



TEAM

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BACKGROUND

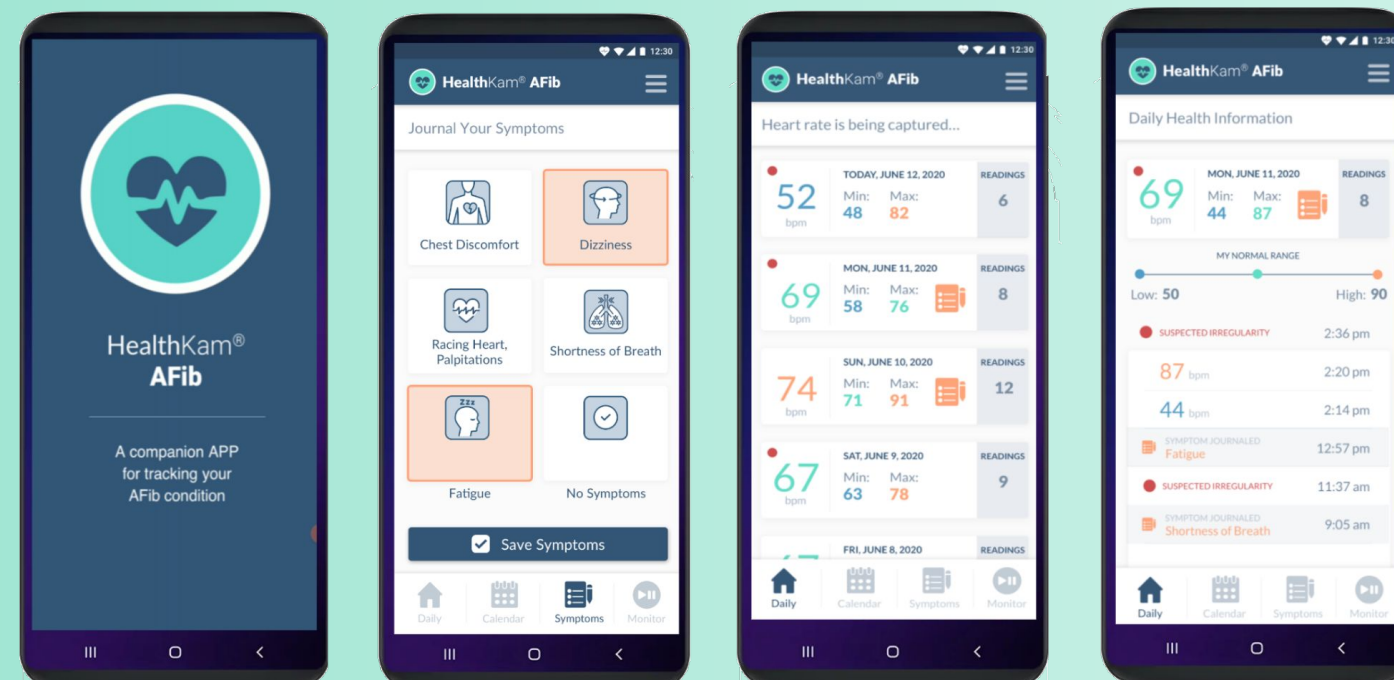
We aim to evaluate a unique technology leveraging the camera from smartphones to passively monitor the pulse of patients with atrial fibrillation and automatically detect the presence of irregular rhythms. The video technology is called facial videoplethysmography (VPG).

This monitoring concept addresses the challenge of compliance of patients with wearable and other home-monitoring devices. Such devices require maintenance and recording procedures which burden patient's lives and lead to device attrition.

The VPG technology is an effortless cardiac monitoring technology which takes advantage of the increasing popularity of smartphone adoption

HealthKam AFib

Main User Interfaces



HealthKam AFib

AFib symptoms

History

Daily reports



Description of the HealthKam AFib Interface block model.

METHODS

INVESTIGATIONAL DEVICE:	HealthKam™ AFib (v1.0)
DEVICE DESCRIPTION	HealthKam AFib is a companion APP for patients diagnosed with atrial fibrillation. The APP provides pulse rate measurements using contactless facial video.
INDICATION FOR USE	HealthKam AFib is indicated for self-testing by patients who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis.
DESIGN	Observational study
OBJECTIVES	To verify the usability and evaluate the impact of human factors of the HealthKam AFib application when loaded on an Android smartphone device and used at home for a period of 15 days. The human factors will be evaluated in 15 patients with the full spectrum of human skin tones (Fitzpatrick scale I to VI).
NUMBERS OF PATIENTS	Fifteen subjects with paroxysmal AFib will be enrolled. Up to an additional 15 patients may be enrolled if the APP requires adjustments to the user interface during the study.
INVESTIGATIONAL CENTER	Single-center, VPG Medical Inc.

Human factor Evaluation

APP Navigation (VPG Medical office)

The subject shall be shown an instructional video. The study staff will give the subject a generic device with HealthKam Afib installed, ask a series of questions related to on-demand capture of VPG signal, and check the subject's ability to use this specific functionality of the APP. The subjects will be enrolled only if they are able to perform the on-demand data collection.

APP Installation (VPG Medical office):

Following the subject's enrollment, the participants shall install the APP on their smartphone and be shown the HealthKam AFib instructional video. Per standard workflow, this video is automatically displayed to users during the product installation and registration process.

APP commissioning (enabling the monitoring account, VPG Medical office)

After installation of the APP, the subject will commission the APP with the help of the study staff who will provide a commission code. The study staff shall monitor this process and note any user difficulties during the installation and registration process.

Readability, Visual Design, Ability of users to interpret and read data, Notifications, and Alerts (call subject's home)

The study staff will call the subject at home after a couple of days, ask a series of questions related to navigation on the APP, and check the subject's ability to understand and access the various functionalities of the APP. The study staff shall also ask the subject to "report" their data to the clinical trial project manager.

IFU and Help Resources (data collection completion survey to be mailed)

A data collection and completion survey will be part of the participant packet with a stamped envelope for mailing the survey at the end of the 15-day period. These will be applicable to the objective and subjective acceptance criteria. Entries on the data collection will be compared to server data to ensure the user was able to accurately interpret their HealthKam Afib heart rate and rhythm results. .

AIMS

The purpose of this protocol is to evaluate the usability and other human factors of the HealthKam™ AFib (v1.0) application when loaded and running on an ANDROID smartphone in real-life conditions.

METHODS

We propose to conduct a prospective cohort study enrolling 15 AFib patients with paroxysmal AFib. In summary, the subjects will be approached by VPG Medical in the Rochester (NY) community via multiple media (newspaper, local hospital, and radio advertisements). Eligibility of the 15 patients will be confirmed via a mailed survey. Upon confirmation of their eligibility, the subjects will consent in person at the VPG Medical office.

DELIVERABLES

HUMAN FACTORS:

Comparison of data collection survey results to values as collected in the database.
Comparison of subjective survey data to study endpoints.

DATA COLLECTION

Load the VPG data collected by the subject using the VPG Medical dashboard.
Compute the rate of capture and the rate of failure as described in Table 2.