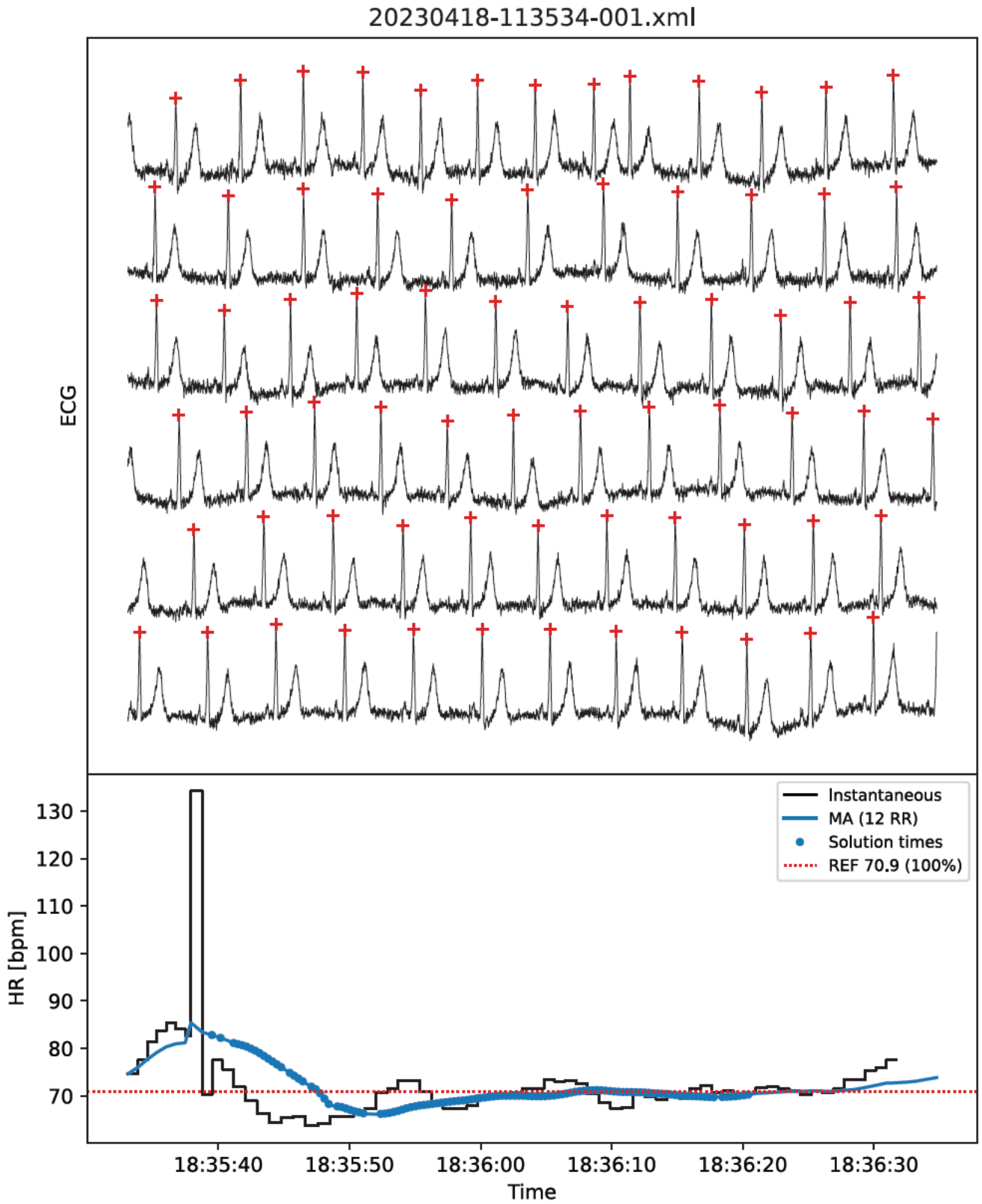
where timezone_name is US/Pacific or US/Mountain etc. Output prints hr reference value and saves ecg with annotations as pdf

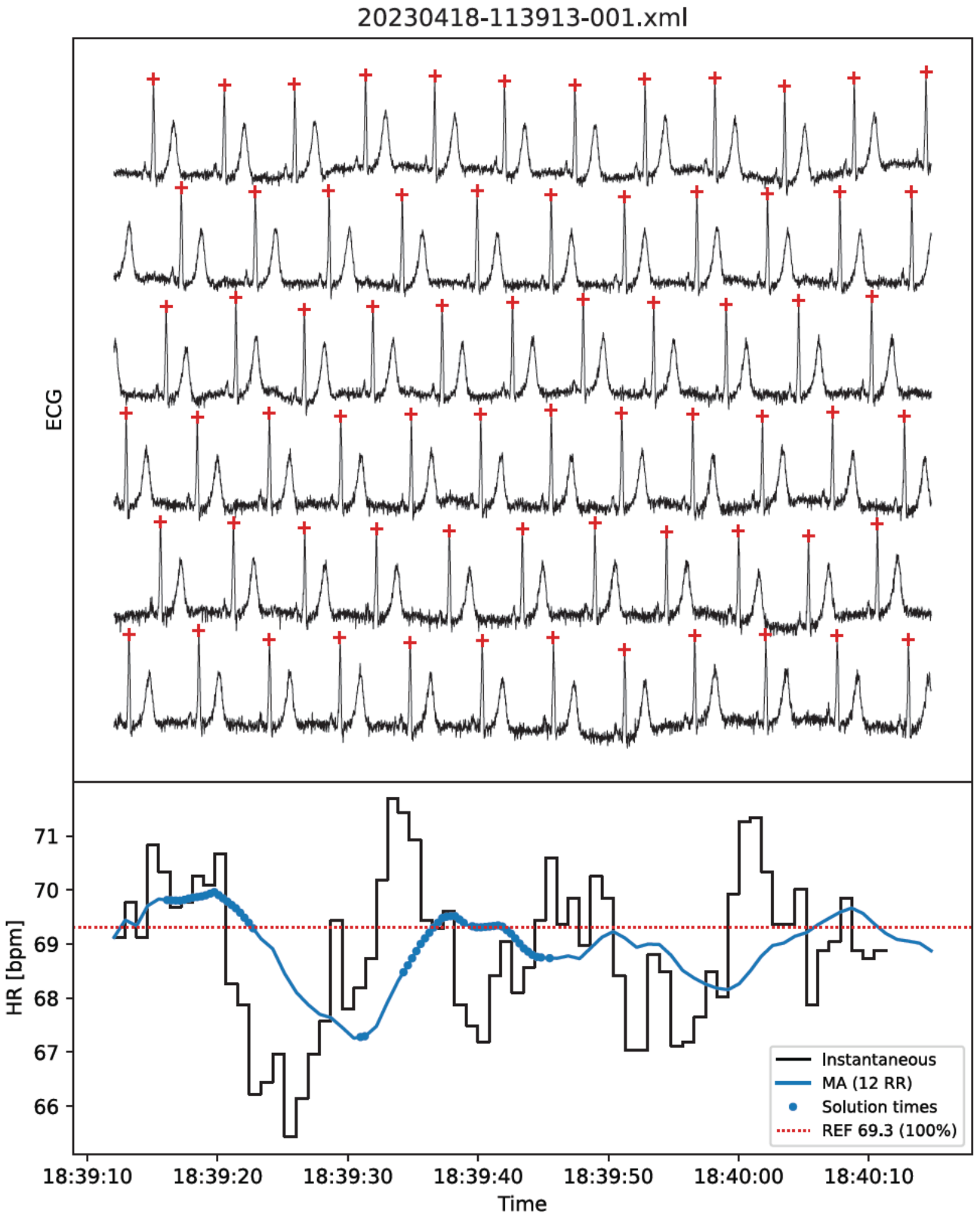
Appendix B – Rhythm Strip Analysis Validation

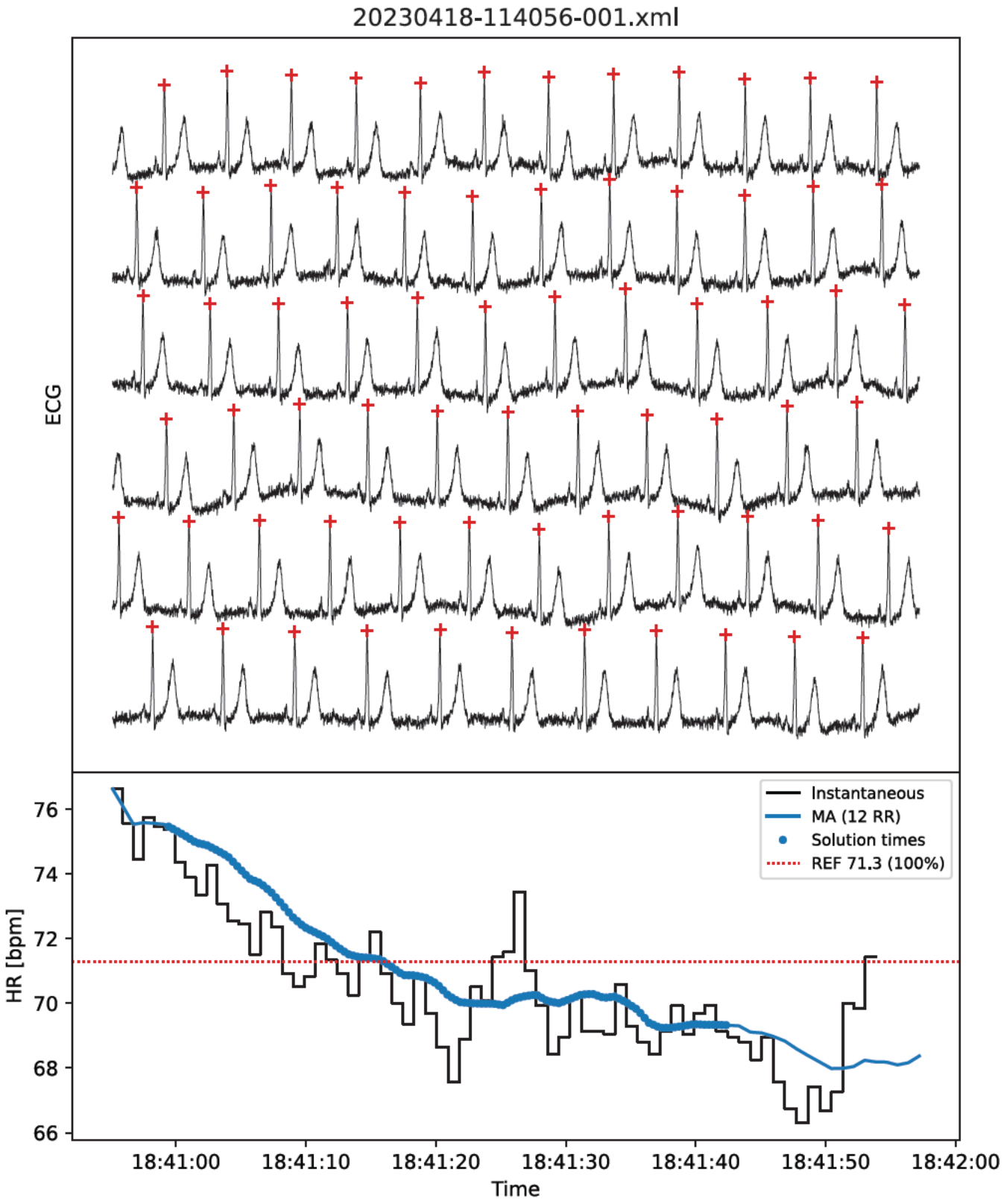
To validate the heart rate Rhythm Analysis Procedure for IVC-400-600 using the ECG XML Rhythm Strip, ten (10) trial sessions simulating the conditions of the clinical protocol were conducted. Validation included following the procedure in Sections 4.1 and 4.2 with 100% accuracy in automated peak detection.

