Minimizing Covid-19 Exposure to Patients and Providers During Cardiac Monitoring

AN APPLICATION NOTE FROM IMEDRIX INC.

At the present time (March 2020), the Covid-19 pandemic is ravaging the world. Early reports indicate that health care workers and chronic heart disease patients form some of the highest risk groups. In fact, a preprint paper from China indicates MI events as contributing most to the fatalities among Covid-19 positive patients. Adding to the burden, health workers on the frontlines have been falling victim to the virus as well. ***Every procedure in the clinic must now focus on minimal patient contact and remote/tele assessment if possible.***

Currently, there are two primary treatments being tried out, both with additional risk to those with heart disease: (1) a treatment with a combination of anti-viral drugs and (2) a combination of Chloroquine Phosphate and Azithromycin. In either case, the therapeutic window is small and patients are frequently at high risk to develop cardiac complications such as arrythmias, prolonged QT etc., calling for proactive cardiac monitoring of the patient.

KardioScreen 1612A (FDA, CE) from iMedrix Inc, can help caregivers in quarantine facilities, clinics and homes to monitor cardiac function without getting exposed to Covid-19 during this active pandemic. KardioScreen integrates an easy to use/self-administered teleECG with triage and parameter alert monitoring (ST elevation, prolonged QT, Tachycardia up to 220 bpm etc.)

The following sections describe simple protocols for contactless ECG/patient distancing in the following scenarios:

1. Eliminate patient contact in hospital for ECG monitoring of isolated Covid-19 patients with underlying conditions
2. Eliminate patient contact and reduce risk for patients under treatment or chemoprophylaxis through remote or contactless monitoring of potential complications
3. Eliminate patient contact through remote monitoring Covid-19 patients quarantined at home
4. Eliminate patient contact in clinic for non-emergency treatment of patients with unknown Covid-19 status
5. Reduce risk for chronic patients through remote ECG monitoring

The posters and videos accompanying this document provide visualizations of how distancing can be accomplished.

Please contact us at +1.866.IMEDRIX (463-3749) or covid19@imedrix.com for more details.

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SCENARIO 1

Eliminate patient contact in hospital for ECG monitoring of isolated Covid-19 patients with underlying conditions

Context:

- Patient is in hospital, Covid-19 status positive.
- ECG monitoring is needed for underlying chronic heart disease or comorbidity.

Why do Covid-19 patients need cardiac monitoring?

Higher chance of fatality due to:

- Cardiac injury by Virus infection, STEMI events, elevated Troponin Levels etc.[1]
- Therapeutic and prophylactic treatment regimens may cause cardiotoxicity.[2]

What is the risk to caregivers?

- Recording ECG using traditional devices puts caregivers in close proximity to patients, increasing personal risk as well as transmission probability.
- Equipment risk and burden – Wheeling ECG cart, paper, gel etc. require elaborate sanitization steps between patients.

How can KardioScreen help?

- KardioScreen is a digitally connected, small and mobile 12 lead ECG device.
- Records safely and accurately from up to ~10 m away from patients
- Pocket sized and easily sanitized with alcohol wipes.
- Low cost and efficient. Facilities can use multiple KardioScreen devices for the cost of a single shared ECG device.
- Short Video Demo of 6 lead ECG: https://youtu.be/fsep8HdWVUo

Suggested Use model (No Patient Contact, Minimal Disinfection Effort):

For Coronavirus Positive Patients who are isolated and responsive:

- A simple chart helps patients self attach electrodes and plug in the device
- Healthcare worker acquires ECG from outside the isolation room/chamber
- Digital ECG can be displayed on any physician phone/computer within system and integrated to EHR
- Real time analysis for STEMI, prolonged QT etc. Custom alerts are possible.
- Once done, disinfect the surface with alcohol wipes and use it for other patients.

For Coronavirus patients who are unresponsive or can't self assist:

- Attach electrodes while wearing PPE and plug in KardioScreen unit and follow the protocol as per points above

Reference:

1. https://jamanetwork.com/journals/jamacardiology/fullarticle/2763524?guestAccessKey=f0e95b50-fbb4-4d35-9306-e55e01f820bd&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfl&utm_term=032520
2. https://www.dicardiology.com/article/covid-19-hydroxychloroquine-treatment-brings-prolonged-qt-arrhythmia-issues

SCENARIO 2

Eliminate patient contact and reduce risk for patients under treatment or chemoprophylaxis through remote or contactless monitoring of potential complications

Context:

- Patient may be at home or in isolation facility.
- Patient is under a treatment plan which causes Cardio-vascular complications.
- Patient needs to be monitored for escalating conditions such as QT prolongation.
- Chemoprophylaxis recipients and possibly healthcare workers may be otherwise asymptomatic.

What is the Risk to Patients and Caregivers:

- Recording ECG using traditional devices puts caregivers in close proximity to patients, increasing personal risk as well as transmission probability.
- Treatment plan may exacerbate underlying CVD conditions or introduce new complications and side effects. Unknown interactions with prior prescribed medications. Hence, needs close monitoring.
- **DO NOT USE THIS WORKFLOW IN AN EMERGENCY. ADVISE PATIENT TO CALL EMERGENCY SERVICES SUCH AS 911 FOR ACUTE NEEDS.**
- **STRONGLY ADVICE PATIENT TO NOT USE CONSUMER GRADE ECG DEVICES BECAUSE THEY OFTEN RESTRICT ANALYSIS TO 50-100 BPM RANGE ETC.**

How can KardioScreen help?

