DIABISOLE: OPTIMIZING DIABETIC FOOT CARE THROUGH MACHINE LEARNING AND IMAGE PROCESSING

Project ID: 2023-170

Project Final (draft) Report - Group

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B.Sc. (Hons) Degree in Information Technology (specialization in Data Science)

Department of Information Technology

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DECLARATION

We declare that this is our own work, and this proposal does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any other university or Institute of higher learning, and to the best of our knowledge and belief, it does not contain any material previously published or written by another person except where the acknowledgment is made in the text.

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The above candidates are carrying out research for the undergraduate Dissertation under my supervision.

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Signature of the Supervisor Date

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Signature of the Co-Supervisor Date

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Finally, we would like to express our heartfelt gratitude to our family and friends who helped us to carry out this project.

ABSTRACT

In recent years, there has been a notable surge in the prevalence of diabetes, leading to a concomitant increase in complications such as diabetic foot ulcers and neuropathic damage. The implementation of customized diabetic insoles has emerged as a pivotal strategy in mitigating these complications by effectively redistributing high-pressure points, a practice commonly referred to as pressure offloading, and providing essential support. Nonetheless, the conventional manual customization process for these insoles is not only time-intensive but also subjective, frequently resulting in erroneous outcomes. This research endeavors to introduce "DiabiSole," a pioneering web-based application engineered to automate several critical aspects of this process. DiabiSole expedites the identification and measurement of calluses and heightened pressure, the identification of regions on the foot exhibiting pressure offloading regions, and the prediction of callus severity. To accomplish these objectives, three distinct datasets were harnessed. A sole image dataset for callus area detection and quantification, a scanned foot image dataset for detecting heightened-pressure areas, and a dataset with callus and pressure area measurements to predict severity. The two distinct U-Net models employed for callus and heightened-pressure area identification achieved commendable accuracies of 93% and 98%, respectively. Measurements of relevant areas were facilitated through the utilization of the OpenCV library, while Pixel Distribution Analysis was incorporated to accentuate areas necessitating pressure offloading. Wound criticality prediction employed a Gaussian Naïve Bayes model, reaching a remarkable 99.21% accuracy. In summary, "DiabiSole" revolutionizes personalized insole creation for diabetic foot ulcers in Sri Lanka. This innovative system enhances patient outcomes, reduces ulceration, and minimizes the need for amputations.

Keywords – Callus, pressure offloading, web application, wound criticality, high-pressure

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LIST OF ABBREVIATIONS

Abbreviation	Description
IP	Image Processing
ML	Machine Learning
DL	Deep Learning
AI	Artificial Intelligence
UI	User Interface
DFU	Diabetic Foot Ulcer
LBP	Local Binary Pattern
GLCM	Grey Level Co-occurrence Matrix
LEA	Lower Extremity Amputations
CHS	Chronic Health Status
ROC	Receiver Operating Characteristic
AUC	Area Under Curve

LIST OF APPENDICES

1 INTRODUCTION

1.1 Background

Diabetes is a pressing global health concern, impacting an estimated 463 million adults worldwide in 2019 [1]. Among the severe complications of diabetes are Diabetic Foot Ulcers (DFUs), persistent sores that often develop on the feet or lower legs of diabetic individuals. It is disheartening to note that between 15% to 25% of diabetic patients will, at some point in their lives, experience the distress of a DFU [2]. These ulcers are frequently the result of a combination of factors, encompassing poor circulation, nerve damage, and impaired wound healing. In diabetic patients, elevated blood sugar levels can inflict damage on blood vessels and nerves, leading to reduced blood flow to the extremities and a diminished ability to perceive pain and injury. Consequently, even minor injuries or blisters on the feet may go unnoticed and become infected, culminating in the development of DFUs.

The management of DFUs is exceptionally challenging, and they often lead to infections and other severe complications, rendering them a primary cause of lower limb amputations in diabetic patients. Astonishingly, more than one million patients worldwide lose part of their lower extremities each year due to the failure to identify and treat DFUs in a timely and appropriate manner [3]. Managing DFUs necessitates periodic checkups, costly medications, and meticulous hygiene, imposing a significant financial burden on patients and their families, particularly in developing countries where the cost of treatment can equate to as much as 5.7 years of the average annual income [4]. Sri Lanka is no exception to this global trend. A recent study in the country revealed a significant rise in the percentage of urban residents with diabetes over the past three decades, affecting an estimated 27.6% of the urban population [6]. This is a particularly concerning development as a significant proportion of these patients also suffer from foot complications, with up to 50% of individuals with type 1 and 2 diabetes developing DFUs [7], [8].

DFUs can be classified into various stages based on their severity, with the Wagner classification system being a commonly used scale, ranging from stage 0, indicating a high-risk foot with no open wounds, to stage 5, indicating gangrene or necrosis of the foot necessitating amputation. Customized footwear is often recommended for patients with stage 2 or higher DFUs, particularly those at moderate to high risk of developing additional foot complications.

To achieve offloading and pressure redistribution, specialized footwear is employed, alleviating pressure on the affected areas and expediting the healing process. Customized footwear tailored to the patient's foot shape, size, and specific ulcer location offers a superior fit compared to standard off-the-shelf options, reducing the risk of injury and infection while enhancing comfort and mobility through proper foot support, cushioning, and protection [9]. These customized shoes feature removable insoles that can be tailored to address specific foot issues such as arch support, pressure relief, and shock absorption [10].

Traditionally, clinicians relied on manual assessments with pressure mapping devices or more efficient static scanners to gauge pressure distribution using pressure-sensitive film. Alternatively, dynamic scanners offered real-time imaging of pressure distribution during movement, aiding in the precise identification of high-pressure areas contributing to DFU development.

The customization of diabetic footwear primarily centers around tailoring the insole. Current practices in Sri Lanka involve creating a foot impression using materials like plaster of Paris, which is then modified based on clinical evaluation to craft a static insole [11]. Another approach involves manually creating holes within the insole at the site of calluses, supplemented with an overlay to prevent contact between the callus and the hole edges. These methods, however, are time-consuming, prone to misidentification of wound sites, and may pose challenges for individuals with sensory deficits [12], [13].

Additionally, predicting the criticality of DFUs is a pivotal consideration when implementing pressure offloading strategies. While high pressure is a recognized factor in DFU occurrences [14], subsequent research has demonstrated that the presence of calluses exhibits greater predictability regarding the development of future ulcers [15]. Relying solely on high pressure as a predictive tool for ulceration has proven to be of limited effectiveness [16]. Given these observations, there is a clear need for a comprehensive DFU criticality prediction system that integrates both callus and elevated pressure areas as crucial elements when customizing pressure offloading insoles. While various wound criticality scoring or prediction systems have been developed to evaluate DFUs, a notable gap exists in systems that simultaneously consider both callus area and pressure distribution in the prediction process.

In response to these challenges, this research initiative seeks to develop a web-based application capable of precisely identifying callus regions, measuring their dimensions, providing visualizations for targeted pressure relief within the insole, and predicting callus criticality. This application aspires to enhance pressure mitigation for DFUs and high-pressure regions by addressing deficiencies inherent in traditional approaches, improving overall patient care and therapeutic outcomes.

1.2 Literature Survey

The UTrack framework for segmenting and measuring dermatological ulcers through telemedicine [17].

The research presented in reference [17] introduces "UTrack," a telemedicine-driven framework tailored for the segmentation and quantitative assessment of dermatological ulcers. This innovative approach comprises a smartphone application coupled with a measurement technique reliant on a simple ruler to quantify ulcer dimensions accurately. Furthermore, it facilitates the longitudinal storage, visualization, and sharing of chronic dermatological ulcer analyses. It is important to underscore that this solution is readily accessible and user-friendly, compatible with standard mobile devices equipped with conventional cameras. Notably, it is exceptionally inclusive, serving patients, caregivers, and healthcare professionals without necessitating specialized equipment like internet connectivity, specific sensors, or advanced cameras. The system efficiently utilizes the ruler-based measurement approach to precisely determine wound dimensions.

The authors use various features of the wound for measuring the area, which include:

- Wound perimeter: The boundary of the ulcer, which is identified by the user tracing around the ulcer using the smartphone application.
- Wound shape: The overall shape of the ulcer, which can be irregular or asymmetrical.
- Wound color: The color of the ulcer and the surrounding skin. Color features were extracted using Red, Green, Blue (RGB) color space.
- Image quality: The quality of the smartphone image.

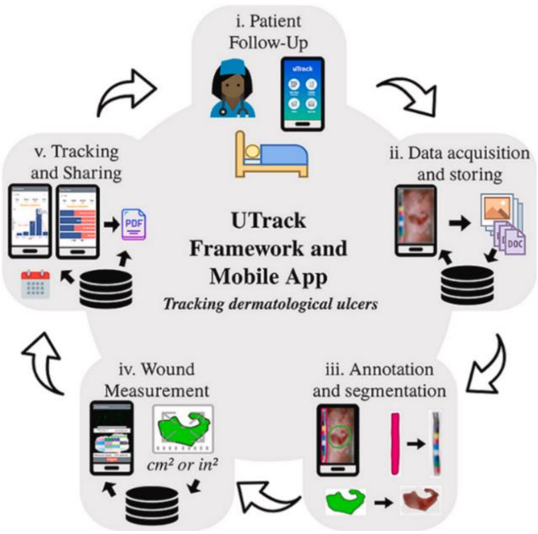

Figure 1.1: Architecture of the Mobile App

Wound area measurement with 3D transformation and smartphone images [18].

The primary aim of the study outlined in reference [18] is to attain a precise and quantitative evaluation of surface wound areas. To achieve this objective, a 3D transformation algorithm is employed, which facilitates the projection of the wound onto a two-dimensional plane, thus enabling accurate measurement of the wound's area. Rooted in photogrammetric principles, this algorithm utilizes user-identified features to reconstruct a three-dimensional model of the wound. Subsequently, the area of the wound is ascertained by incorporating the user-identified perimeter and dimensions within the generated 3D model.