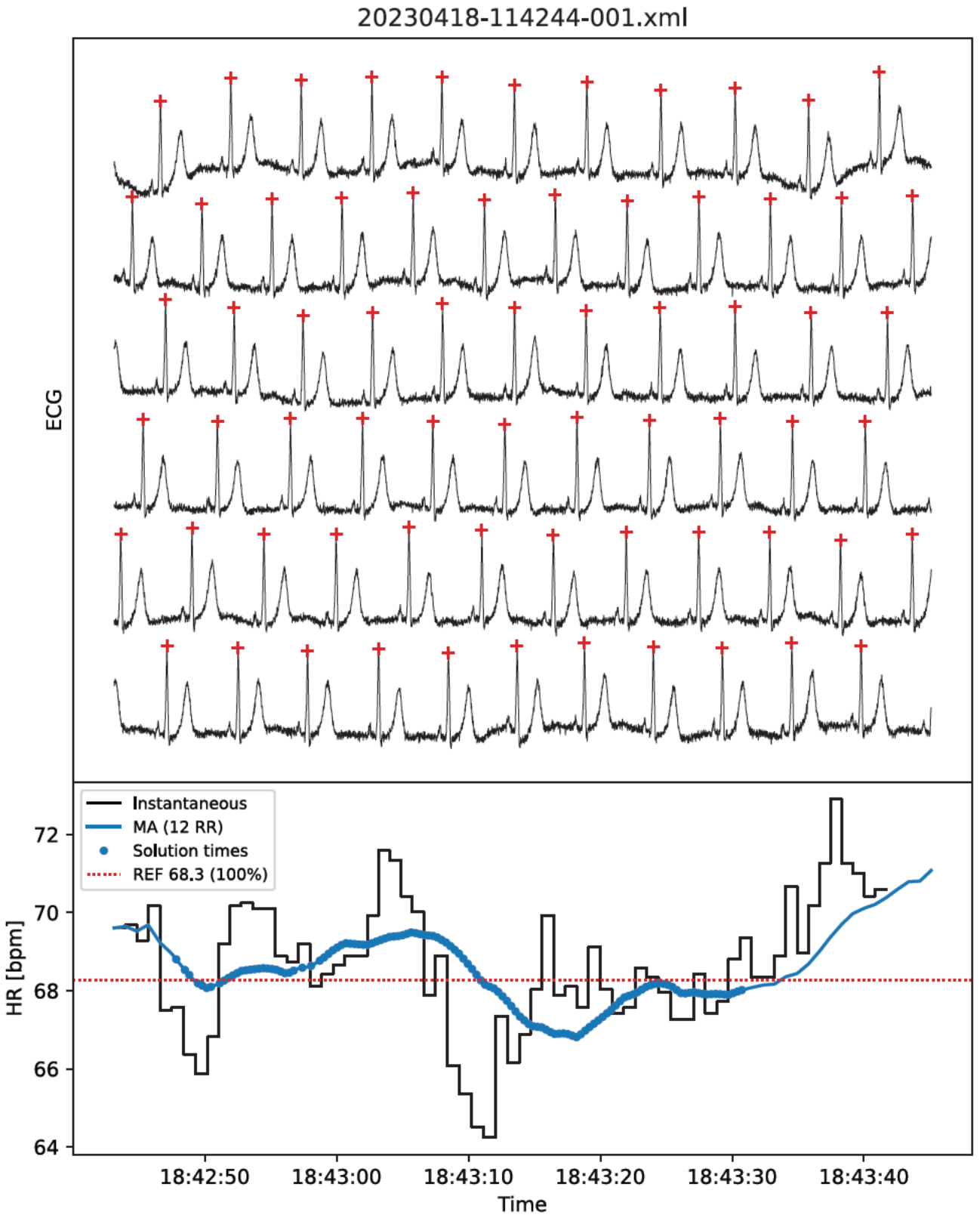
Demonstrated accuracy is evaluated by visual inspection of two reviewers using the annotated report generated by the standard script. Though the official implementation allows for documented human correction, the validation standard is zero false positive or false negative automated classifications.

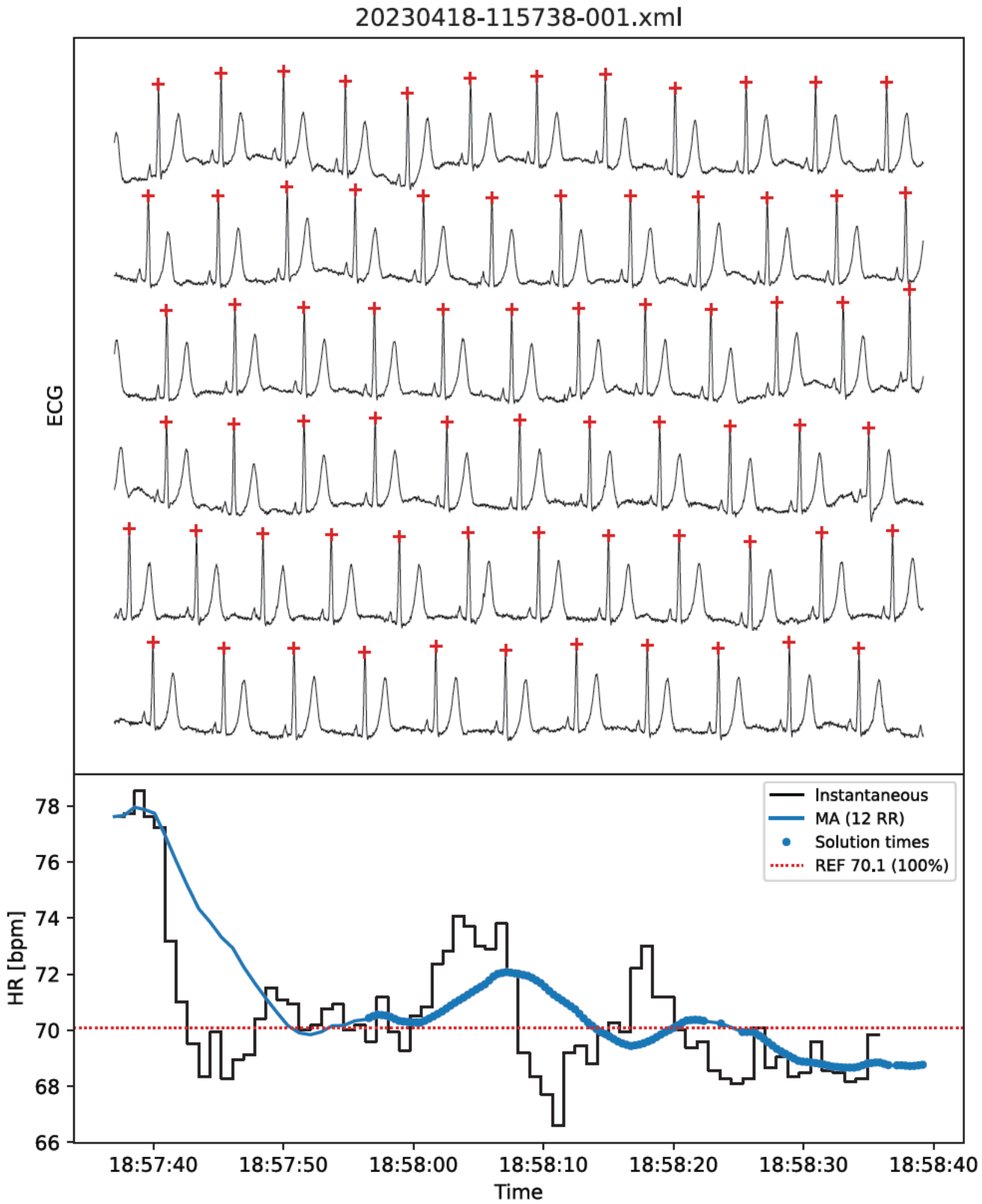
Each of these criteria has been successfully met as can be verified in the annotated figures included in the appendix. The black signal line reproducing the cardiograph confirms the first requirement. Red crosses indicate automated peak detections. If there are corrected false positives they would be overlaid with large gray x's; false negatives corrected by a reviewer would be indicated with large blue crosses. The absence of such annotations indicates automated accuracy of 100% for this sample. The bottom plot shows the instantaneous heart rate and its 10 second moving average; blue dots on that MA line show the IVC sample timestamps synchronized with ECG demonstrate completion of criteria two.

