Respiratory Rate Validation Study – Binah.ai Visual Vitals Application

NCT Number: 05539612

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RESEARCH SUBJECT INFORMATION AND CONSENT FORM

SPONSOR:	Binah.ai LTD
CITY AND STATE:	Ramat Gan, Israel
PROTOCOL NUMBER AND TITLE:	Respiratory Rate Validation Study – Binah.ai Visual Vitals Application PR 2021-455
STUDY DOCTOR:	Arthur Ruiz Cabrera, MD
STUDY SITE:	Clinimark, LLC 80 Health Park Drive, Suite 20 Louisville, CO 80027
STUDY RELATED PHONE NUMBERS:	Mr. Paul Batchelder 303-717-4820 Ms. Dena Raley 303-249-6010
24-HOUR TELEPHONE NUMBER:	303-717-4820

INFORMED CONSENT

Subject Name: _____ Date: _____

The following information describes this study and your rights and obligations as a participant. The study doctor or one of the study staff will answer any questions you may have about this study or this form.

Introduction and Purpose
You are being asked to participate in a research study to evaluate the accuracy of a visual vital sign monitor. If at any time during this process you have questions, please ask the study staff to explain the words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family and friends before making your decision.

A physiological monitor is a device which measures vital signs like heart rate and respiratory rate in a non-invasive way. This vital sign monitor use sensors and cameras in a phone to take videos of the face and finger tips.

The purpose of this study is to conduct a direct comparison of an investigational device and an FDA cleared device that measures respiratory rate of adult human volunteers.

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"Investigational" means that the device being tested has not been approved by the United States Food and Drug Administration (FDA) for prescription or over-the-counter use. The following device in this research study is considered investigational:

- Binah.ai Visual Vitals Application

The following marketed devices have been cleared by the FDA for use and will be used for comparison to the investigational device and clinical monitoring:

- Datex-Ohmeda S5 Compact Monitor – Multiparameter
- GE, Datex-Ohmeda 3900 TruTrak + Pulse Oximeter with Oxy-F-UN Finger sensor and Oxy-OL3 cable
- Nellcor N600x Pulse Oximeter

Participation in Study

You are being asked to participate in this study because we believe you meet the acceptance criteria. Your decision to be in this study is voluntary. There will be 30 – 60, male and female subjects taking part in the study. To participate in this study, you must be at least 18 years of age. To determine your eligibility for this study, you will be asked several questions to assess your current state of health. If you have any medical conditions, you must be honest and provide complete information about them so that consideration can be given for your eligibility to participate in this study.

The study will take place at the study site listed on page 1. It is expected that your visit will take approximately 1-2 hours. If you decide to participate in this study and then change your mind, you can leave the study at any time.

Description of Study / Procedures

Once you have reviewed this information, had all of your questions answered to your satisfaction and signed your consent, a health assessment form will be provided to you. Upon completing the health assessment form, a health screen will be initiated on the day of your study.

The health screen will include a review of the information you reported in the health assessment form. Adhesive patches will be placed to check your heart rhythm and heart rate as measured by an ECG. A pulse oximeter sensor will be placed on your finger to obtain your oxygen readings. A cuff will be placed on your arm to check your blood pressure. Additionally, a visual check for evidence of intravenous drug use and a check for the scent of recent alcohol use will be performed.

You will be given a mouthpiece or a nasal cannula to breathe through during the study. If you are using a mouthpiece, a nose clip will be used so you can only breath through your mouth. The mouthpiece or nasal cannula is connected to the sampling line that goes to the patient monitor.

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A clinical monitoring system will be used during the study to observe your vital signs including heart rate, ECG, respiratory rate, end-tidal CO_2 (carbon dioxide) with capnography (to measure exhaled carbon dioxide levels in your breath). The device under test will be multiple cell phones that are taking video of your face.

During data collection you will be asked to change your rate of breathing from slow breaths to short and fast breaths. An app on a cell phone will make noise indicating to you when to inhale and exhale.

At the end of the study the devices and mouthpiece/nasal cannula will be removed. You will then be paid for your assistance and released from the study.

You may withdraw from the study at any time.

Risks and Discomforts
The adhesive and gel in the ECG pads may cause irritation to the skin. Typical skin irritations include redness of skin and in some cases allergic reaction. Because the adhesive is strong on the ECG pads, it may cause pulling of the skin or hair upon removal

Occasionally sensors are very warm to the touch and may cause some discomfort. The sensors are expected to be warm but not hot enough to burn the site. If this happens during the test, you should tell the study staff during the test and the offending sensor will be removed and later inspected for faulty conditions. The sensor's operating temperature should not cause burns under normal conditions.

The reported risks associated with non-invasive blood pressure (NIBP) cuff measurement include: discomfort upon inflation of the cuff, possible bruising, rash (small red or purple spots on the skin, caused by a minor break in capillary blood vessels) and discoloration of the skin beneath the cuff. They may also include nerve injuries, skin tear, compartment syndrome (swelling of muscles in the limb causing the reduction of the blood supply to the muscle).

More than 3,946 adults, children, and newborn babies have had their blood pressures taken repeatedly in 104 studies using similar equipment. In these previous studies, the complications of taking repeated blood pressures were temporary and involved either bruising/rash, skin redness/lines or tingling/discoloration in the arm wearing the cuff while the cuff is inflated.

The mouthpiece, nose clip, and nasal cannula are made of soft, flexible plastic so as to minimize the discomfort level as much as is reasonably possible. Materials may cause some skin irritations. Insertion and removal of a nasal cannula may cause nasal irritation, discomfort, or pain.