The authors use various features of the wound for measuring the area, which include:

- ❖ Wound perimeter: The border between the ulcer and the surrounding healthy tissue, which is identified by tracing around the wound using the smartphone camera.
- ❖ Wound shape: The overall shape of the ulcer, which can be irregular or have asymmetrical edges.
- ❖ Wound dimensions: The length and width of the ulcer, which are used to calculate the wound area.
- ❖ Wound texture: The texture of the ulcer area.
- ❖ Wound color: The color of the ulcer area.
- ❖ Image quality: The quality of the smartphone image,

The wound extraction and calculation process is shown in Figure 1.4.

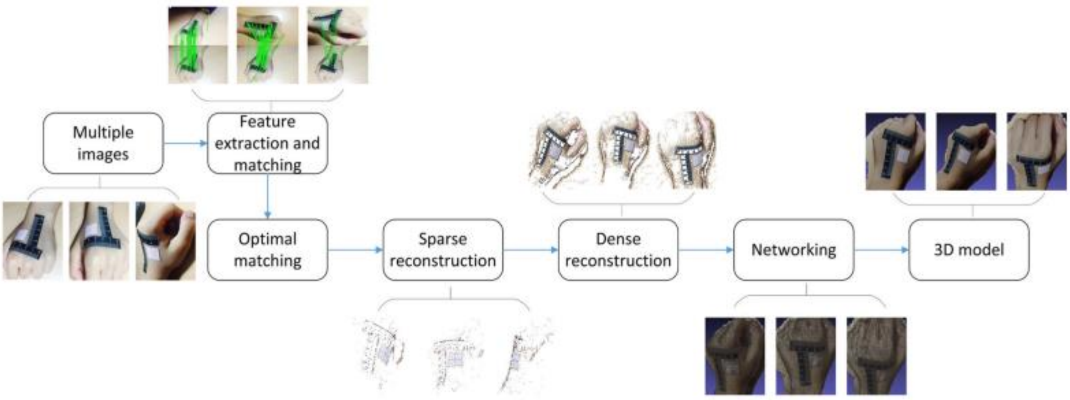

Figure 1.2: Process of 3D reconstruction

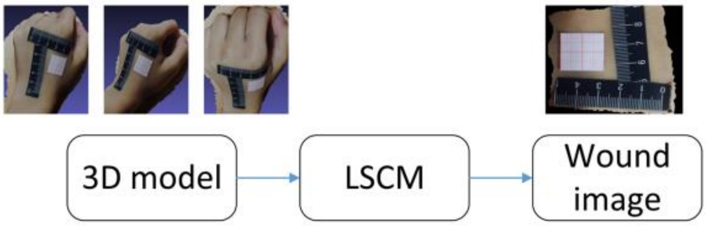

Figure 1.3: Process of 3D unwrapping

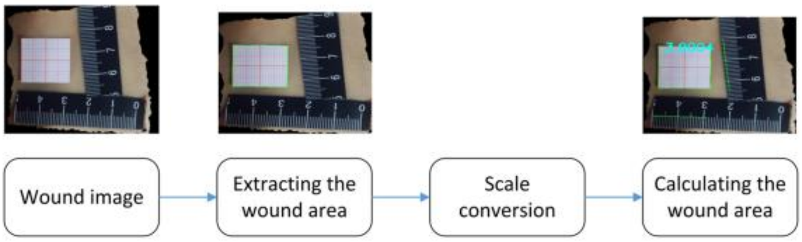

Figure 1.4: Process of calculating wound area

The effectiveness of this methodology is validated through a rigorous comparison between simulated and actual wounds, confirming its high level of accuracy. Importantly, this technique is adaptable to wounds captured by various cameras, regardless of factors such as acquisition angle, distance, or the specific imaging device employed.

A new diabetic foot risk assessment tool: DIAFORA [19].

In 2016, the “Diabetic Foot Risk Assessment (DIAFORA)” tool was developed in Portugal, comprising eight distinct variables. The variables are commonly used clinical factors for diabetic foot risk assessment, such as the presence of neuropathy, foot deformities, peripheral arterial disease, and previous foot complications. Additionally, it considered factors like the extent of diabetic foot ulcers, infection, gangrene, and bone involvement. This classification system serves a dual purpose, as it can be divided into two sections, each serving a different objective. The initial four variables, related to foot conditions, are primarily utilized for predicting the onset of foot ulcers. Meanwhile, the comprehensive version, encompassing all eight variables, is employed to forecast the likelihood of Lower Extremity Amputations (LEA) in individuals already diagnosed with DFUs.

DIAFORA employs a point-based system to categorize individuals into different risk groups, as outlined in Figure 1.5. There has been no external validation or assessment of the tool's reliability.

Foot related			DFU related		
Variables	Definition	Points	Variables	Definition	Points
DPN	Inability to feel SWM at ≥1 of 4 points (hallux pulp, first, third and fifth MTT heads)	4	Multiple DFU	Presence of ≥1 DFU	4
Foot deformity	Foot alteration increasing pressure in ≥1 sites of the foot	1	Infection	Purulent discharge with another two local signs (warmth, erythema, lymphangitis, lymphadenopathy, oedema or pain)	4
PAD	≤1 palpable pedal pulse (posterior tibial and dorsalis pedis arteries)	7	Gangrene	Presence of necrosis (dry or wet)	10
Previous DFU or LEA	History of previous DFU or LEA	3	Bone involvement	Bone exposure identified through visual inspection, touch with sterile probe and/or bone affection identified through X-ray	7
Risk groups					
Less than 15 points	Low risk of LEA	Between 15 and 25 points	Medium risk of LEA	More than 25 points	High risk of LEA

Figure 1.5: Rules for prediction

Diabetic neuropathic foot ulcers: predicting which ones will not heal [20].

Margolis et al. introduced various models based on data gathered from 150 wound care facilities operated by a single organization in the United States. These models aimed to predict the healing outcomes of neuropathic ulcers within a 20-week timeframe. The most straightforward model in their analysis incorporated factors such as a wound duration exceeding 2 months, wound size greater than 2 cm^2, and a Chronic Health Status (CHS) wound grade of 3 or higher. Each of these components contributed 1 point to the scoring system.

This scoring system demonstrated a noteworthy performance, achieving an area under the receiver operating characteristic (AUROC) curve of 0.8 for predicting non-healing outcomes, which encompassed lower extremity amputations (LEA) and death, within the 20-week period during an internal validation study. Notably, the research revealed that 35% of uncomplicated neuropathic Diabetic Foot Ulcers (DFUs) did not heal by the 20-week mark, highlighting the importance of these predictive models. However, there is a lack of published information regarding the reliability assessment of this model in the existing literature.

A Compact Wearable System for Detection of Plantar Pressure for Diabetic Foot Prevention [21].

This system is designed to provide wearable shoe-pads with built-in pressure sensors that can detect and track changes in the plantar pressure of the feet. The system includes a complete data collection circuit, wireless transmission circuit, and data analysis tools. The pressure sensors gather plantar pressure data and send analog signals to a microcontroller. A Bluetooth module is used to transmit the data to a computer for analysis, and a hot map of the plantar pressure is generated. The color patterns on the hot map can be used by users or medical staff to determine if a patient, especially one with diabetes, is at risk of developing foot ulcers. Additionally, the system includes an alarm feature to alert patients when necessary. Main steps of their system are,

- The device user has the capability to view a heat map on the screen, presenting an overview of the general planta profile.
- As the user walks, the heat map undergoes updates, revealing changes in plantar pressure distribution.
- The placement of pressure sensors encompasses the plantar region's most sensitive areas. As a result, the heat map provides accurate and scientifically sound data. The data's primary objective is to assist users in gaining a better understanding of their foot conditions.
- Moreover, the integration of wireless Bluetooth transmission makes the device wearable and enables it to deliver real-time heat maps to users.

Customized Foot Pressure Redistribution Insole Design using Image-based Rapid Pressure Measuring System [11].

The objective of the system developed in this research is to tailor adaptive multi-airbag foot pressure redistribution insole designs and manufacturing methodologies through the utilization of an image-based rapid pressure measurement system. The core component of this system is the Ground Contact Pattern Identification Scanning Mechanism, designed to assess the foot-to-ground contact pattern formed when the body's weight is supported by the foot. This mechanism operates by detecting variations in local contact pressure, which lead to altered blood flow within the sole's blood capillaries, resulting in distinct foot-to-ground contact patterns discernible by color differentiation. This system can identify and analyzing how an individual's foot engages with the ground, offering valuable insights applicable to tasks such as gait analysis and sports performance assessment. The system's workflow can be visualized through a three-part flowchart. They are,

- Measurement Devices
- Computer Interface Software
- Product Manufacturing

The computer interface software can identify the boundaries of the foot and determine its size. Additionally, it can calculate the weight-bearing distribution of different regions of the foot. This information is then used in the manufacturing process to create an adaptive multi-airbag insole. This innovative insole is designed to adapt to the unique contours of the wearer's foot and provide support and cushioning where it is needed most.

Footwear and insole design features for offloading the diabetic at risk foot-A systematic review and meta-analyses [22]

The goal of this study was to determine the best shoe and insole design elements for individuals with diabetic peripheral neuropathy (DPN) and type 1 or type 2 diabetes in order to offload the plantar surface and avoid the development of ulcers. To identify the footwear and insole designs that were most successful in lowering pressure on the plantar area and preventing the emergence of ulcers, which can result in more catastrophic consequences including amputation, the study evaluated fifty-four studies. The results of this study can aid medical practitioners in suggesting the best kind of shoes and insoles for DPN patients. The study used random-effects modeling, three meta-analyses, and patients with diabetic peripheral neuropathy to identify the best offloading features for preventing plantar ulcers. The findings revealed that the best methods for lowering peak plantar pressure were an arch profile, metatarsal addition, and pressure-informed design. The study's particular goals are to pinpoint the essential design elements of the following:

- The insole and shoe outsole's shape, as well as the insole.
- Shoe's upper and outsole's material composition and characteristics.
- Alterations to the shoe's outsole and insole.
- Insole and shoe construction methods.

