An Automated Deep Vein Thrombosis Risk Assessment Device

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Abstract

Deep Vein Thrombosis (DVT) is a condition where a blood clot forms in the deep veins from a lack of contraction in the leg muscles leading to decreased blood flow and increased clotting. The proposed device detects the early signs of DVT in hospitalized patients both automatically and non-invasively.The device will use camera sensors to image parts of the skin and use LEDs to sample under uniform lighting conditions. Then the device calculates the patient's risk of developing a DVT; by checking how much the calculated inflammation probability and systemic O_2 levels deviated from their respective threshold ranges.

Introduction

Long term bedridden and regularly hospitalized patients who spend more than 14.3 hours a day in bed, have a significantly increased risk of developing a DVT (Tun 2004), (Arpaia, 2001).The current methods of detecting DVT occurrence include; ultrasound scans, venography techniques, pressure cuff readings, blood tests for clotting proteins, and manual checks for signs of inflammation. However these methods are unable to detect the early signs of DVT without the presence of a medical practitioner and frequently enough to allow for early preventive measures to be given. Therefore this device aims to provide "A novel way to detect the early formation of DVT in hospitalized individuals".

Design Inputs

1.The device must be able to detect inflammation presented on the skin surface for all different skin tones.
Justification: Skin discoloration is a symptom of reduced blood flow, which is a correlate for DVT.
Specifications: 1.1) The device correctly identifies presentation of erythema from digital images regardless of skin tone over 85% of the time.[3]
1.2) All medical images collected by the device will not collect any PID from the patient.

2.The device must be able to obtain the patient's Hemoglobin bound Oxygen levels.
Justification: Low systemic O_2 levels are related to early blood clot formation. Hemoglobin bound Oxygen accounts for 97% of Systemic Oxygen.
Specifications: 2.1) Obtains measurement at 1Hz from hospital oximeter.[5]
2.2) Maintaining the "fidelity" of bluetooth transferred data.

3.The device must accommodate a wide range of sizes to match the user.
Justification: A wide range of sizes will allow the device to be worn comfortably as well as prevent the device interfering with DVT assessment.
Specifications: 3.1) Ankle (Mean ± SD) Male: 23.5 cm ± 1.5 cm (19.0 - 28.0 cm) Female: 21.9 cm ± 1.3 cm (18.0 - 25.8 cm)
3.2) Must be able to adjust circumference to accommodate the area of interest.

4.The device must have sufficient battery life to monitor the patient's stats for long periods of time.
Justification: A long battery life will allow for continuous monitoring of patients without disruption.
Specifications: 4.1) More than 12 hours to allow changing of nurse shifts.

5.Device must cause little to no reaction to the skin of the patient.
Justification: Reactions to the skin can cause interferences with inflammation monitoring and affect DVT risk assessment.
Specifications: 5.1) The power delivered to the skin from the LEDs is less than 180 mW/cm^2 and/or 0.2 mJ/cm^2.[6]
5.2) The material that contacts skin should be compliant with ISO 10993-10:2010(E).[7]

6.The device must be able to alert healthcare workers when DVT risk reaches threshold level set by healthcare workers.
Justification: Early alerts to healthcare workers will allow for preventive measures to be taken and prevent further clot formation and damage to the blood vessels.
Specifications: 6.1) Trigger alarm within <1s when the risk thresholds are reached.
6.2) SpO_2 threshold can be set between 95% and 100% with 1% resolution.
6.3) Erythema threshold can be set between 85-100% probability of the skin displaying inflammation with 1% resolution.

7.The device must be electrically safe for use.
Justification: The device is electrically powered through a battery.
Specifications: 7.1) The leakage current < 500 uA to adhere to IEC 60601-1.

8.The device must be reusable from patient to patient.
Justification: Making the device reusable will make it more cost effective as well as easily transferable from patient to patient.
Specifications: 8.1) The device must have an IP14 rating.
8.2) Strap material must be washable/sterilizable/detactiable.

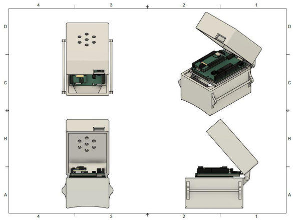
Design Solution

Verifications:

1.1) Test the algorithm using a new dataset of skin images and verify that 85% of true positives are identified.
1.2) No verification testing, specification is more of a design constraint in order to adhere to ISO 12052:2017.
2.1) Measure the frequency for obtaining the oximeter readings (≧1 Hz).
2.2) Send sample oximeter data over bluetooth and ensure all data is accurate.
3.1 & 3.2) Verify that the size of the device will be incrementally changeable to accommodate the desired ranges (18.0 - 28.0 cm) by measuring the device's length's to the nearest 0.10 cm.
4.1) Calculate the power consumption of the device and its constituent parts.
5.1) Estimate the power output for the LED's from the power delivered to it.
5.2) Place material on participant skins and check for discoloration, damage, and inflammation.
6.1) The device alarm will be artificially triggered and the time delay will be programmatically timed.
6.2 & 6.3) Device UI will be used to adjust the SpO_2 and erythema thresholds and system was adjusted in appropriate increments.
7.1) Measure the leakage current on the chassis of the prototype.
8.1) The device will be tested to ensure that any object > 50 mm and water splashing against the enclosure will not penetrate the device for a minimum of 10 minutes.
8.2) Strap must survive 10 wash cycles at least.

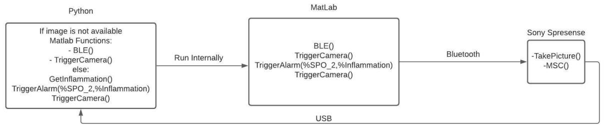
Validations:

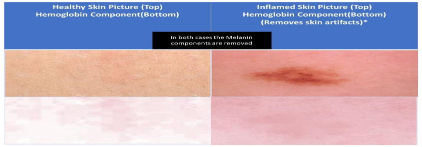
1) Test the device on human skins of varying tones and determine that the device correctly identifies when the skin has inflammation 85% of the time.
2) Can take % O_2 readings from the hospital's oximeter and transmit through the bluetooth module.
3) Test it on a range of different sized people.
4) The device will be powered on by the chosen battery pack for 12 continuous hours and all parts are functioning as intended.
5) Evaluate redness after using the prototype for 12 hours.
6) The device will be placed on normal and artificially inflamed skin and set to log SpO_2 and erythema values, which will be used to determine if an alarm was sounded when thresholds were reached.


Final CAD model of the intended device.

Testing

1.We used a radial basis function Kernel statistical vector machine that was trained using a sample size of 110 images (55 healthy/55 inflamed). The algorithm had an average accuracy of 86.48%. The system runs 30-40 seconds and a sound will alarm whenever a threshold is reached.
2. The bluetooth part of the device did not work as intended, as an agent only bluetooth module is the only one that's compatible with the Sony Spresense board.
3. All safety and comfortability requirements were passed apart from requirement 8 as the device must have holes for a louder alarm sound to pass through. Therefore, the device is doesn't have an IP14 rating for water proofing electrical devices.





Conclusions

Our device can accurately access and warn nearby physicians when a bedridden patient is at a higher risk of DVT through changes in skin discoloration and SpO_2 readings. The device can distinguish with approximate accuracy of 86.48% of the time when a bedridden patient is showing symptoms of DVT prior to the event. Future considerations for optimizing the vector machine algorithm would be to add a larger sample size in addition to incorporating a deep learning component to better the analysis of the images.

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Acknowledgements

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