- KardioScreen is a digitally connected, small and mobile 12 lead ECG device.
- Records safely and accurately from home or in a clinical facility
- ECGs acquired at home can be seen by a remote nurse/physician in real time
- ECGs performed in a facility can be administered with no/minimal patient contact and sent wirelessly within network.
- Short Video Demo of 6 lead ECG: https://youtu.be/fsep8HdWVUo

Suggested Use model (Self use at home):

- Physician or Nurse advises patient to do 12 or 6 lead ECG.
- Video and Simple chart helps patients self attach electrodes and plug in Device
    - In case only a 6 lead ECG is needed, only 4 clamps need be used. Do not share clamps with other patients or family members.
- Acquire ECG on Android Tablet.
- Digital ECG can be displayed on any physician phone/computer system and integrated to EHR
- Real time analysis for STEMI, prolonged QT etc. Custom alerts possible.
- Await instructions from nurse/physician before disconnecting equipment.
- Once done, disinfect the device, clamps and cable with alcohol wipes and store.

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SCENARIO 3

Eliminate patient contact through remote monitoring Covid-19 patients quarantined at home

Context:

- Patient is at home, Covid-19 status positive.
- ECG needed to monitor underlying co-morbidities

What is the risk to caregivers?

- Recording ECG using traditional devices puts caregivers in close proximity to patients, increasing personal risk as well as transmission probability.
- Patient should be in isolation to the extent possible and avoid contact with other persons.
- **DO NOT USE THIS WORKFLOW IN AN EMERGENCY. ADVISE PATIENT TO CALL EMERGENCY SERVICES SUCH AS 911 FOR ACUTE NEEDS.**

How can KardioScreen help?

- KardioScreen is a digitally connected, small and mobile 12 lead ECG device.
- Records safely and accurately from home
- ECGs acquired at home can be seen by a remote nurse/physician in real time
- Short Video Demo of 6 lead ECG: https://youtu.be/fsep8HdWVUo

Suggested Use model (Self use at home):

- Physician or Nurse advises patient to do 12 or 6 lead ECG.
- Video and Simple chart helps patients self attach electrodes and plug in Device
    - In case only a 6 lead ECG is needed, only 4 clamps need be used. Do not share clamps with other patients or family members.
- Acquire ECG on Android Tablet.
- Digital ECG can be displayed on any physician phone/computer system and integrated to EHR
- Real time analysis for STEMI, prolonged QT etc. Custom alerts possible.
- Await instructions from nurse/physician before disconnecting equipment.
- Once done, disinfect the device, clamps and cable with alcohol wipes and store.

SCENARIO 4

Eliminate patient contact in clinic for non-emergency treatment of patients with unknown Covid-19 status

Context:

- Patient is at clinical facility, Covid-19 status unknown.
- ECG is needed for diagnostic reasons.

What is the risk to caregivers?

- Recording ECG using traditional devices puts caregivers in close proximity to patients, increasing personal risk as well as transmission probability.
- Equipment risk and burden – Wheeling ECG cart, paper, gel etc. require elaborate sanitization steps between patients.

How can KardioScreen help?

- KardioScreen is a digitally connected, small and mobile 12 lead ECG device.
- Records safely and accurately from up to ~10 m away from patients
- Pocket sized and easily sanitized with alcohol wipes.
- Low cost and efficient. Facilities can use multiple KardioScreen devices for the cost of a single shared ECG device.
- Short Video Demo of 6 lead ECG: https://youtu.be/fsep8HdWVUo

Suggested Use model (No Patient Contact, Minimal Disinfection Effort):

- Simple chart helps patients self attach electrodes and plug in Device
- In case only a 6 lead ECG is needed, only 4 electrodes need be used. Do not use clamps unless disinfection method is available.
- Acquire ECG from outside the exam room/ > 6ft away from bed
- Digital ECG can be displayed on any physician phone/computer within system and integrated to EHR
- Real time analysis for STEMI, prolonged QT etc. Custom alerts possible.
  Once done, disinfect the device and cable with alcohol wipes and use it for other patients.

SCENARIO 5

Reduce risk for chronic patients through remote ECG monitoring

Context:

- Chronic CVD patient in need of regular checkup.
- Presumed Covid-19 negative.
- Eliminate exposure, contact and travel.

Risk to Patient:

- Visiting a clinic for checkup exposes patient to multiple social contacts and risks transmission from healthcare workers who may be exposed themselves.
- **DO NOT USE THIS WORKFLOW IN AN EMERGENCY. ADVISE PATIENT TO CALL EMERGENCY SERVICES SUCH AS 911 FOR ACUTE NEEDS.**

How can KardioScreen help?

- KardioScreen is a digitally connected, small and mobile 12 lead ECG device.
- Records safely and accurately from home
- ECGs acquired at home can be seen by a remote nurse/physician in real time
- Short Video Demo of 6 lead ECG: https://youtu.be/fsep8HdWVUo

Suggested Use model (Self use or assisted use at home):

- Physician or Nurse advises patient to do 12 or 6 lead ECG.
- Video and Simple chart helps patients self attach electrodes (In some assisted living situations, a caregiver at home may be part of this workflow.) and plug in Device
    - In case only a 6 lead ECG is needed, only 4 clamps need be used. Do not share clamps with other patients or family members.
- Acquire ECG on Android Tablet.
- Digital ECG can be displayed on any physician phone/computer system and integrated to EHR
- Real time analysis for STEMI, prolonged QT etc. Custom alerts possible.
- Await instructions from nurse/physician before disconnecting equipment.
- Once done, disinfect the device, clamps and cable with alcohol wipes and store.