According to the study, people with diabetic peripheral neuropathy can successfully relieve pressure on the plantar surface and avoid ulcers by changing their shoes and insoles to include characteristics like metatarsal additions, apertures, and arch profiles. Although many casting methods and materials also seem to be efficient, there is currently insufficient data to offer particular suggestions about their use. In order to prevent plantar ulcers in people with DPN, the study advises including the tested adjustments in the design of their footwear and insoles.

Techniques for Fusion of Multimodal Images: Application to Breast Imaging [23].

To capture various features of breast tissue, multimodal breast imaging employs a variety of imaging modalities. However, it's possible that evaluating the images from each modality separately won't yield enough details for a precise diagnosis. In order to provide more complete information, two modalities might be combined, such as mammography and ultrasonography. The act of registering and fusing the images from each modality to produce a single image is known as image fusion. In order to increase diagnostic accuracy, the focus of this research is on picture fusion in multimodal breast imaging to get a complete picture of the patient's health and to help with diagnosis and treatment. The two images are combined using the traditional finite element method, and the study covers three methods for visualizing the combined image as color mixing, using other color spaces, and interlacing.

Comparison of existing systems:

Table 1.1: Comparison of existing systems

Feature	01	02	03	04	05	06	07	08	DiabiSole
Identification of DFUs in the image	✓	✓	✗	✗	✗	✗	✗	✗	✓
Measure DFU areas	✓	✓	✗	✗	✗	✗	✗	✗	✓
High pressure (red color) areas identification	✗	✗	✗	✗	✗	✗	✗	✗	✓
Image processing techniques	✓	✗	✗	✗	✗	✓	✗	✗	✓
Assess DFU criticality	✗	✗	✓	✓	✗	✗	✗	✗	✓
Use high-pressure areas for criticality prediction.	✗	✗	✗	✗	✗	✗	✗	✗	✓
Comparison of two images	✗	✗	✗	✗	✗	✗	✗	✓	✓
Identification of pressure-offloading areas	✗	✗	✗	✗	✗	✗	✓	✗	✓

01- The UTrack framework for segmenting and measuring dermatological ulcers through telemedicine [17]
02 - Wound area measurement with 3D transformation and smartphone images [18]
03 - A new diabetic foot risk assessment tool: DIAFORA [19]
04 - Diabetic neuropathic foot ulcers: predicting which ones will not heal [20]
05 - A Compact Wearable System for Detection of Plantar Pressure for Diabetic Foot Prevention [21]
06 - Customized Foot Pressure Redistribution Insole Design using Image-based Rapid Pressure Measuring System [11]
07 - Footwear and insole design features for offloading the diabetic at risk foot-A systematic review and meta-analyses [22]
08 - Techniques for Fusion of Multimodal Images: Application to Breast Imaging [23]

1.3 Research Gap

Within the domain of diabetic wound management, there exists a profound research gap, one that revolves around the accurate identification and subsequent treatment of wounds on the feet of diabetic patients. Despite various strategies and techniques designed for pressure offloading in wound management, the current methods are fraught with limitations and challenges, demanding innovative solutions to effectively bridge this critical gap in research and healthcare practices.

A comprehensive review of the existing literature underscores a compelling and urgent need for a more precise and efficient approach to pinpointing the exact location of wounds on the feet of diabetic patients. Present practices predominantly rely on visual observations, introducing an inherent risk of human error in wound site identification. This susceptibility to misidentification carries grave implications, as it can precipitate severe complications such as infections and, in the direst cases, necessitate amputation. Furthermore, individuals afflicted with reduced vision or sensory numbness due to diabetic neuropathy face added complexities in their attempts to accurately discern and communicate the precise location of their wounds. Thus, the pressing research gap at hand centers on the development of a reliable and accessible method for the precise localization of diabetic foot wounds.

Concurrently, another noteworthy research gap emerges within the sphere of pressure offloading techniques. The conventional method entails the creation of custom insoles through the utilization of plaster of Paris molds of the patient's feet. This traditional approach brings with it several inherent drawbacks. Patients experience inconveniences as they are compelled to make multiple visits to healthcare professionals, which can lead to not only logistical challenges but also delays in treatment. Moreover, these plaster molds may not invariably yield a perfect fit for the patient's foot, resulting in discomfort and, crucially, potentially rendering the pressure offloading strategy ineffective. This glaring research gap serves to underscore the need for a patient-centric, alternative methodology that not only streamlines the process but also ensures the effective offloading of pressure points.

Hence, the critical research gap in diabetic wound management spans two interconnected dimensions. Firstly, it revolves around enhancing the precision and accessibility of wound localization, recognizing the limitations of current practices, especially in catering to patients with sensory impairments. Secondly, it underscores the necessity for an innovative, patient-friendly approach to pressure offloading that obviates the inconveniences associated with traditional methods, promoting both timely intervention and comfort. The pursuit of solutions to these research gaps is paramount, promising not only improved patient outcomes but also the advancement of diabetic foot care on a broader scale.

1.4 Research Problem

The current method of identifying the exact location for cutting holes in the insole in diabetic foot care presents a substantial research problem. Visual observations, while widely used, are inherently subjective and dependent on the clinician's expertise. This introduces a significant risk of misidentification of the wound site or incorrect placement of incisions, potentially exacerbating the patient's condition and leading to complications such as ulcers or infections. Moreover, patients with compromised sensory perception may struggle to actively participate in this process, further amplifying the risk of misidentification. Therefore, addressing the challenge of accurate wound site identification is paramount to improving the overall quality of care for diabetic foot patients.

Another pertinent research problem in diabetic foot care relates to pressure offloading methods involving custom insoles. The conventional approach of creating custom insoles using plaster of Paris molds has several shortcomings. Firstly, it necessitates multiple visits to healthcare professionals, imposing an inconvenience on patients.

This process also entails significant time delays, as it can take several days to complete, further impeding timely wound management. Additionally, the resulting molds may not always provide a perfect fit for the patient's foot, potentially causing discomfort and rendering the pressure offloading ineffective. Thus, the need for a more efficient and patient-friendly method for creating custom insoles that accurately reflect the foot's shape and pressure points is a crucial research problem in diabetic foot care.

The proposed solution, the Diabisole application, aims to address these research problems by utilizing modern technology to enhance wound site identification and pressure offloading in diabetic foot care. By capturing images of the foot sole with wounds and pressure distribution scans, the system can offer a data-driven and objective approach to wound detection and pressure point assessment. This technology promises to greatly improve the accuracy of wound identification and pressure offloading, thereby reducing the risk of misidentification and associated complications. Furthermore, it provides healthcare professionals with precise guidance on how to adjust insoles to alleviate pressure effectively and prevent future wounds. As such, the Diabisole application represents a promising avenue for bridging the existing research gap and addressing the critical research problems in diabetic foot care.

1.5 Background Research

Visiting to meet the stakeholders related to this system is a must to get a clear idea about the existing insole customization methods and the importance of developing a system for customizing the insole of a diabetic shoe to offload the pressure on calluses and high-pressure areas on foot. To achieve this, we have visited several places that we identified as our stakeholders. The main places are shown below,

- Beta Diabetic Footware Solutions – The main shoe production company (DSI) where the basic diabetic shoe is produced and distributed to the places where customization of the shoe takes place.
- Dr. Namaratne from Diabetic Footcare and Rehabilitation Center – A private hospital that treats patients who have diabetic feet. The primary method to offload pressure on DFUs is using Gauze Bandage Rolls on low-pressure areas to remove the high pressure on DFUs and instruct them to wear diabetic shoes.
- Ragama Rehabilitation Hospital – The main method to offload pressure on DFUs are, after wrapping the whole foot from bandages, use Plaster of Paris to build a mold of the foot and create a customize insole by hand using the mold.
- Exceed Prosthetics and Orthotics Footbalance Lanka Pvt Ltd – Use the same method as Ragama Rehabilitation Hospital to offload pressure on DFUs.
- Diabetic Foot and Wound Care Clinic of Kings Hospital – The primary method to offload pressure on DFUs is to cut holes in the insole where the callus is located to reduce pressure on the affected area and add another thin layer on top of the insole to avoid the collision between the edges of callus and hole to remove unnecessary pressure on the callus.

After meeting the stakeholders, we have come to a few conclusions,

1) All the above-mentioned pressure offloading methods are entirely manual.
2) As a result, it consumes a considerable amount of time to customize an insole.
3) The risk of misidentifications and inaccuracies is high.
4) Prosthetist and Orthotist surgeons seemed to be interested in the idea of automating the pressure offloading process and the DFU criticality prediction feature.

Therefore, we decided to automate the pressure offloading method used in "Diabetic Foot and Wound Care Clinic of Kings Hospital" which is to cut holes in the insole where the calluses are located. We have identified two main users of our system as prosthetists and Orthotist surgeons and Orthopedic shoe Technicians.

Below,

- Figure 1.6 displays the Pressure Offloading Method at Ragama Rehabilitation Hospital,
- Figure 1.7 displays the Pressure Offloading Method at Exceed Prosthetics and Orthotics Footbalance Lanka Pvt Ltd,

- Figure 1.8 displays the treatment method of Dr. Namaratne from Diabetic Footcare and Rehabilitation Center,
- Figure 1.9 displays the Pressure Offloading Method at Diabetic Foot and Wound Care Clinic of Kings hospital (using dynamic scanner and a customized insole by cutting hole).