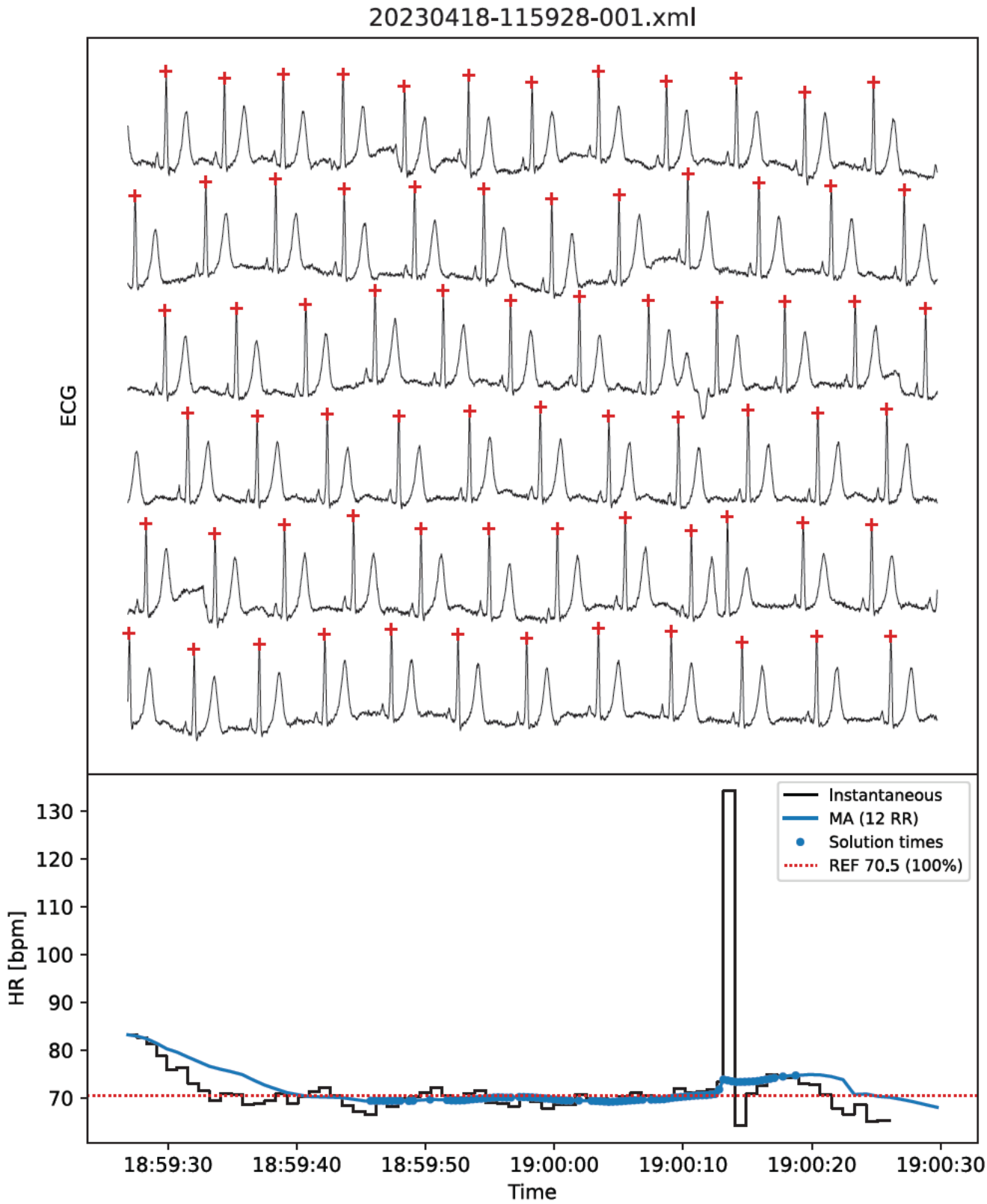


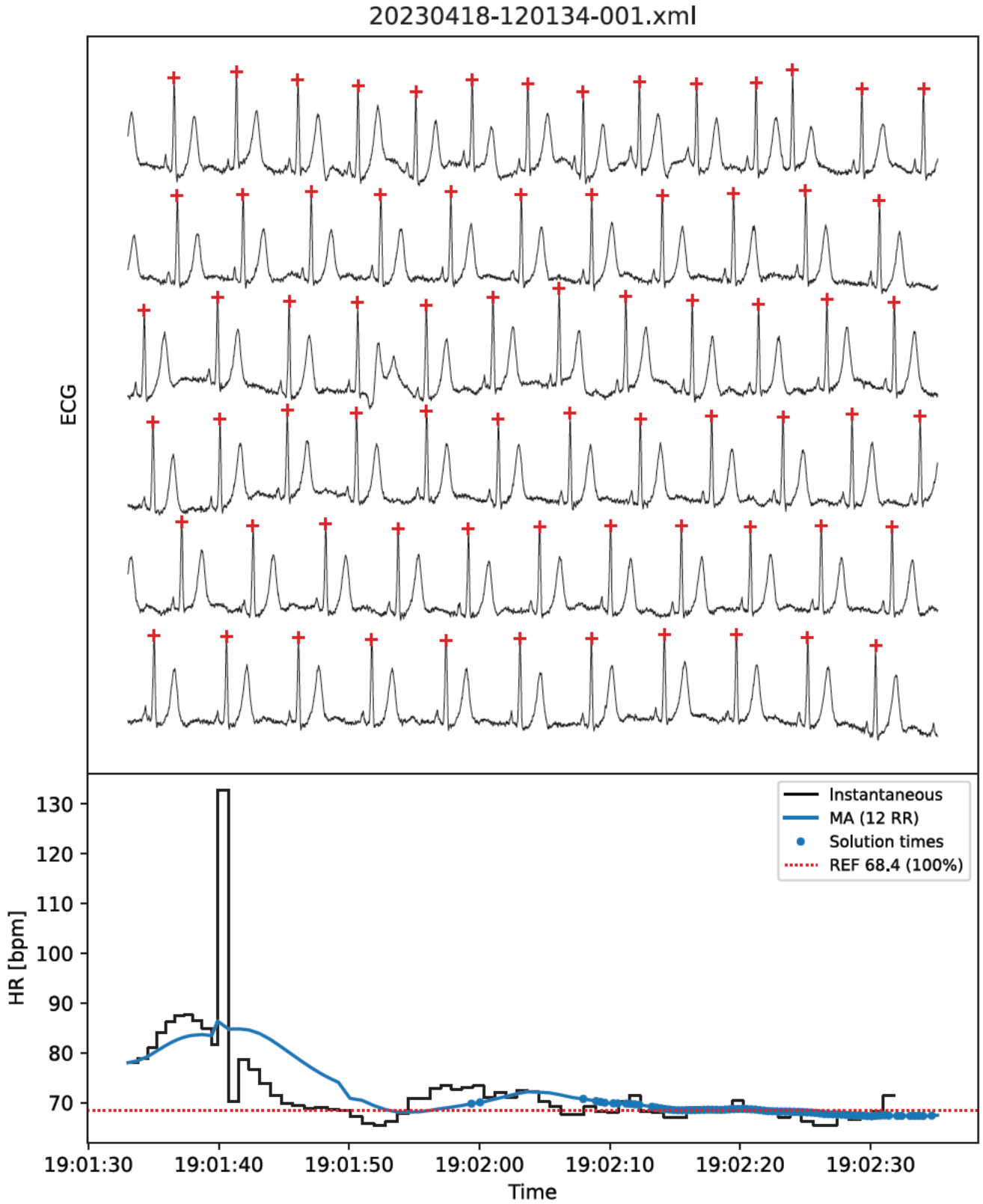


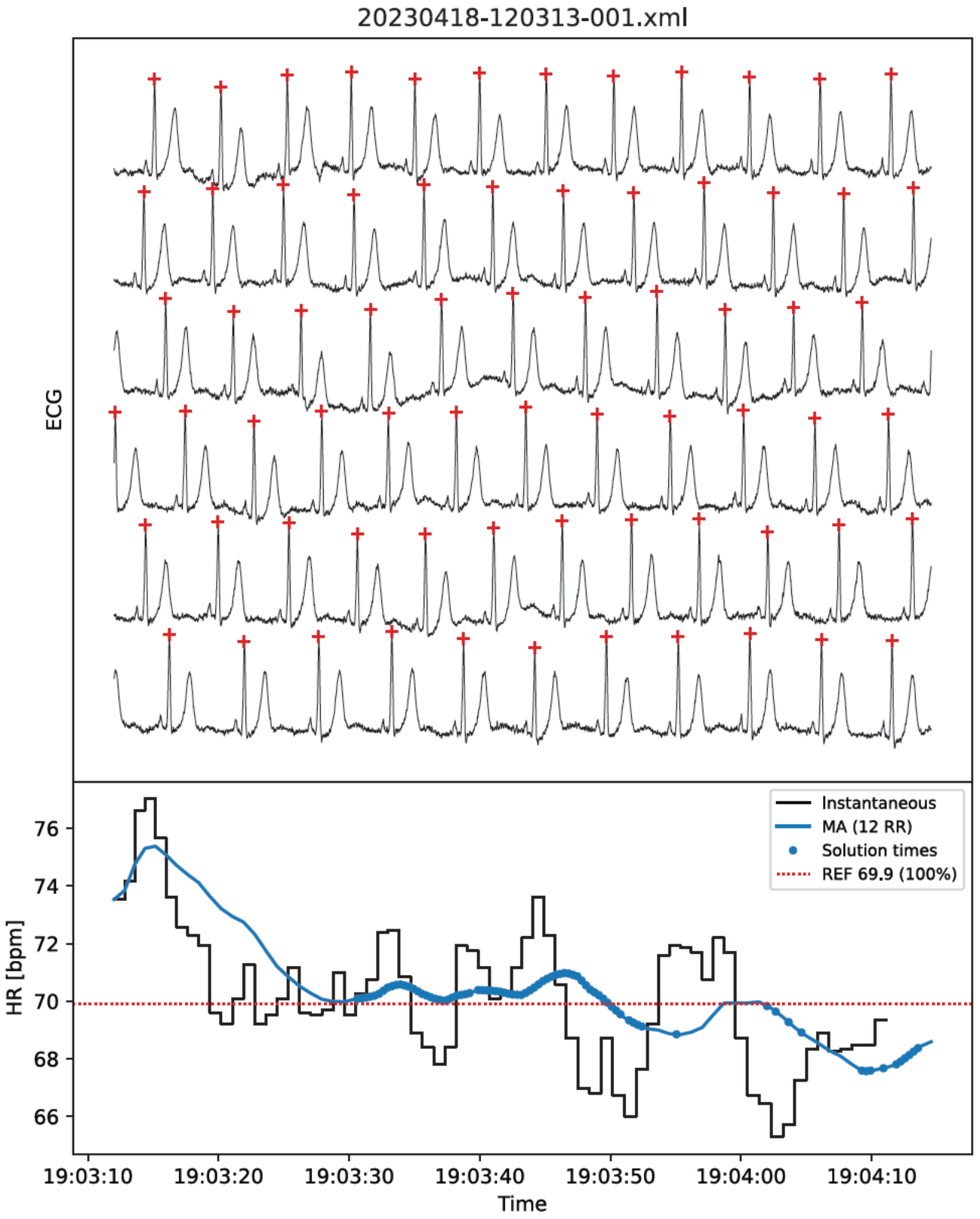


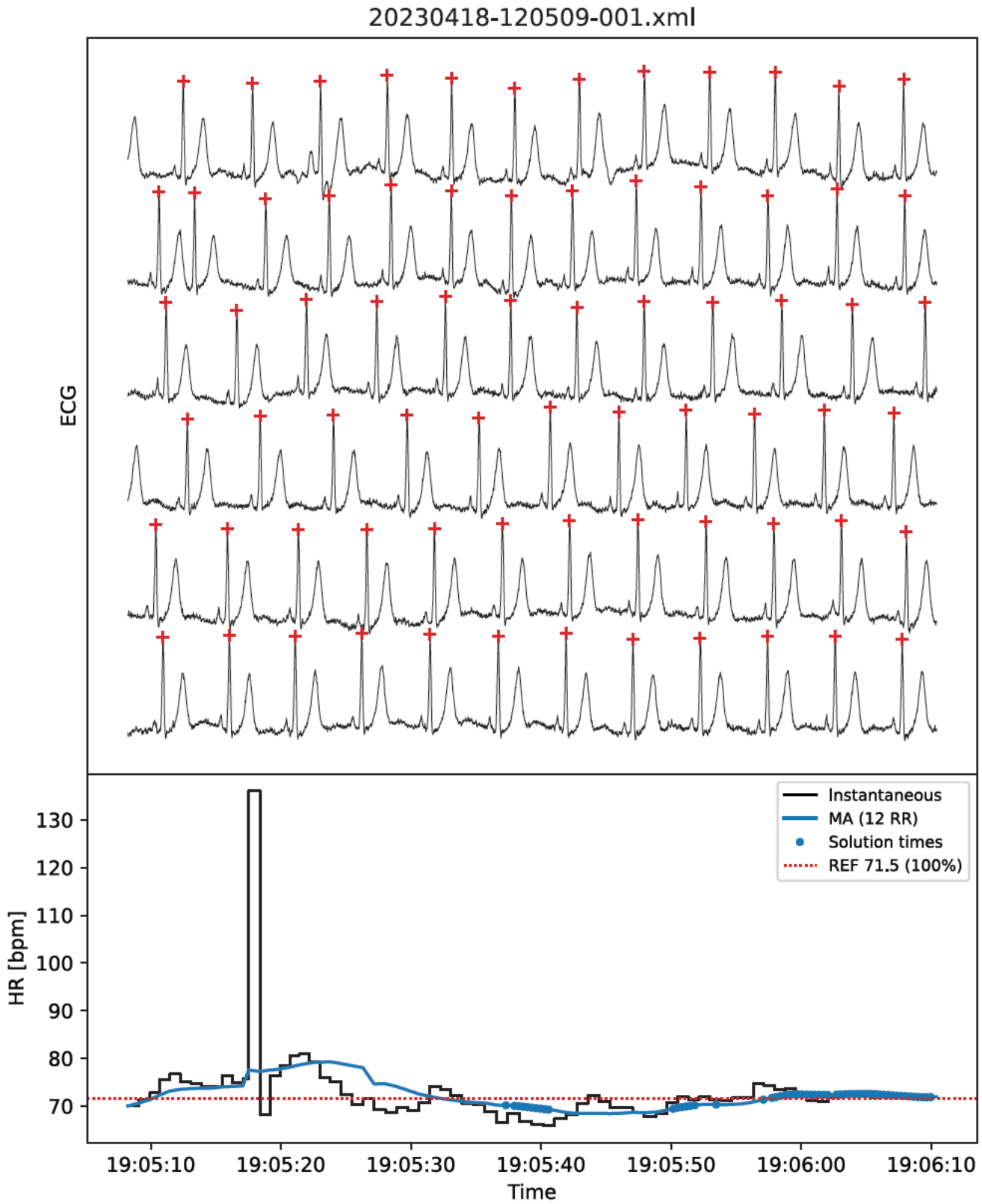


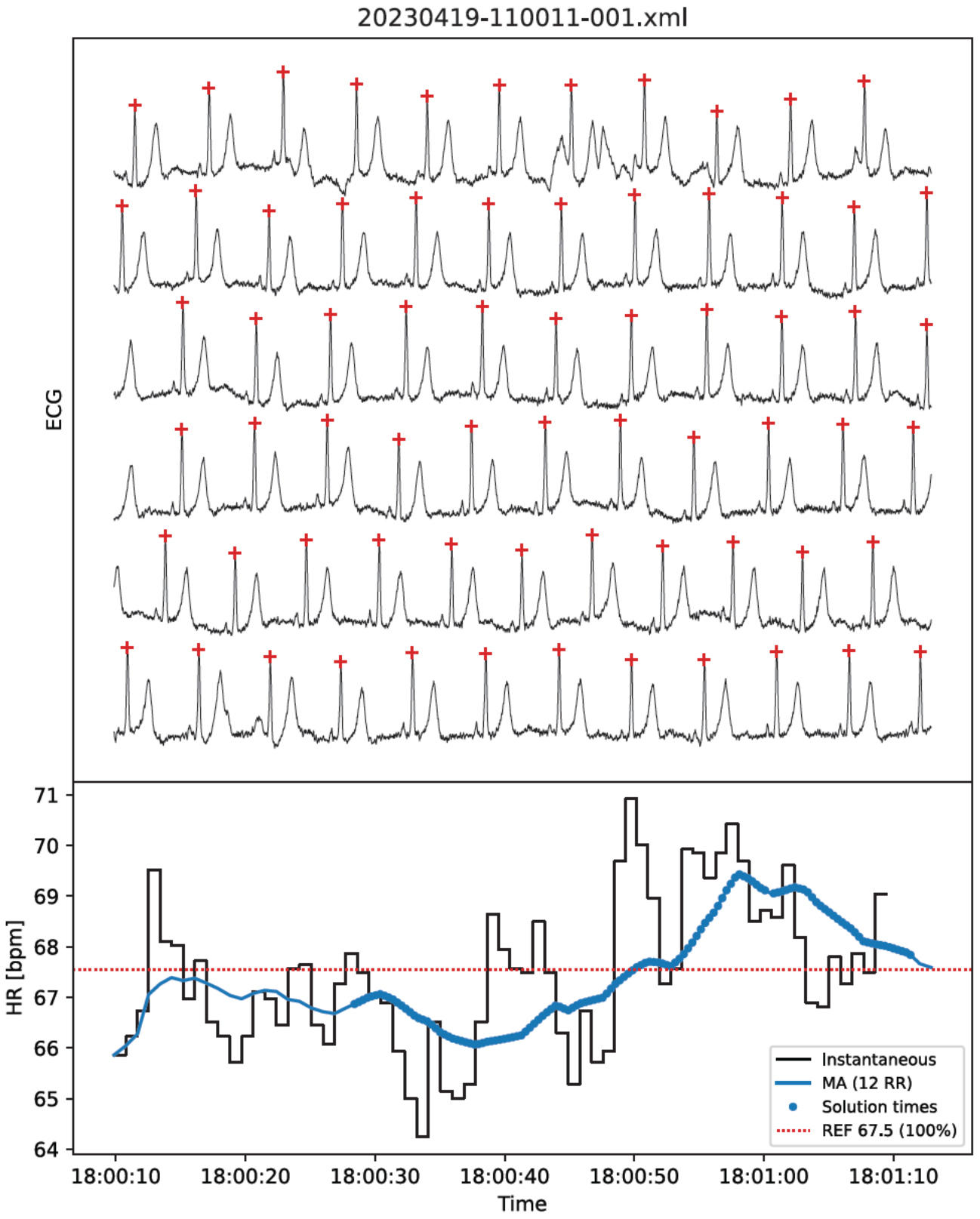












Listing 16.2.1.1
Subject Disposition
All-Enrolled Population

Subject ID	Date of Informed Consent	Completion or Discontinuation Date	Status	Reason for Discontinuation	ITC Population	PP Population	Reason ITC subject is excluded from PP population
301-001	02JUN2023	02JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
301-002	02JUN2023	02JUN2023	COMPLETED		Yes	Yes	
301-003	09JUN2023	09JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
301-004	12JUN2023	12JUN2023	COMPLETED		Yes	Yes	
301-005	13JUN2023	13JUN2023	COMPLETED		Yes	Yes	
301-006	13JUN2023	13JUN2023	COMPLETED		Yes	Yes	
301-007	14JUN2023	14JUN2023	DISCONTINUED	SCREEN FAILURE	No	No	
301-008	14JUN2023	14JUN2023	COMPLETED		Yes	Yes	
301-009	15JUN2023	15JUN2023	COMPLETED		Yes	Yes	
301-010	16JUN2023	16JUN2023	COMPLETED		Yes	Yes	
301-011	16JUN2023	16JUN2023	COMPLETED		Yes	Yes	
301-012	16JUN2023	16JUN2023	COMPLETED		Yes	Yes	
301-013	20JUN2023	20JUN2023	COMPLETED		Yes	Yes	
301-014	20JUN2023	20JUN2023	COMPLETED		Yes	Yes	
301-015	21JUN2023	21JUN2023	COMPLETED		Yes	Yes	
301-016	21JUN2023	21JUN2023	COMPLETED		Yes	Yes	
301-017	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
301-018	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
301-019	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	