Electrical hazards are a potential risk with all electrical equipment. The equipment used in this study has been designed to meet applicable safety standards. The equipment will be safety and functionally tested by the sponsor prior to subject's use. The possibility of any electrical hazard is extremely remote.

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Reasonable precautions have been taken to minimize foreseeable risks and discomforts. However, this experiment may involve risks and discomforts to you (or your unborn baby if you are pregnant) that are currently unforeseeable.

You must tell the study doctor or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

New Findings
You will be told about any new findings or the reasons for any changes to the study that may affect your continued participation in a timely manner.

Expected Benefits
There will be no direct benefits to your health. It is our hope that testing like this will lead to the advancement of non-invasive medical monitoring of patients by improving accuracy and performance of pulse oximeters and multiparameter monitors.

Alternatives
Since this study is for research only, the only alternative to this study is to NOT participate.

Costs
There are no anticipated costs to you.

Payment for Participation
You will be paid $75 for this study whether or not you complete the study. Subjects who are disqualified for unknown health reasons will be given a complimentary “thank you for trying” gift of value not to exceed $10. If you fail to meet the advertised criteria as discussed with you previous to this appointment, you will be dismissed from the study without compensation.

Payment will be made at the end of your test on the day of the study.

Sponsorship / Funding of this Study
Sponsorship / funding of this study is provided by Binah.ai and given to Clinimark to perform this study on behalf of the sponsor.

Confidentiality
By signing this document, you agree to keep the sponsor of this study confidential, and to NOT discuss or publish the sponsor of this study or the details of the device being tested with anyone other than family members or friends who may help in your decision to participate in this study.

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HIPAA Authorization to Use and Disclose Information for Research Purposes
Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What information may be used and given to others?
If you choose to be in this study, the study doctor and study staff will get personal information about you. This may include information that might identify you, including video recording. The study doctor and study staff may also get information about your health including:

- Basic demographic information
- Medical information provided during the health screen / health questionnaire
- Records made through observations during the study
- Records made through phone calls as part of this research
- Records about your study visit

Who may use and give out information about you?
Information about your health may be used and given to others by the study doctor, study staff or by Binah.ai, the sponsor of this study. Your identity will be kept confidential to the extent allowed by the law and will not be made publicly available.

Clinical Trials - This section ☒ Applies Does Not Apply
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.

Who might get this information?
- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Salus Independent Review Board
- The Sponsor or Sponsor's representatives

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The representatives from Clinimark or the sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site to be available for technical support and run the data acquisition system, as needed. They will follow how the study is done, and they will be reviewing your information for this purpose.

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The information may be given to the FDA or to Salus IRB. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for a new product resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by an independent review board (IRB). IRB is a group of people who perform independent review of research as required by regulations.

This authorization does not expire.

What if you decide not to give permission to use and give out your health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

Can you review or copy the information obtained from you or created about you?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

Can you withdraw or revoke (cancel) your permission?
Yes, but this permission will not stop automatically and does not expire.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to Paul Batchelder. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is your health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission. Every effort will be made to keep your identity confidential.

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Compensation for Injury
If you are injured or become ill as a direct result of your participation in this study, contact the study doctor or study staff immediately. Emergency medical treatment will be provided. The cost of this care will be covered by Clinimark and Binah.ai. No other compensation is routinely offered by the study doctor or study staff or sponsor.

Voluntary Participation / Withdrawal
Your participation in this study is voluntary and confidential. You may decide not to participate, and you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or study staff without your consent because:

- Your failure to cooperate fully (as determined by the study doctor or study staff) with the required conduct of this study.
- Your development of an illness.
- A determination by a Clinimark representative, for whatever cause, that the study should be discontinued.
- Technical issues with the equipment that prevent adequate collection of the data.
- A decision was made by the Sponsor, FDA, or Salus IRB to discontinue the study.

Questions
If you have any questions, concerns or complaints about this study or questions about your participation in this study, or if at any time you feel you have experienced a research-related injury, contact the study staff or study doctor listed on the first page of this form.

You may contact Salus IRB if you:

- would like to speak with someone unrelated to the research,
- have questions, concerns, or complaints regarding the research study, or
- have questions about your rights as a research participant.

Salus IRB
2111 West Braker Lane, Suite 100
Austin, TX 78758
Phone: 855-300-0815 between 8:00 AM and 5:00 PM Central Time
Email: clinicaltrials@versiti.org

If you would like additional information about your rights, research in general, or IRBs, you may visit www.versiticlinicaltrials.org

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It is recommended that you inform your personal physician of your participation in this clinical investigation.

You will receive a copy of this signed and dated informed consent and any other written information provided to the subjects in this study, if applicable, for your records.

Subject Responsibilities
You are responsible for reporting any concerns or discomforts that occur during the study so they may be addressed, understanding of the procedures, or asking the study staff to explain, following instruction given by the study staff and letting the study staff know if you wish to stop your participation in the study.

Photos / Video
In this study we will take videos of your face and fingertips for data collection purposes and for the Sponsor's internal research and development purposes only. Additional photos may be taken of any site where we have placed equipment. Photographs and video of your face will be unavoidable. In order to protect your identity, your name will be kept confidential at all times.

This consent will remain in effect for as long it is needed for the Study Sponsor's internal research and development purposes or 15 years, whichever is longer.

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Consent

I have read the information in this consent form. All my questions about the study and my participation in it have been answered. I freely consent to be in this research study and will follow the study doctor and study staff's instructions with the understanding that I may withdraw at any time without penalty of the compensation for participation once enrolled.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

CONSENT SIGNATURES:

Adult Subject Name

Signature of Adult Subject Date

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion Time Date

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