Figure 1.6: mold of a patient and a customized insole

Figure 1.7: creation of a customized insole

Figure 1.8: treating a patient

Figure 1.9: dynamic scanner and custom insole by cutting hole

2 OBJECTIVES

2.1 Main Objective

The main objective of this research is to address the growing challenge of diabetes-related complications, particularly diabetic foot ulcers and neuropathic damage, by introducing an innovative web-based application called "DiabiSole." The primary aim is to automate critical aspects of the conventional manual customization process for diabetic insoles, which have proven to be time-intensive and subject to errors. DiabiSole strives to expedite the identification and measurement of calluses and high-pressure areas on the feet, crucial for effective pressure offloading. Additionally, the application predicts the severity of calluses, providing valuable insights into wound criticality. The central goal of "DiabiSole" is to revolutionize the creation of personalized insoles, improving patient outcomes, reducing ulceration, and minimizing the need for amputations in diabetic individuals in Sri Lanka.

2.2 Specific Objectives

2.2.1 Detect high-pressure areas and measure the locations of those areas to offload the insole in an accurate manner.

When there is high pressure on diabetic feet, it can cause skin breakdown, which can lead to ulcers and calluses. DFUs are areas of thick, hardened skin that form due to constant pressure or friction on a particular area of the foot. They can become infected due to the high pressure on diabetic feet. To prevent infection, it is essential for people with diabetes to take good care of their feet and avoid high pressure on their feet [24]. Since this is a complex problem, we are predicting an accurate structure of customized insole to prevent complications is the major objective here. With a primary focus on accurately detecting and measuring high-pressure areas, this innovative tool promises to deliver precise results that will positively impact patient care. By addressing the critical function of high-pressure area detection and measurement, we are taking a significant step towards advancing diabetic foot care, making it more accessible and effective for everyone involved.

2.2.2 Analyze the images of the soles of patients with DFU to locate the wound locations.

A primary objective of this system is to identify wound areas on the soles of the feet by analyzing sole images. DFUs take a long time to heal and may become infected, leading to further complications. Customized insoles are worn inside diabetic shoes to lower the risk of developing new ulcers and relieve pressure on existing ulcers [9]. These insoles are customized by making holes where the wounds are located. Before doing so, the wound regions must first be precisely defined. The current practice of identifying the location of wounds on the feet is done through visual observation, which can be subjective and prone to errors. Therefore, this function focuses on using ML techniques to analyze sole images and identify the exact location of diabetic foot ulcers.

2.2.3 Measure the identified wound areas to get the hole sizes in the insole and predict DFU criticality.

There are mainly six stages of a DFUs. Customizations to reduce the pressure (pressure offloading) on the DFUs in insoles are mostly done in the second stage where the DFU is called as a Callus. Main objective in this function is to measure the callus area to get the hole size to be cut in the insole according to callus measurements.

As mentioned previously, the prediction of DFU criticality is a key factor to consider when customizing the insole to offload high-pressure. Such a system is essential for doctors to make more informed decisions about the urgency and type of interventions required for individual patients. This predictive capability can significantly enhance patient outcomes by allowing for early and targeted interventions, ultimately reducing the risk of complications and amputations. The main objective here is to measure the callus area sizes and to predict the criticality of the DFU in an accurate manner.

2.2.4 Analyze the two datasets containing images of diabetic feet and identify pressure offloading areas.

The primary objective of this function is to achieve precise identification of pressure offloading areas within the insoles designed for diabetic patients. This is accomplished through a comparative analysis of two images: the first image depicts the patient's foot afflicted with DFUs, and the second image represents a scanned image of the patient's foot. By meticulously comparing these two datasets, the program can accurately pinpoint regions on the foot that endure the highest levels of pressure. Subsequently, it can formulate customized insole designs tailored to effectively distribute pressure in these specific areas. The ultimate outcome of this research objective is to enhance the effectiveness of offloading insoles for diabetic patients, consequently contributing to the prevention of recurrent foot ulcers. Instead of relying on potentially subjective and error-prone visual assessments, the DiabiSole web-based application offers a more optimized and reliable approach to the offloading process.

3 METHODOLOGY

3.1 Methodology

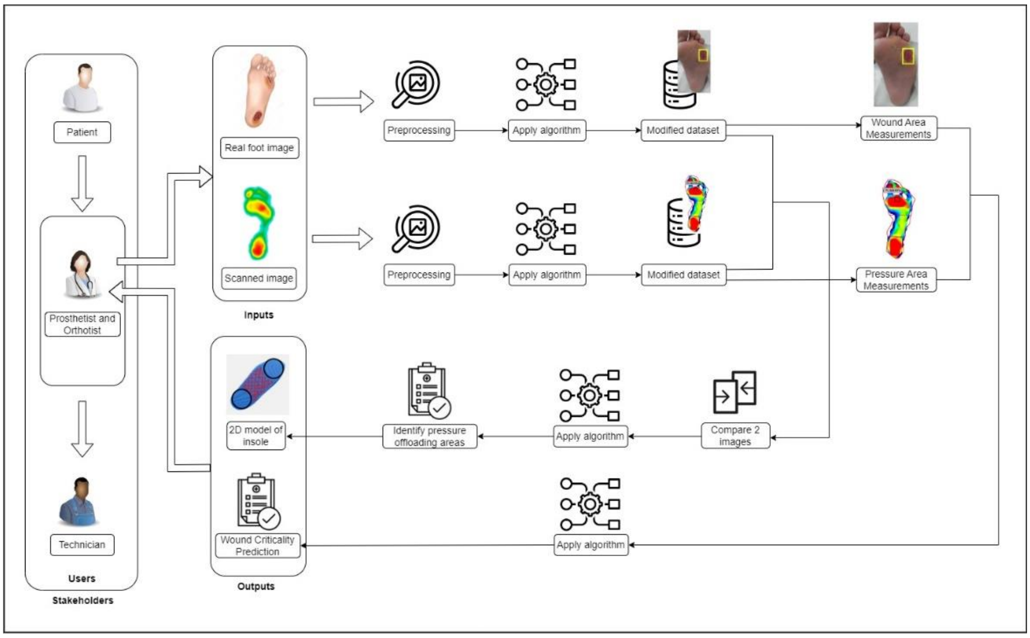

Figure 3.1: System high level diagram

All four sub-functions integral to this research are depicted in Figure 3.1 above. To construct the web application, we have harnessed PHP in conjunction with the Laravel framework. This web application relies on a MySQL database to securely store user data and test records. Furthermore, we have established a Python-based API, developed using Flask, as a pivotal component to seamlessly interconnect all the essential processes.

The web application's structure revolves around four principal functions: DFU area detection and measurement, high-pressure area detection and measurement, identification of offloading areas, and wound severity detection, culminating in the final system's implementation. Prosthetic and Orthotic surgeons and Orthopedic shoe technicians are the primary users of the system. The workflow commences with the submission of a Diabetic patient's sole image containing DFUs and a scanned image depicting the sole's pressure distribution. These images undergo preprocessing and enable the system to identify the DFU and high-pressure areas and measure their sizes using deep learning models. Subsequently, through a comparison between the identified DFU regions and high-pressure areas, the system proposes new locations for pressure offloading on the foot. Lastly, employing an analysis of callus areas and high-pressure area measurements, the system gauges the severity level of the wounds as 'severe' or 'not severe.' The user can view a 2D insole model, highlighting DFU areas and high-pressure regions in red, while pressure offloading areas are delineated in blue. Additionally, the system generates a comprehensive DFU severity report.

3.1.1 Detect high pressure areas and measure the locations of those areas to offload the insole in an accurate manner.

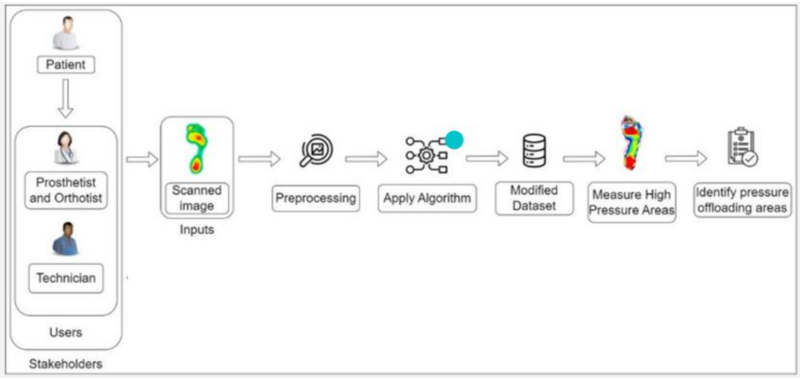

Figure 3.2: High-level diagram of identifying high pressure areas by analyzing scanned images

A comprehensive overview of the system's components, specifically its capability to identify and measure high-pressure areas in scanned foot images, is presented in the figure. This holistic approach promises to advance the field of diabetic foot care, offering enhanced accuracy and efficiency in assessing and addressing patient needs.

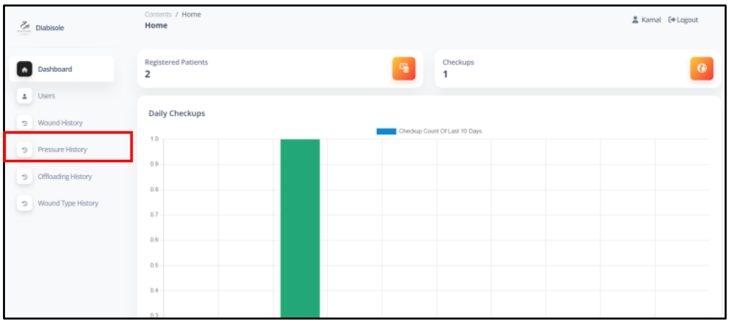

Figure 3.3: Navigation bar

The application's core features encompass image selection, high-pressure area detection with measurements, and a user-friendly sub-menu for tracking and comparing pressure history as shown in the figure.