ITC = Intent-to-Capture, PP = Per-Protocol

Listing 16.2.1.1
Subject Disposition
All-Enrolled Population

Subject ID	Date of Informed Consent	Completion or Discontinuation Date	Status	Reason for Discontinuation	ITC Population	PP Population	Reason ITC subject is excluded from PP population
301-020	23JUN2023	23JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
301-021	26JUN2023	26JUN2023	COMPLETED		Yes	Yes	
301-022	27JUN2023	27JUN2023	COMPLETED		Yes	Yes	
302-001	02JUN2023	02JUN2023	COMPLETED		Yes	Yes	
302-002	05JUN2023	05JUN2023	COMPLETED		Yes	Yes	
302-003	06JUN2023	06JUN2023	COMPLETED		Yes	Yes	
302-004	07JUN2023	07JUN2023	COMPLETED		Yes	Yes	
302-005	07JUN2023	07JUN2023	COMPLETED		Yes	Yes	
302-006	13JUN2023	13JUN2023	COMPLETED		Yes	Yes	
302-007	14JUN2023	14JUN2023	COMPLETED		Yes	Yes	
302-008	14JUN2023	14JUN2023	COMPLETED		Yes	Yes	
302-009	15JUN2023	15JUN2023	COMPLETED		Yes	Yes	
302-010	15JUN2023	15JUN2023	COMPLETED		Yes	Yes	
302-011	16JUN2023	16JUN2023	COMPLETED		Yes	Yes	
302-012	16JUN2023	16JUN2023	COMPLETED		Yes	Yes	
302-013	20JUN2023	20JUN2023	COMPLETED		Yes	Yes	
302-014	21JUN2023	21JUN2023	COMPLETED		Yes	Yes	
302-015	21JUN2023	21JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
302-016	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
302-017	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	

ITC = Intent-to-Capture, PP = Per-Protocol

Listing 16.2.1.1
Subject Disposition
All-Enrolled Population

Subject ID	Date of Informed Consent	Completion or Discontinuation Date	Status	Reason for Discontinuation	ITC Population	PP Population	Reason ITC subject is excluded from PP population
302-018	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
302-019	23JUN2023	23JUN2023	COMPLETED		Yes	Yes	
302-020	27JUN2023	27JUN2023	COMPLETED		Yes	Yes	
302-021	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
304-001	20JUN2023	20JUN2023	COMPLETED		Yes	Yes	
304-002	20JUN2023	20JUN2023	DISCONTINUED	PROTOCOL DEVIATION	No	No	Rhythm strip not uploaded
304-003	21JUN2023	21JUN2023	COMPLETED		Yes	Yes	
304-004	21JUN2023	21JUN2023	COMPLETED		Yes	Yes	
304-005	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
304-006	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
304-007	27JUN2023	27JUN2023	COMPLETED		Yes	Yes	
304-008	27JUN2023	27JUN2023	COMPLETED		Yes	Yes	
304-009	27JUN2023	27JUN2023	COMPLETED		Yes	Yes	
304-010	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
304-011	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
304-012	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
304-013	29JUN2023	29JUN2023	COMPLETED		Yes	Yes	
305-001	06JUN2023	06JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
305-002	06JUN2023	06JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
305-003	08JUN2023	08JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded

ITC = Intent-to-Capture, PP = Per-Protocol

Listing 16.2.1.1
Subject Disposition
All-Enrolled Population

Subject ID	Date of Informed Consent	Completion or Discontinuation Date	Status	Reason for Discontinuation	ITC Population	PP Population	Reason ITC subject is excluded from PP population
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305-005	23JUN2023	23JUN2023	COMPLETED		Yes	Yes	
305-006	23JUN2023	23JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
305-007	26JUN2023	26JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
305-008	26JUN2023	26JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
305-009	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
305-010	29JUN2023	29JUN2023	COMPLETED		Yes	Yes	
305-011	29JUN2023	29JUN2023	DISCONTINUED	OTHER	No	No	Study closed prior to assessment.
305-012	29JUN2023	29JUN2023	COMPLETED		Yes	Yes	
306-001	22JUN2023	22JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
306-002	22JUN2023	22JUN2023	COMPLETED		Yes	No	Rhythm strip not uploaded
306-003	26JUN2023	26JUN2023	COMPLETED		Yes	Yes	
306-004	26JUN2023	26JUN2023	COMPLETED		Yes	No	The reference device does not collect data
306-005	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
306-006	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	
306-007	29JUN2023	29JUN2023	COMPLETED		Yes	Yes	
307-001	14JUN2023	14JUN2023	COMPLETED		Yes	Yes	
307-002	14JUN2023	14JUN2023	COMPLETED		Yes	Yes	
307-003	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	
307-004	22JUN2023	22JUN2023	COMPLETED		Yes	Yes	

ITC = Intent-to-Capture, PP = Per-Protocol

Listing 16.2.1.1
Subject Disposition
All-Enrolled Population

Subject ID	Date of Informed Consent	Completion or Discontinuation Date	Status	Reason for Discontinuation	ITC Population	PP Population	Reason ITC subject is excluded from PP population
307-005	22JUN2023	22JUN2023	COMPLETED		Yes	No	The reference device does not collect data
307-006	23JUN2023	23JUN2023	COMPLETED		Yes	Yes	
307-007	23JUN2023	23JUN2023	DISCONTINUED	SCREEN FAILURE	No	No	
307-008	23JUN2023	23JUN2023	COMPLETED		Yes	Yes	
307-009	26JUN2023	26JUN2023	COMPLETED		Yes	Yes	
307-010	26JUN2023	26JUN2023	COMPLETED		Yes	No	Thumb drive not recognized by pixel phone. USB was sent back to sponsor for review on 7/20/23
307-011	28JUN2023	28JUN2023	COMPLETED		Yes	Yes	

ITC = Intent-to-Capture, PP = Per-Protocol

Listing 16.2.1.3
Protocol Deviation
All-Enrolled Subjects

Subject ID	Date of Deviation	Type of Deviation	Specification for Other	Brief Description of Deviation
301-015	21JUN2023	Other	The ECG was conducted but not uploaded to the drive	The first ECG that I performed on the subject was not saved due to the disk drive was not in the ecg
302-019	23JUN2023	Deviation From Protocol Defined Procedure		ECG limb leads were inadvertently reversed.
304-002	20JUN2023	Deviation From Protocol Defined Procedure		PR PRO's were not completed per protocol.
305-001	06JUN2023	Deviation From Protocol Defined Procedure		PRO HR data not captured despite multiple attempts and 2nd visit attempts per PM instructions.
305-002	06JUN2023	Deviation From Protocol Defined Procedure		The second PRO assessment was not completed per protocol per PM instruction.
306-001	22JUN2023	Deviation From Protocol Defined Procedure		Leads on ECG were reversed
				Less than 2 PROs collected in the mainstudy.

Listing 16.2.1.2
Eligibility Criteria
All-Enrolled Population

Subject ID	Did the subject meet all the inclusion and none of the exclusion criteria?	Criterion Type	Description
301-001	Yes		
301-002	Yes		
301-003	Yes		
301-004	Yes		
301-005	Yes		
301-006	Yes		
301-007	No	EXCLUSION	SUBJECTS WITH CARDIAC ARRHYTHMIA
301-008	Yes		
301-009	Yes		
301-010	Yes		
301-011	Yes		
301-012	Yes		
301-013	Yes		
301-014	Yes		
301-015	Yes		
301-016	Yes		
301-017	Yes		
301-018	Yes		
301-019	Yes		

Listing 16.2.1.2
Eligibility Criteria
All-Enrolled Population

Subject ID	Did the subject meet all the inclusion and none of the exclusion criteria?	Criterion Type	Description
301-020	Yes		
301-021	Yes		
301-022	Yes		
302-001	Yes		
302-002	Yes		
302-003	Yes		
302-004	Yes		
302-005	Yes		
302-006	Yes		
302-007	Yes		
302-008	Yes		
302-009	Yes		
302-010	Yes		
302-011	Yes		
302-012	Yes		
302-013	Yes		
302-014	Yes		
302-015	Yes		
302-016	Yes		
302-017	Yes		

Listing 16.2.1.2
Eligibility Criteria
All-Enrolled Population

Subject ID	Did the subject meet all the inclusion and none of the exclusion criteria?	Criterion Type	Description
302-018	Yes		
302-019	Yes		
302-020	Yes		
302-021	Yes		
304-001	Yes		
304-002	Yes		
304-003	Yes		
304-004	Yes		
304-005	Yes		
304-006	Yes		
304-007	Yes		
304-008	Yes		
304-009	Yes		
304-010	Yes		
304-011	Yes		
304-012	Yes		
304-013	Yes		
305-001	Yes		
305-002	Yes		
305-003	Yes		