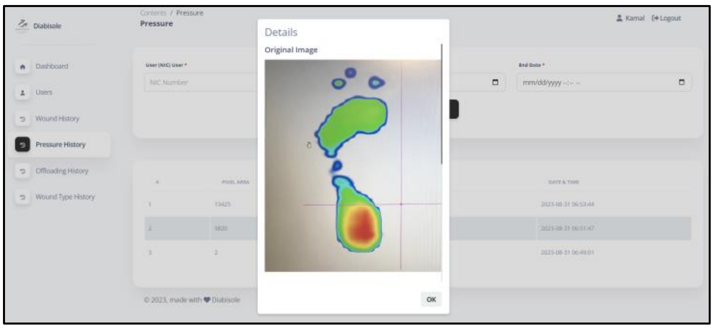

Figure 3.4: uploaded image

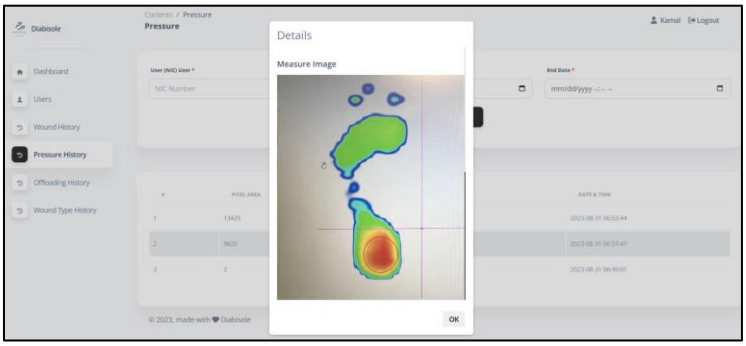

Figure 3.5: high pressure area circulation

The application employs a U-Net deep learning model to analyze scanned foot pressure images, identifying and quantifying high-pressure areas. Users can upload images via a user-friendly interface, and the application visually displays the segmented high-pressure regions while also providing quantitative data, allowing for medical analysis and communication with an API for further processing or storage.

3.1.2 Analyze the images of the soles of patients with DFU to locate the wound locations.

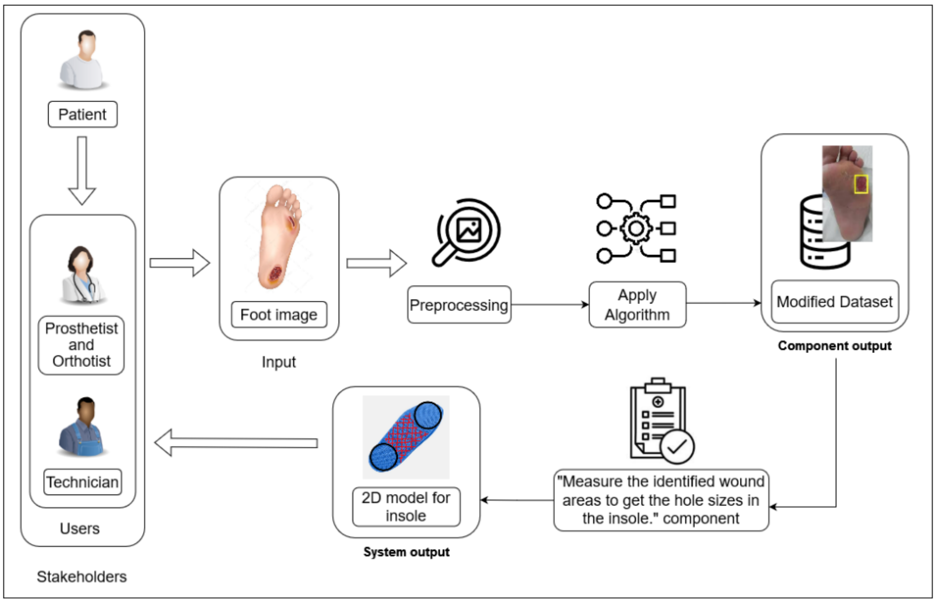

Figure 3.6: High-level diagram of identifying wound areas by analyzing the real sole images

The component overview diagram for identifying wound areas by analyzing the real sole images is shown in Figure 3.6. To precisely identify and locate wound regions, patient foot images with diabetic foot ulcers were augmented using the Augmenter library. The dataset was then annotated with pixel-level precision using the LabelMe image annotator tool. A U-Net deep learning model was employed for wound segmentation, with TensorFlow and Keras. Training involved data split, parameter configuration, and an early stopping mechanism to prevent overfitting. The model identifies wounds, encircles them, and provides localized images for doctors' use. An intuitive interface simplifies DFU wound assessment.

The web application development focuses on identifying and highlighting wound areas. Upon uploading patient foot images with DFUs, the application swiftly and accurately identifies the wound areas with remarkable precision. It highlights these areas with clearly circled markings, aiding healthcare professionals in accurately assessing and addressing diabetic foot ulcers. This feature streamlines the complex task of wound identification, improving patient care and outcomes for DFU patients. Figure 3.7 depicts the process of uploading foot images, and Figure 3.8 illustrates a foot image with wound areas highlighted for further clarity.

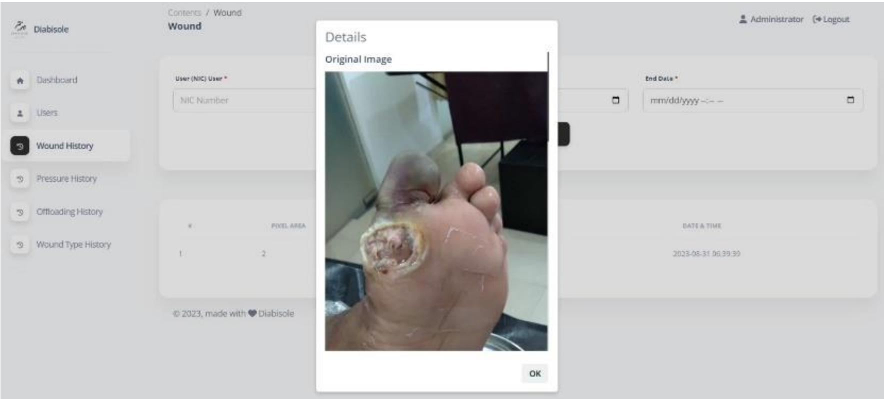

Figure 3.7: Upload foot image

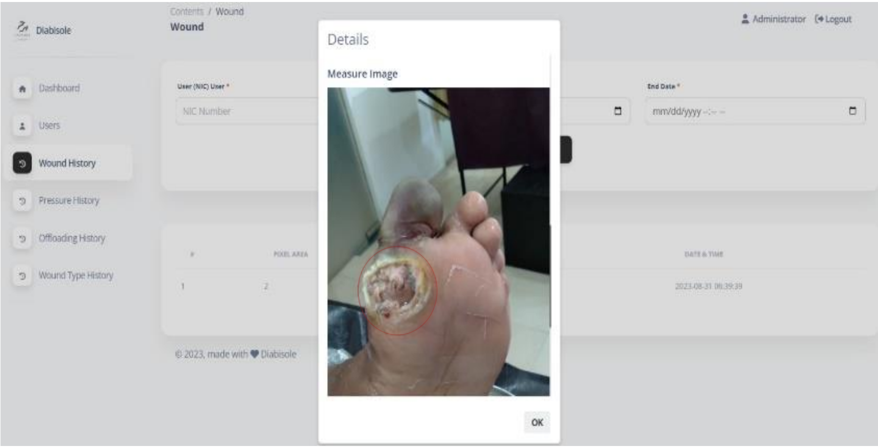

Figure 3.8: Foot image with wound areas highlighted

3.1.3 Measure the identified wound areas to get the hole sizes in the insole and predict DFU criticality.

The component overview diagram for measuring the DFU areas and predicting DFU criticality is shown in Figure 3.9.

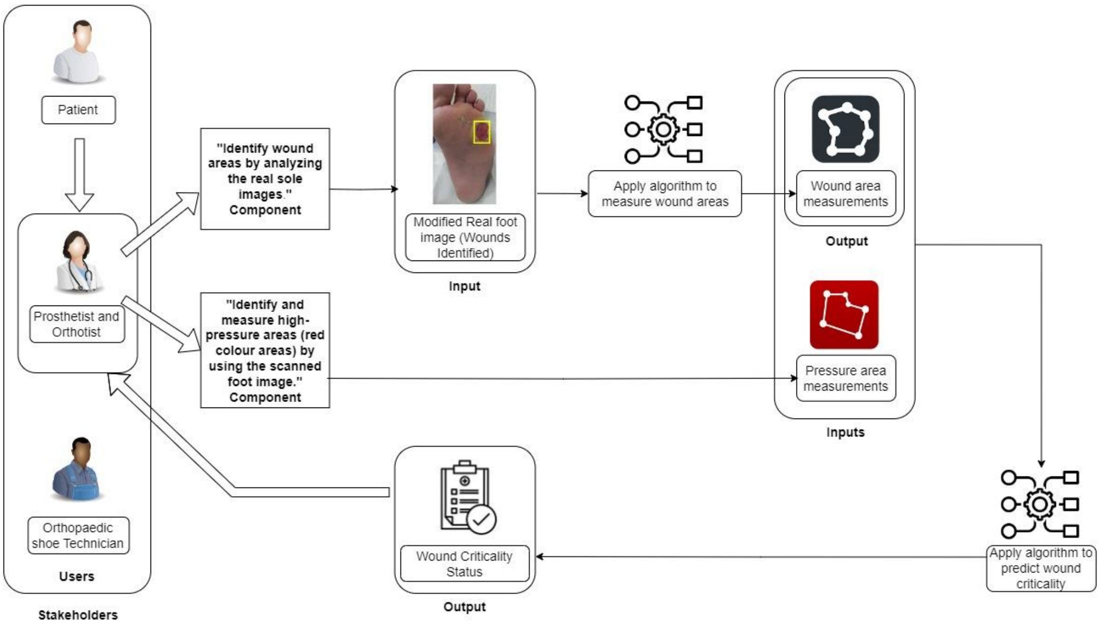

Figure 3.9: High level diagram of measuring the DFU areas and predicting DFU criticality

To obtain callus area measurements, the user initiates the process by providing the system with the pertinent sole image of the diabetic patient. Subsequently, the system autonomously identifies the callus area using OpenCV library and diligently records the measurements in pixels, along with a timestamp, in the MYSQL database. These recorded measurements can be conveniently accessed by the user at a later time by perusing the patient's checkup history, as illustrated in Figure 3.10.

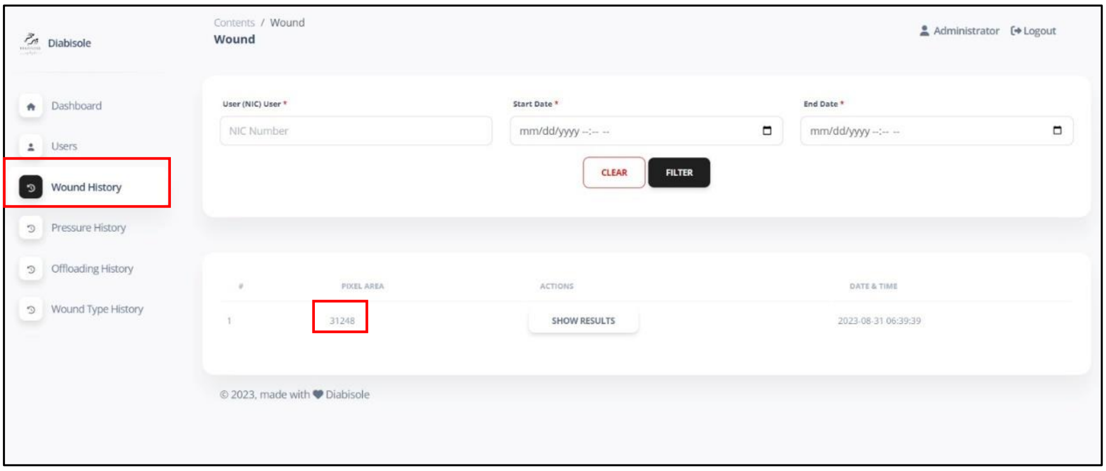

Figure 3.10: UI for callus area measurement history

To obtain predictions regarding the criticality of DFUs for a given patient, the user is required to provide input data encompassing callus area and high-pressure area measurements in the prompted interface. Subsequently, the system leverages its trained model to predict the DFU's criticality. To select a model for the prediction, five machine learning models were considered: 'Decision Tree,' 'Random Forest,' 'XGBoost Classifier,' 'Gaussian Naïve Bayes,' and 'K-Nearest Neighbor Classifier.' The 'Gaussian Naïve Bayes' model, with the highest accuracy, was selected for training the model. The system categorizes the prediction as either 'severe' or 'not severe' as indicated in Figure 3.11.

Figure 3.11: Criticality status prediction

This criticality status is then stored in the MySQL database, accompanied by a timestamp for reference. Much akin to the aforementioned procedure, users have the capability to access and review the DFU criticality status of all patients within their checkup history as illustrated in Figure 3.12.

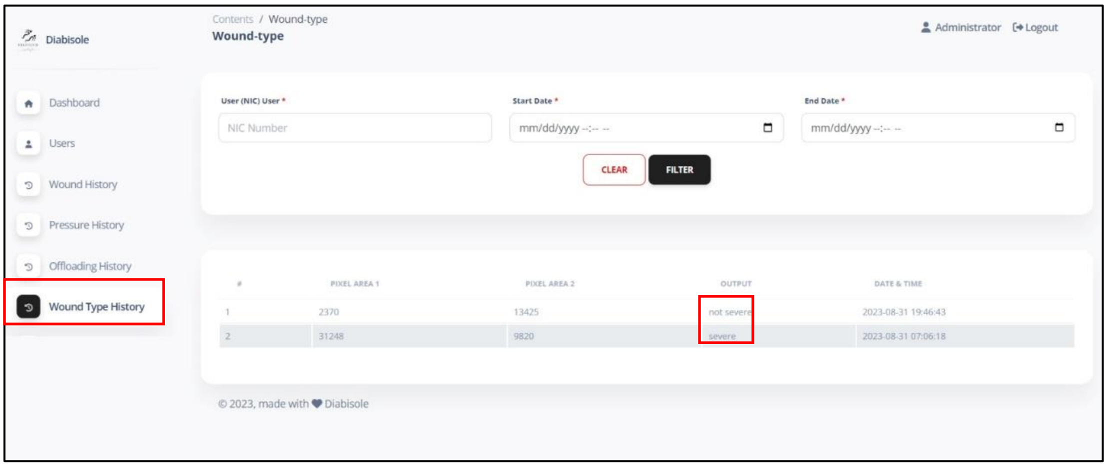

Figure 3.12: UI for DFU criticality status history

3.1.4 Analyze the two datasets containing images of diabetic feet and identify pressure offloading areas.

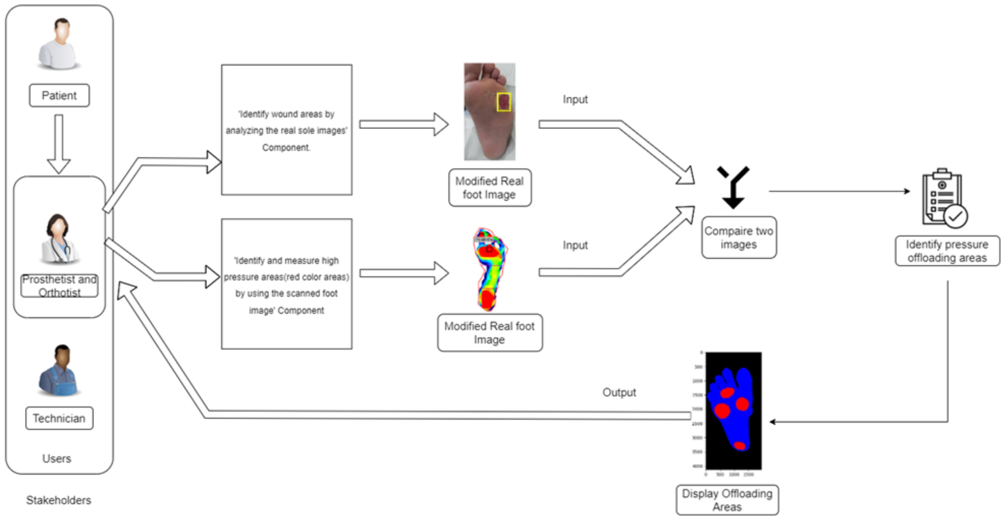

Figure 3.13: High-level diagram of identify pressure offloading areas.

A real wound image and an annotated pressure image of the same foot were uploaded, and their analysis will serve as the main method for identifying offloading areas. The technology seeks to precisely identify and emphasize areas of high pressure and wounds by comparison and output offloading areas in pixels.

As in Figure 3.14, real foot image that was uploaded has a black background, yellow wound spots, and a brown color for the foot. To accurately isolate and recognize these distinctive parts within the image and improve the system's diagnostic capabilities, pixel-level segmentation is performed using OpenCV, a powerful computer vision framework.

The pressure foot image that was uploaded has a black background, green pressure patches, and a brown foot. A neural network model is developed for picture segmentation using TensorFlow, a potent deep-learning platform. As a result, high-pressure areas and the foot in the image may be precisely identified, improving segmentation accuracy and reliability. As in Figure 3.15.

By looking at specific pixels, pixel distribution analysis can identify unloading areas. These areas are highlighted in a relaxing blue color and are measured in pixels thanks to this cutting-edge technology. The diagnostics for diabetic foot care are improved since this gives an accurate and detailed measurement of offloading areas. It is shown in Figure 3.16.

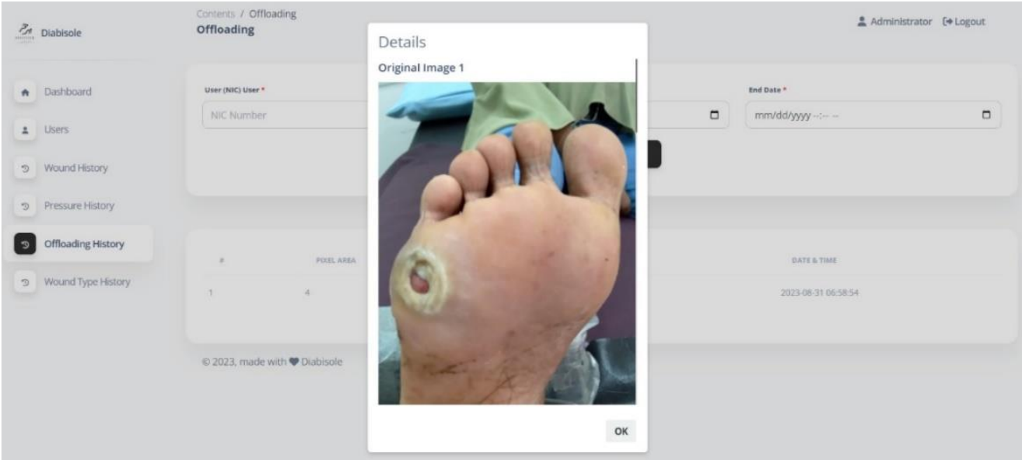

Figure 3.14: Uploaded real foot image.