Listing 16.2.1.2
Eligibility Criteria
All-Enrolled Population

Subject ID	Did the subject meet all the inclusion and none of the exclusion criteria?	Criterion Type	Description
305-004	Yes		
305-005	Yes		
305-006	Yes		
305-007	Yes		
305-008	Yes		
305-009	Yes		
305-010	Yes		
305-011	Yes		
305-012	Yes		
306-001	Yes		
306-002	Yes		
306-003	Yes		
306-004	Yes		
306-005	Yes		
306-006	Yes		
306-007	Yes		
307-001	Yes		
307-002	Yes		
307-003	Yes		
307-004	Yes		

Listing 16.2.1.2
Eligibility Criteria
All-Enrolled Population

Subject ID	Did the subject meet all the inclusion and none of the exclusion criteria?	Criterion Type	Description
307-005	Yes		
307-006	Yes		
307-007	No	EXCLUSION	SUBJECTS WITH CARDIAC ARRHYTHMIA
307-008	Yes		
307-009	Yes		
307-010	Yes		
307-011	Yes		

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
301-001	1	No	App not able to measure vitals	Yes		Yes		Null IVC solution		
	2	No	App not able to measure vitals	Yes		Yes		Null IVC solution		
301-002	1	Yes		Yes		Yes			60	60
	2	Yes		Yes		Yes			66	62
301-003	1	No	App was not able to measure vitals	No		Yes				
	2	No	App was not able to measure vitals	No		Yes				
301-004	1	Yes		Yes		Yes			69	69
	2	Yes		Yes		Yes			67	68
301-005	1	Yes		Yes		Yes			57	58
	2	Yes		Yes		Yes			57	57
301-006	1	Yes		Yes		Yes			69	69
	2	Yes		Yes		Yes			66	66

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
301-008	1	Yes		Yes		Yes			67	67
	2	Yes		Yes		Yes			68	69
301-009	1	Yes		Yes		Yes			71	70
	2	Yes		Yes		Yes			71	71
301-010	1	Yes		Yes		Yes			81	81
	2	Yes		Yes		Yes			79	78
301-011	1	Yes		Yes		Yes			64	65
	2	Yes		Yes		Yes			60	61
301-012	1	Yes		Yes		Yes			76	77
	2	Yes		Yes		Yes			78	78
301-013	1	Yes		Yes		Yes			72	72
	2	Yes		Yes		Yes			73	74
301-014	1	Yes		Yes		Yes			67	67

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
301-014	2	Yes		Yes		Yes			68	69
301-015	1	Yes		No		Yes			70	
	2	Yes		Yes		Yes			67	66
301-016	1	Yes		Yes		Yes			73	73
	2	Yes		Yes		Yes			73	73
301-017	1	Yes		Yes		Yes			84	83
	2	Yes		Yes		Yes			83	83
301-018	1	Yes		Yes		Yes			67	67
	2	Yes		Yes		Yes			67	67
301-019	1	Yes		Yes		Yes			60	60
	2	Yes		Yes		Yes			60	60
301-020	1	No	App not able to measure vitals	Yes		Yes		Null IVC solution		
	2	No	App not able to measure vitals	Yes		Yes		Null IVC solution		
301-021	1	Yes		Yes		Yes			54	53

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
301-021	2	Yes		Yes		Yes			53	53
301-022	1	Yes		Yes		Yes			61	61
	2	Yes		Yes		Yes			64	63
302-001	1	Yes		Yes		Yes			80	80
	2	Yes		Yes		Yes			79	79
302-002	1	Yes		Yes		Yes			81	80
	2	Yes		Yes		Yes			80	79
302-003	1	Yes		Yes		Yes			65	67
	2	Yes		Yes		Yes			68	68
302-004	1	Yes		Yes		Yes			60	61
	2	Yes		Yes		Yes			61	62
302-005	1	Yes		Yes		Yes			69	69
	2	Yes		Yes		Yes			69	69
302-006	1	Yes		Yes		Yes			78	79

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
302-006	2	Yes		Yes		Yes			78	78
302-007	1	Yes		Yes		Yes			64	64
	2	Yes		Yes		Yes			64	64
302-008	1	Yes		Yes		Yes			53	54
	2	Yes		Yes		Yes			55	55
302-009	1	Yes		Yes		Yes			53	53
	2	Yes		Yes		Yes			53	53
302-010	1	Yes		Yes		Yes			57	57
	2	Yes		Yes		Yes			54	55
302-011	1	Yes		Yes		Yes			67	68
	2	Yes		Yes		Yes			71	70
302-012	1	Yes		Yes		Yes			64	64
	2	Yes		Yes		Yes			64	64
302-013	1	Yes		Yes		Yes			75	75

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
302-013	2	Yes		Yes		Yes			75	75
302-014	1	Yes		Yes		Yes			76	76
	2	Yes		Yes		Yes			78	78
302-015	1	No	App not able to measure vitals	Yes		Yes		null IVC solution		
	2	No	App not able to measure vitals	Yes		Yes		null IVC solution		
302-016	1	Yes		Yes		Yes			60	60
	2	Yes		Yes		Yes			61	61
302-017	1	Yes		Yes		Yes			86	87
	2	Yes		Yes		Yes			87	87
302-018	1	Yes		Yes		Yes			103	103
	2	Yes		No		Yes			105	
302-019	1	Yes		Yes		Yes			50	50
	2	Yes		Yes		Yes			50	50
302-020	1	Yes		Yes		Yes			85	84

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
302-020	2	Yes		Yes		Yes			82	83
302-021	1	Yes		Yes		Yes			74	75
	2	Yes		Yes		Yes			78	79
304-001	1	Yes		Yes		Yes			67	68
	2	Yes		Yes		Yes			71	70
304-003	1	Yes		Yes		Yes			53	53
	2	Yes		Yes		Yes			53	52
304-004	1	Yes		Yes		Yes			96	95
	2	Yes		Yes		Yes			96	96
304-005	1	Yes		Yes		Yes			71	70
	2	Yes		Yes		Yes			71	70
304-006	1	Yes		Yes		Yes			78	79

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
304-006	2	Yes		Yes		Yes			78	78
304-007	1	Yes		Yes		Yes			68	69
	2	Yes		Yes		Yes			74	73
304-008	1	Yes		Yes		Yes			74	73
	2	Yes		Yes		Yes			75	75
304-009	1	Yes		Yes		Yes			78	79
	2	Yes		Yes		Yes			78	77
304-010	1	Yes		Yes		Yes			67	67
	2	Yes		Yes		Yes			67	67
304-011	1	Yes		Yes		Yes			75	74
	2	Yes		Yes		Yes			74	74
304-012	1	Yes		Yes		Yes			71	70
	2	Yes		Yes		Yes			68	69
304-013	1	Yes		Yes		Yes			71	70

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
304-013	2	Yes		Yes		Yes			73	72
305-001	1	No	app unable to measure	Yes		Yes		Null IVC solution		
	2	No	app unable to measure	No		Yes				
305-002	1	No	app not able to measure	Yes		Yes		Null IVC solution		
	2	No	The second PRO assessment was not completed per protocol per PM instruction.	No		Yes				
305-003	1	No	App not able to measure vitals.	No		Yes				
	2	No	App not able to measure vitals.	No		Yes				

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
305-004	1	Yes		Yes		Yes			64	65
	2	Yes		Yes		Yes			64	64
305-005	1	Yes		Yes		Yes			50	49
	2	Yes		Yes		Yes			50	49
305-006	1	No	App unable to measure	Yes		Yes		Null IVC solution		
	2	No	App unable to measure	Yes		Yes		Null IVC solution		
305-007	1	No	App unable to measure	Yes		Yes		Null IVC solution		
	2	No	App unable to measure	Yes		Yes		Null IVC solution		
305-008	1	No	App unable to measure	Yes		Yes		Null IVC solution		
	2	No	App unable to measure	Yes		Yes		Null IVC solution		
305-009	1	Yes		Yes		Yes			71	71
	2	Yes		Yes		Yes			73	73
305-010	1	Yes		Yes		Yes			53	53
	2	Yes		Yes		Yes			52	53
305-012	1	Yes		Yes		Yes			68	68
	2	Yes		Yes		Yes			73	72
306-001	1	No	App not able to measure vitals	Yes		Yes		Null IVC solution		
	2	No	App not able to measure vitals	No		Yes				
306-002	1	No	App not able to measure vitals	No		Yes				

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
306-002	2	No	App not able to measure vitals	No		Yes				
306-003	1	Yes		No		Yes			95	
	2	Yes		Yes		Yes			93	94
306-004	1	No	app not able to measure vitals	Yes		Yes		Null IVC solution		
	2	Yes		No		Yes			60	
306-005	1	Yes		Yes		Yes			63	62
	2	Yes		Yes		Yes			60	61
306-006	1	Yes		Yes		Yes			87	88
	2	Yes		Yes		Yes			87	87
306-007	1	Yes		Yes		Yes			77	77
	2	Yes		Yes		Yes			75	75
307-001	1	Yes		Yes		Yes			73	73
	2	Yes		Yes		Yes			75	74
307-002	1	Yes		Yes		Yes			84	83

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
307-002	2	Yes		Yes		Yes			82	83
307-003	1	Yes		Yes		Yes			62	63
	2	Yes		Yes		Yes			62	62
307-004	1	Yes		Yes		Yes			64	65
	2	Yes		Yes		Yes			61	61
307-005	1	Yes		No		Yes			92	
	2	Yes		No		Yes			92	
307-006	1	Yes		Yes		Yes			77	76
	2	Yes		Yes		Yes			80	80
307-008	1	No	app unable to measure	Yes		Yes		Null IVC solution		
	2	Yes		Yes		Yes			79	79
307-009	1	No	unable to measure vitals	Yes		Yes		Null IVC solution		

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
307-009	2	Yes		Yes		Yes			75	74
307-010	1	No	no Pulse Rate obtained- App not able to measure vitals	No		No	Thumb drive not recognized by pixel phone. USB was sent back to sponsor for review on 7/20/23			
	2	No	no Pulse Rate obtained- App not able to measure vitals	No		No	Thumb drive not recognized by pixel phone. USB was sent back to sponsor for review on 7/20/23			
307-011	1	Yes		Yes		Yes			60	59
	2	Yes		Yes		Yes			57	58

ITC = Intent-to-Capture.

Listing 16.2.4.1
Demographic and Other Baseline Characteristics
ITC Population

Subject ID	Age (years)	Sex	Race	Ethnicity	Fitzpatrick Scale Assignment	Is the subject wearing Glasses ?	Does the subject have facial hair?
301-001	29	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	6 - Deeply Pigmented Dark Brown to Black Skin	Yes	No
301-002	36	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	No
301-003	43	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	Yes
301-004	51	Male	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	Yes	Yes
301-005	56	Male	WHITE	HISPANIC OR LATINO	3 - Light Brown Skin	Yes	No
301-006	27	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	No
301-008	70	Female	WHITE	NOT HISPANIC OR LATINO	1 - Pale White Skin	No	No
301-009	69	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	Yes	No
301-010	62	Female	ASIAN	NOT HISPANIC OR LATINO	4 - Moderate Brown Skin	No	No
301-011	53	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	Yes	No
301-012	40	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	3 - Light Brown Skin	No	No
301-013	60	Female	WHITE	NOT HISPANIC OR LATINO	1 - Pale White Skin	Yes	No
301-014	35	Male	WHITE	NOT HISPANIC OR LATINO	3 - Light Brown Skin	No	No
301-015	45	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	Yes	No
301-016	37	Female	WHITE	NOT HISPANIC OR LATINO	1 - Pale White Skin	No	No
301-017	67	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	Yes	No
301-018	62	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	6 - Deeply Pigmented Dark Brown to Black Skin	No	Yes

ITC = Intent-to-Capture.

Listing 16.2.4.1
Demographic and Other Baseline Characteristics
ITC Population

Subject ID	Age (years)	Sex	Race	Ethnicity	Fitzpatrick Scale Assignment	Is the subject wearing Glasses ?	Does the subject have facial hair?
301-019	66	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	Yes	No
301-020	33	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	6 - Deeply Pigmented Dark Brown to Black Skin	No	No
301-021	30	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	Yes
301-022	62	Male	WHITE	NOT HISPANIC OR LATINO	3 - Light Brown Skin	Yes	No
302-001	48	Male	WHITE	HISPANIC OR LATINO	5 - Dark Brown Skin	No	Yes
302-002	76	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	Yes	No
302-003	32	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	6 - Deeply Pigmented Dark Brown to Black Skin	No	Yes
302-004	55	Female	WHITE	NOT HISPANIC OR LATINO	3 - Light Brown Skin	No	No
302-005	53	Female	WHITE	NOT HISPANIC OR LATINO	1 - Pale White Skin	Yes	No
302-006	61	Male	ASIAN	NOT HISPANIC OR LATINO	3 - Light Brown Skin	Yes	Yes
302-007	65	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	No
302-008	52	Female	WHITE	HISPANIC OR LATINO	3 - Light Brown Skin	No	No
302-009	39	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	6 - Deeply Pigmented Dark Brown to Black Skin	No	Yes
302-010	43	Male	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	NOT HISPANIC OR LATINO	6 - Deeply Pigmented Dark Brown to Black Skin	Yes	Yes
302-011	22	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	No
302-012	44	Male	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	Yes
302-013	68	Female	WHITE	NOT HISPANIC OR LATINO	1 - Pale White Skin	No	No
302-014	48	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	No

ITC = Intent-to-Capture.

Listing 16.2.4.1
Demographic and Other Baseline Characteristics
ITC Population

Subject ID	Age (years)	Sex	Race	Ethnicity	Fitzpatrick Scale Assignment	Is the subject wearing Glasses ?	Does the subject have facial hair?
302-015	44	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	Yes
302-016	22	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	6 - Deeply Pigmented Dark Brown to Black Skin	No	No
302-017	57	Male	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	Yes
302-018	32	Female	ASIAN	NOT HISPANIC OR LATINO	3 - Light Brown Skin	No	No
302-019	42	Male	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	Yes
302-020	62	Male	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	Yes
302-021	44	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	No
304-001	60	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	Yes
304-003	38	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	No
304-004	33	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	No
304-005	61	Male	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	Yes	No
304-006	69	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	No
304-007	77	Female	WHITE	NOT HISPANIC OR LATINO	1 - Pale White Skin	Yes	No
304-008	63	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	4 - Moderate Brown Skin	No	No
304-009	55	Male	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	Yes
304-010	33	Male	ASIAN	NOT HISPANIC OR LATINO	2 - White Skin	No	No
304-011	34	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	No
304-012	53	Female	WHITE	NOT HISPANIC OR LATINO	3 - Light Brown Skin	No	No

ITC = Intent-to-Capture.

Listing 16.2.4.1
Demographic and Other Baseline Characteristics
ITC Population

Subject ID	Age (years)	Sex	Race	Ethnicity	Fitzpatrick Scale Assignment	Is the subject wearing Glasses ?	Does the subject have facial hair?
304-013	27	Male	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	Yes
305-001	49	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	6 - Deeply Pigmented Dark Brown to Black Skin	No	Yes
305-002	51	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	6 - Deeply Pigmented Dark Brown to Black Skin	No	No
305-003	69	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	6 - Deeply Pigmented Dark Brown to Black Skin	No	No
305-004	31	Female	OTHER	HISPANIC OR LATINO	2 - White Skin	No	No
305-005	74	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	No
305-006	52	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	6 - Deeply Pigmented Dark Brown to Black Skin	No	Yes
305-007	46	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	No
305-008	38	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	Yes
305-009	62	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	Yes	No
305-010	73	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	Yes	Yes
305-012	69	Female	ASIAN	NOT HISPANIC OR LATINO	3 - Light Brown Skin	Yes	No
306-001	22	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	Yes
306-002	23	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	Yes
306-003	37	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	4 - Moderate Brown Skin	No	No
306-004	38	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	6 - Deeply Pigmented Dark Brown to Black Skin	No	Yes
306-005	70	Female	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	No
306-006	30	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	No

ITC = Intent-to-Capture.

Listing 16.2.4.1
Demographic and Other Baseline Characteristics
ITC Population

Subject ID	Age (years)	Sex	Race	Ethnicity	Fitzpatrick Scale Assignment	Is the subject wearing Glasses ?	Does the subject have facial hair?
306-007	36	Female	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	No
307-001	66	Female	WHITE	NOT HISPANIC OR LATINO	3 - Light Brown Skin	No	No
307-002	66	Male	AMERICAN INDIAN OR ALASKA NATIVE/BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	Yes
307-003	24	Male	WHITE	HISPANIC OR LATINO	4 - Moderate Brown Skin	No	No
307-004	34	Male	WHITE	NOT HISPANIC OR LATINO	3 - Light Brown Skin	No	Yes
307-005	59	Male	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	Yes
307-006	23	Male	AMERICAN INDIAN OR ALASKA NATIVE	HISPANIC OR LATINO	3 - Light Brown Skin	No	Yes
307-008	44	Male	WHITE	HISPANIC OR LATINO	4 - Moderate Brown Skin	No	Yes
307-009	63	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	No
307-010	44	Male	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO	5 - Dark Brown Skin	No	Yes
307-011	58	Male	WHITE	NOT HISPANIC OR LATINO	2 - White Skin	No	Yes

ITC = Intent-to-Capture.

Table 14.1.2.1
Summary of Subject Demographic and Other Baseline Characteristics
ITC Population

Characteristic	Statistic or Category	Total (N=82) n (%)
Sex, n (%)	Male	40 (48.8)
	Female	42 (51.2)
Ethnic Group, n (%)	Hispanic or Latino	7 (8.5)
	Not Hispanic or Latino	75 (91.5)
Race, n (%)	American Indian or Alaska Native/Black or African American	1 (1.2)
	American Indian or Alaska Native	1 (1.2)
	Asian	5 (6.1)
	Black or African American	32 (39.0)
	Native Hawaiian or Other Pacific Islander	1 (1.2)
	White	41 (50.0)
	Other	1 (1.2)
Fitzpatrick Scale, n (%)	1 - Pale White Skin	6 (7.3)
	2 - White Skin	26 (31.7)
	3 - Light Brown Skin	13 (15.9)
	4 - Moderate Brown Skin	5 (6.1)
	5 - Dark Brown Skin	20 (24.4)
	6 - Deeply Pigmented Dark Brown to Black Skin	12 (14.6)
Fitzpatrick Scale Group, n (%) [a]	Light	32 (39.0)
	Medium	18 (22.0)
	Dark	32 (39.0)

% = 100 x n/N. ITC = Intent-to-Capture.
[a] Fitzpatrick scale skin tones are grouped into light (Fitzpatrick 1 and 2), medium (Fitzpatrick 3 and 4) and dark (Fitzpatrick 5 and 6).
See Listing 16.2.4.1

Table 14.1.2.1
Summary of Subject Demographic and Other Baseline Characteristics
ITC Population

Characteristic	Statistic or Category	Total (N=82) n (%)
Age (years)	n	82
	Mean	48.7
	Standard deviation	15.40
	Median	48.5
	Minimum	22
	Maximum	77

% = 100 x n/N. ITC = Intent-to-Capture.
[a] Fitzpatrick scale skin tones are grouped into light (Fitzpatrick 1 and 2), medium (Fitzpatrick 3 and 4) and dark (Fitzpatrick 5 and 6).
See Listing 16.2.4.1