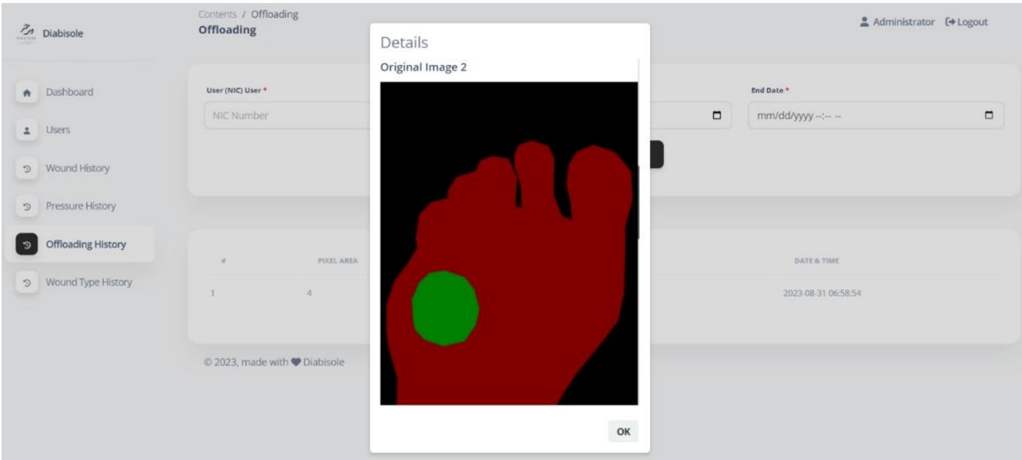

Figure 3.15: Uploaded annotated pressure foot image.

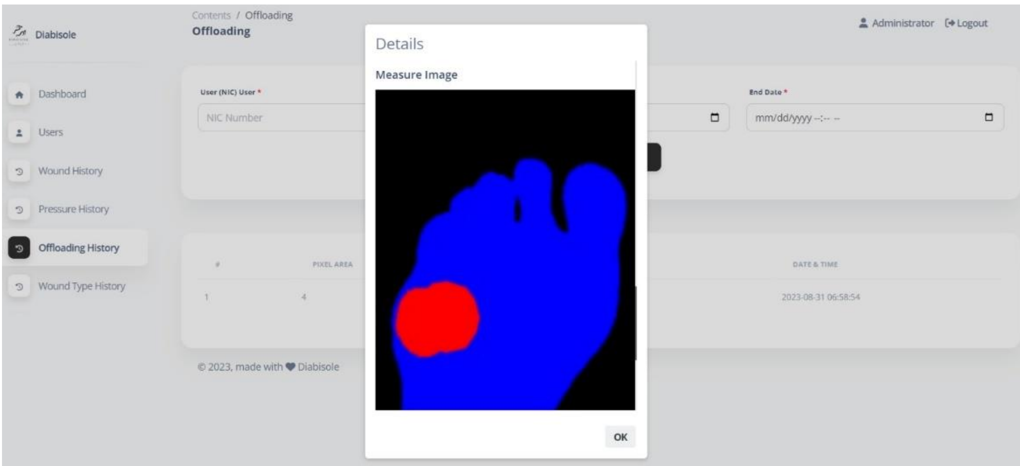

Figure 3.16: The main output of the system, identifying the offloading areas.

3.2 Commercialization Aspects of Product

The developed web application "Diabisole" is designed to help prosthetic and orthotic surgeons when treating the diabetic patients who are at the initial stages of DFUs and to help orthopedic shoe technicians who are customizing the insoles of diabetic shoes. Since the awareness about cutting holes in the insole to offload pressure on calluses method is at a very low level, hardly any solution or research has been conducted in this field. Considering these facts, in the market, our system has a high market value.

We hope to provide this system as a free service for Kings Hospital, Colombo since we got the research idea and relevant guidelines from there. Also, it will be given as a free service for the hospitals that cannot afford to pay the subscription fee. Any other prosthetic and orthotic surgeon or orthopedic shoe technician who uses this application will be required to register for a month-wise or annual-wise subscription plan.

Additionally, we hope to use social media such as Facebook, LinkedIn also YouTube for commercialization to increase awareness of the developed solution.

Figure 3.17: DiabiSole commercialization plan

3.3 Testing and Implementation

Table 3.1: Use case detecting high-pressure areas of scanned image.

Test case ID	PA001
Test case scenario	Identification and circulation of high-pressure areas – User upload image without high pressure areas.
Test input data	Scanned foot pressure image
Test procedure	1. Uploads an image. 2. Record is saved in pressure history. 3. Click on the Show Results button. 4. Scroll to view the original image and the circled image. 5. Press the Ok button to go to history.
Expected outcome	Detecting there is no high-pressure area on the image.
Actual outcome	No circled area coming as an output.
Test result	Pass

Table 3.2: Use case measuring the high-pressure locations.

Test case ID	PA001
Test case scenario	Identification and circulation of high-pressure areas – User upload image with high pressure areas.
Test input data	Scanned foot pressure image
Test procedure	1. Uploads an image. 2. Record is saved in pressure history. 3. Click on the Show Results button. 4. Scroll to view the original image and the circled image. 5. Press the Ok button to go to history.
Expected outcome	Detecting high-pressure areas on the image.
Actual outcome	High pressure areas are circled and displayed.
Test result	Pass

Table 3.3: Wound detection test case (in a clear sole image)

Test case ID	WC001
Test Case Scenario	Detect DFU wound in a clear sole image.
Test Input Data	Upload a sole image with a clear DFU wound.
Test Procedure	1. Log in to the web application using valid credentials. 2. On the dashboard, select an existing patient from the patient database, or if the patient is not in the system, click on the "Add New Patient" button and provide the required patient information. 3. After selecting or adding the patient, upload a sole image for DFU detection. 4. Use the file upload dialogue to select and upload a sole image that contains a clear DFU wound. 5. Click on the "Show Results" button to view the uploaded wound image along with the circled wound areas.
Expected Outcome	The application accurately identifies and highlights the DFU wound area with a clearly circled marking.
Actual Outcome	The application accurately identifies and highlights the DFU wound area.
Test Result	Pass

Table 3.4: DFUs area measurement test case (input image with 1 DFU)

Test Case ID	WM001
Test Case Scenario	Measure the identified callus area of a sole image with one DFU.
Test Input Data	Upload a sole image with a DFU.
Test Procedure	1. Log in to the web application using valid credentials. 2. Navigate to Users tab in the navigation bar, fill the patient’s relevant details and click on the "Add New Patient" button add the patient or select an existing patient. 3. Select the option to upload a sole image for DFU detection. 4. Click on the "Upload Sole Image" button. 5. Wait for the application to process and prompt the identified callus area. 6. Click on the “Measure Area” button to get the callus area measurements in pixels. 7. Check the displayed result to see if the application accurately measures the identified callus area.
Expected Outcome	The application accurately measures the identified callus area.
Actual Outcome	The application accurately measures the identified callus area.
Test Result	Pass

Table 3.5: DFUs criticality prediction test case (input valid inputs)

Test Case ID	WCP001
Test Case Scenario	Acquire the DFU criticality prediction for valid pixel areas. (Measurements should only contain numeric values)
Test Input Data	Input valid pixel areas for both callus and high-pressure area measurements.
Test Procedure	1. Log in to the web application using valid credentials. 2. Navigate to Users tab in the navigation bar, fill the patient’s relevant details and click on the "Add New Patient" button add the patient or select an existing patient. 3. Select the option to predict DFU criticality. 4. Input valid callus and high-pressure area measurements. 5. Click on the “Predict” button to get the DFU criticality prediction. 6. Check the displayed result to see if the prediction is accurate.
Expected Outcome	The application prompts the DFU criticality status whether ‘severe’ or ‘not severe.’
Actual Outcome	The application prompts the DFU criticality status whether ‘severe’ or ‘not severe.’
Test Result	Pass

Table 3.6: View pressure offloading area.

Test Case ID	UC01
Test Case Scenario	View offloading area.
Test Input Data	Click on ‘show result’ button.
Test Procedure	1. Select ‘offloading’ tab. 2. Press for “show result.” 3. View identified wounds in real foot offloading areas. 4. View identified high pressure areas in scanned foot. 5. View offloaded area.
Expected Outcome	The application displays offloading area in the image.
Actual Outcome	The application displays offloading area in the image.
Test Result	Pass

4 RESULTS & DISCUSSION

4.1 Results

4.1.1 Detect high pressure areas and measure the locations of those areas to offload the insole in an accurate manner.

The web application, built on PHP Laravel with MySQL for data storage, utilizes a TensorFlow-based U-Net CNN model for advanced image analysis, particularly in the realm of image segmentation for foot pressure images. The dataset comprises 1000 images from King's Hospital, enhanced with annotations using the Label Me tool to specify regions of interest. This annotated dataset plays a vital role in training the model to accurately identify and outline areas of interest in scanned foot pressure images, proving invaluable in medical diagnosis and research in podiatry and foot pressure analysis.