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
301-001	1	No	App not able to measure vitals	Yes		Yes		Null IVC solution		
	2	No	App not able to measure vitals	Yes		Yes		Null IVC solution		
301-002	1	Yes		Yes		Yes			60	60
	2	Yes		Yes		Yes			66	62
301-003	1	No	App was not able to measure vitals	No		Yes				
	2	No	App was not able to measure vitals	No		Yes				
301-004	1	Yes		Yes		Yes			69	69
	2	Yes		Yes		Yes			67	68
301-005	1	Yes		Yes		Yes			57	58
	2	Yes		Yes		Yes			57	57
301-006	1	Yes		Yes		Yes			69	69
	2	Yes		Yes		Yes			66	66

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
301-008	1	Yes		Yes		Yes			67	67
	2	Yes		Yes		Yes			68	69
301-009	1	Yes		Yes		Yes			71	70
	2	Yes		Yes		Yes			71	71
301-010	1	Yes		Yes		Yes			81	81
	2	Yes		Yes		Yes			79	78
301-011	1	Yes		Yes		Yes			64	65
	2	Yes		Yes		Yes			60	61
301-012	1	Yes		Yes		Yes			76	77
	2	Yes		Yes		Yes			78	78
301-013	1	Yes		Yes		Yes			72	72
	2	Yes		Yes		Yes			73	74
301-014	1	Yes		Yes		Yes			67	67

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
301-014	2	Yes		Yes		Yes			68	69
301-015	1	Yes		No		Yes			70	
	2	Yes		Yes		Yes			67	66
301-016	1	Yes		Yes		Yes			73	73
	2	Yes		Yes		Yes			73	73
301-017	1	Yes		Yes		Yes			84	83
	2	Yes		Yes		Yes			83	83
301-018	1	Yes		Yes		Yes			67	67
	2	Yes		Yes		Yes			67	67
301-019	1	Yes		Yes		Yes			60	60
	2	Yes		Yes		Yes			60	60
301-020	1	No	App not able to measure vitals	Yes		Yes		Null IVC solution		
	2	No	App not able to measure vitals	Yes		Yes		Null IVC solution		
301-021	1	Yes		Yes		Yes			54	53

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
301-021	2	Yes		Yes		Yes			53	53
301-022	1	Yes		Yes		Yes			61	61
	2	Yes		Yes		Yes			64	63
302-001	1	Yes		Yes		Yes			80	80
	2	Yes		Yes		Yes			79	79
302-002	1	Yes		Yes		Yes			81	80
	2	Yes		Yes		Yes			80	79
302-003	1	Yes		Yes		Yes			65	67
	2	Yes		Yes		Yes			68	68
302-004	1	Yes		Yes		Yes			60	61
	2	Yes		Yes		Yes			61	62
302-005	1	Yes		Yes		Yes			69	69
	2	Yes		Yes		Yes			69	69
302-006	1	Yes		Yes		Yes			78	79

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
302-006	2	Yes		Yes		Yes			78	78
302-007	1	Yes		Yes		Yes			64	64
	2	Yes		Yes		Yes			64	64
302-008	1	Yes		Yes		Yes			53	54
	2	Yes		Yes		Yes			55	55
302-009	1	Yes		Yes		Yes			53	53
	2	Yes		Yes		Yes			53	53
302-010	1	Yes		Yes		Yes			57	57
	2	Yes		Yes		Yes			54	55
302-011	1	Yes		Yes		Yes			67	68
	2	Yes		Yes		Yes			71	70
302-012	1	Yes		Yes		Yes			64	64
	2	Yes		Yes		Yes			64	64
302-013	1	Yes		Yes		Yes			75	75

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
302-013	2	Yes		Yes		Yes			75	75
302-014	1	Yes		Yes		Yes			76	76
	2	Yes		Yes		Yes			78	78
302-015	1	No	App not able to measure vitals	Yes		Yes		null IVC solution		
	2	No	App not able to measure vitals	Yes		Yes		null IVC solution		
302-016	1	Yes		Yes		Yes			60	60
	2	Yes		Yes		Yes			61	61
302-017	1	Yes		Yes		Yes			86	87
	2	Yes		Yes		Yes			87	87
302-018	1	Yes		Yes		Yes			103	103
	2	Yes		No		Yes			105	
302-019	1	Yes		Yes		Yes			50	50
	2	Yes		Yes		Yes			50	50
302-020	1	Yes		Yes		Yes			85	84

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
302-020	2	Yes		Yes		Yes			82	83
302-021	1	Yes		Yes		Yes			74	75
	2	Yes		Yes		Yes			78	79
304-001	1	Yes		Yes		Yes			67	68
	2	Yes		Yes		Yes			71	70
304-003	1	Yes		Yes		Yes			53	53
	2	Yes		Yes		Yes			53	52
304-004	1	Yes		Yes		Yes			96	95
	2	Yes		Yes		Yes			96	96
304-005	1	Yes		Yes		Yes			71	70
	2	Yes		Yes		Yes			71	70
304-006	1	Yes		Yes		Yes			78	79

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
304-006	2	Yes		Yes		Yes			78	78
304-007	1	Yes		Yes		Yes			68	69
	2	Yes		Yes		Yes			74	73
304-008	1	Yes		Yes		Yes			74	73
	2	Yes		Yes		Yes			75	75
304-009	1	Yes		Yes		Yes			78	79
	2	Yes		Yes		Yes			78	77
304-010	1	Yes		Yes		Yes			67	67
	2	Yes		Yes		Yes			67	67
304-011	1	Yes		Yes		Yes			75	74
	2	Yes		Yes		Yes			74	74
304-012	1	Yes		Yes		Yes			71	70
	2	Yes		Yes		Yes			68	69
304-013	1	Yes		Yes		Yes			71	70

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
304-013	2	Yes		Yes		Yes			73	72
305-001	1	No	app unable to measure	Yes		Yes		Null IVC solution		
	2	No	app unable to measure	No		Yes				
305-002	1	No	app not able to measure	Yes		Yes		Null IVC solution		
	2	No	The second PRO assessment was not completed per protocol per PM instruction.	No		Yes				
305-003	1	No	App not able to measure vitals.	No		Yes				
	2	No	App not able to measure vitals.	No		Yes				

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
305-004	1	Yes		Yes		Yes			64	65
	2	Yes		Yes		Yes			64	64
305-005	1	Yes		Yes		Yes			50	49
	2	Yes		Yes		Yes			50	49
305-006	1	No	App unable to measure	Yes		Yes		Null IVC solution		
	2	No	App unable to measure	Yes		Yes		Null IVC solution		
305-007	1	No	App unable to measure	Yes		Yes		Null IVC solution		
	2	No	App unable to measure	Yes		Yes		Null IVC solution		
305-008	1	No	App unable to measure	Yes		Yes		Null IVC solution		
	2	No	App unable to measure	Yes		Yes		Null IVC solution		
305-009	1	Yes		Yes		Yes			71	71
	2	Yes		Yes		Yes			73	73
305-010	1	Yes		Yes		Yes			53	53
	2	Yes		Yes		Yes			52	53
305-012	1	Yes		Yes		Yes			68	68
	2	Yes		Yes		Yes			73	72
306-001	1	No	App not able to measure vitals	Yes		Yes		Null IVC solution		
	2	No	App not able to measure vitals	No		Yes				
306-002	1	No	App not able to measure vitals	No		Yes				

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
306-002	2	No	App not able to measure vitals	No		Yes				
306-003	1	Yes		No		Yes			95	
	2	Yes		Yes		Yes			93	94
306-004	1	No	app not able to measure vitals	Yes		Yes		Null IVC solution		
	2	Yes		No		Yes			60	
306-005	1	Yes		Yes		Yes			63	62
	2	Yes		Yes		Yes			60	61
306-006	1	Yes		Yes		Yes			87	88
	2	Yes		Yes		Yes			87	87
306-007	1	Yes		Yes		Yes			77	77
	2	Yes		Yes		Yes			75	75
307-001	1	Yes		Yes		Yes			73	73
	2	Yes		Yes		Yes			75	74
307-002	1	Yes		Yes		Yes			84	83

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
307-002	2	Yes		Yes		Yes			82	83
307-003	1	Yes		Yes		Yes			62	63
	2	Yes		Yes		Yes			62	62
307-004	1	Yes		Yes		Yes			64	65
	2	Yes		Yes		Yes			61	61
307-005	1	Yes		No		Yes			92	
	2	Yes		No		Yes			92	
307-006	1	Yes		Yes		Yes			77	76
	2	Yes		Yes		Yes			80	80
307-008	1	No	app unable to measure	Yes		Yes		Null IVC solution		
	2	Yes		Yes		Yes			79	79
307-009	1	No	unable to measure vitals	Yes		Yes		Null IVC solution		

ITC = Intent-to-Capture.

Listing 16.2.6.1
IVC App Pulse Rate and ECG Reference Device Heart Rate
ITC Population

Subject ID	Session	Was the pulse rate taken by IVC?	Reason Pulse was Not Taken	Was ECG performed?	Reason ECG was Not performed	Was ECG Strip Uploaded?	Reason ECG Strip Was Not Uploaded	Reason not able to Analyze	Pulse Rate (BPM) by IVC app	ECG Reference Device Heart Rate (BPM)
307-009	2	Yes		Yes		Yes			75	74
307-010	1	No	no Pulse Rate obtained- App not able to measure vitals	No		No	Thumb drive not recognized by pixel phone. USB was sent back to sponsor for review on 7/20/23			
	2	No	no Pulse Rate obtained- App not able to measure vitals	No		No	Thumb drive not recognized by pixel phone. USB was sent back to sponsor for review on 7/20/23			
307-011	1	Yes		Yes		Yes			60	59
	2	Yes		Yes		Yes			57	58

ITC = Intent-to-Capture.

Listing 16.2.7.1
Adverse Events
ITC Population

Subject ID	MedDRA System Organ Class/ Preferred Term/ Investigator AE Term	Start Date	End Date	Ongoing?	SAE?	SAE Criteria	Severity	Relationship to Study Process	Any Unanticipated Adverse Device Effect	Outcome	Caused Study Discontinuation
No Data To Report											

ITC = Intent-to-Capture. SAE = Serious Adverse Events.