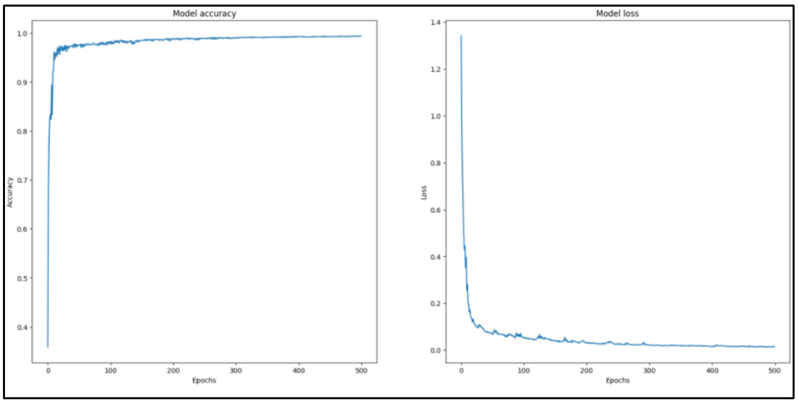

Figure 4.1: Model accuracy and loss plots

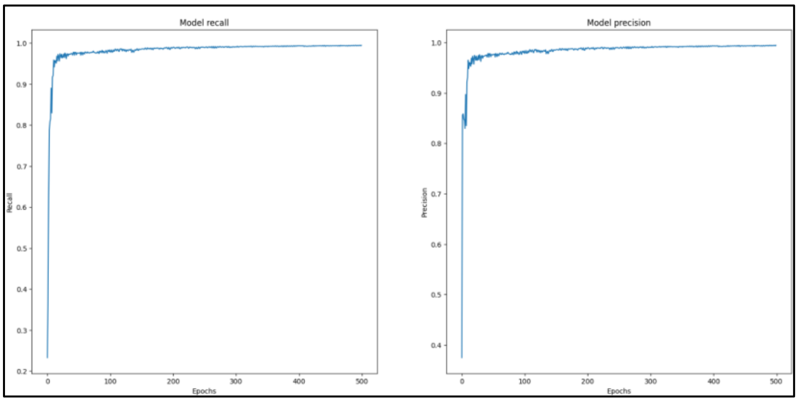

Figure 4.2: Model recall and precision

The U-Net model demonstrated outstanding performance in training, achieving an impressive 99% test accuracy after an extensive 500-epoch training regimen. This remarkable accuracy highlights the model's proficiency in accurately segmenting and identifying regions of interest within scanned foot pressure images.

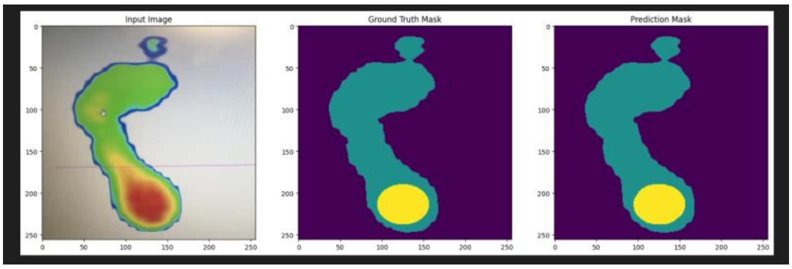

Figure 4.3: Ground truth and prediction mask

The diagram allows users to compare ground truth and model predictions, assessing accuracy, precision, and recall in disease area identification. This visual evaluation is crucial for quality control and research, ensuring model outputs align with expert annotations and are trustworthy for medical analysis.

A summary of the model's key layers, parameters, and configurations is provided to offer insights into its architecture and capabilities, essential for achieving precise image segmentation results in medical applications and research.

```
 Layer (type)                   Output Shape          Param #     Connected to
==========================================================================================
 input (InputLayer)             [(None, 256, 256, 3  0           []
                                )]

 conv2d (Conv2D)                (None, 256, 256, 32  896         ['input[0][0]']
                                )

 dropout (Dropout)              (None, 256, 256, 32  0           ['conv2d[0][0]']
                                )

 conv2d_1 (Conv2D)              (None, 256, 256, 32  9248        ['dropout[0][0]']
                                )

 max_pooling2d (MaxPooling2D)   (None, 128, 128, 32  0           ['conv2d_1[0][0]']
                                )

 conv2d_2 (Conv2D)              (None, 128, 128, 64  18496       ['max_pooling2d[0][0]']
                                )

 dropout_1 (Dropout)            (None, 128, 128, 64  0           ['conv2d_2[0][0]']
                                )

...
Total params: 914,371
Trainable params: 914,371
Non-trainable params: 0
```

Figure 4.4: Model summary

4.1.2 Analyze the images of the soles of patients with DFU to locate the wound locations.

The U-Net model achieved an impressive 95% accuracy in localizing diabetic foot wounds, as demonstrated in Figure 4.5. This underscores its precision and reliability in identifying these critical wound areas. Figure 4.6 depicts the model's performance in detail by displaying numerous graphs illustrating key metrics such as accuracy, loss, recall, and precision. These metrics quantify the model's performance, highlighting its remarkable consistency and precision in detecting diabetic foot wounds.

```
Epoch 490/500
12/12 [==============================] - 44s 4s/step - loss: 0.0174 - accuracy: 0.9917 - recall: 0.9917 - precision: 0.9918 - val_loss: 0.3442 - val_accuracy: 0.9508 - val_recall: 0.9507 - val_precision: 0.9510
Epoch 491/500
12/12 [==============================] - 43s 4s/step - loss: 0.0173 - accuracy: 0.9920 - recall: 0.9919 - precision: 0.9921 - val_loss: 0.3286 - val_accuracy: 0.9509 - val_recall: 0.9507 - val_precision: 0.9510
Epoch 492/500
12/12 [==============================] - 40s 3s/step - loss: 0.0172 - accuracy: 0.9920 - recall: 0.9919 - precision: 0.9921 - val_loss: 0.3404 - val_accuracy: 0.9500 - val_recall: 0.9499 - val_precision: 0.9502
Epoch 493/500
12/12 [==============================] - 42s 4s/step - loss: 0.0178 - accuracy: 0.9920 - recall: 0.9919 - precision: 0.9921 - val_loss: 0.3177 - val_accuracy: 0.9528 - val_recall: 0.9527 - val_precision: 0.9530
Epoch 494/500
12/12 [==============================] - 43s 4s/step - loss: 0.0178 - accuracy: 0.9916 - recall: 0.9915 - precision: 0.9917 - val_loss: 0.3146 - val_accuracy: 0.9529 - val_recall: 0.9528 - val_precision: 0.9532
Epoch 495/500
12/12 [==============================] - 42s 4s/step - loss: 0.0167 - accuracy: 0.9918 - recall: 0.9918 - precision: 0.9919 - val_loss: 0.3266 - val_accuracy: 0.9513 - val_recall: 0.9512 - val_precision: 0.9516
Epoch 496/500
12/12 [==============================] - 41s 3s/step - loss: 0.0169 - accuracy: 0.9919 - recall: 0.9918 - precision: 0.9919 - val_loss: 0.3492 - val_accuracy: 0.9497 - val_recall: 0.9496 - val_precision: 0.9499
Epoch 497/500
12/12 [==============================] - 39s 3s/step - loss: 0.0164 - accuracy: 0.9922 - recall: 0.9921 - precision: 0.9922 - val_loss: 0.3487 - val_accuracy: 0.9509 - val_recall: 0.9508 - val_precision: 0.9510
Epoch 498/500
12/12 [==============================] - 39s 3s/step - loss: 0.0168 - accuracy: 0.9920 - recall: 0.9919 - precision: 0.9921 - val_loss: 0.3559 - val_accuracy: 0.9488 - val_recall: 0.9487 - val_precision: 0.9490
Epoch 499/500
12/12 [==============================] - 41s 3s/step - loss: 0.0176 - accuracy: 0.9920 - recall: 0.9919 - precision: 0.9921 - val_loss: 0.3252 - val_accuracy: 0.9517 - val_recall: 0.9515 - val_precision: 0.9519
Epoch 500/500
12/12 [==============================] - 41s 3s/step - loss: 0.0175 - accuracy: 0.9917 - recall: 0.9917 - precision: 0.9918 - val_loss: 0.3304 - val_accuracy: 0.9500 - val_recall: 0.9499 - val_precision: 0.9502
Final Validation Accuracy: 95.00%
```

Figure 4.5: U-net model accuracy

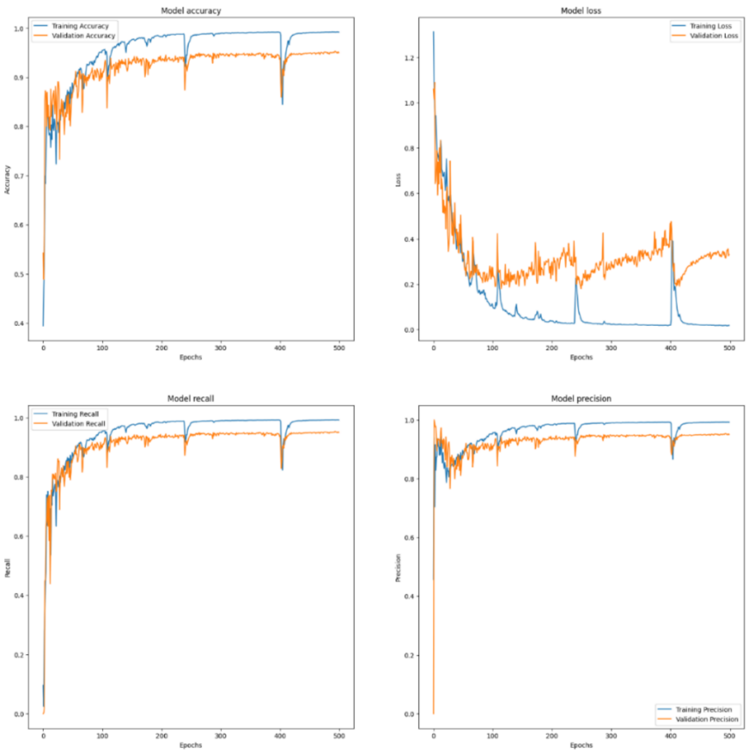

Figure 4.6: U-net model accuracy, loss, precision and recall graphs

Figure 4.7 goes a step further in demonstrating the model's capabilities by including input images, manually annotated ground truth, and model-generated prediction masks. The model's remarkable accuracy and proficiency in identifying and delineating diabetic foot wounds is highlighted by a comparison of ground truth and prediction masks. Figure 4.8 depicts the original image with clearly drawn circles, highlighting the model's ability to identify regions of interest within the images. This visual representation provides compelling evidence of the model's accuracy in locating diabetic foot wounds.

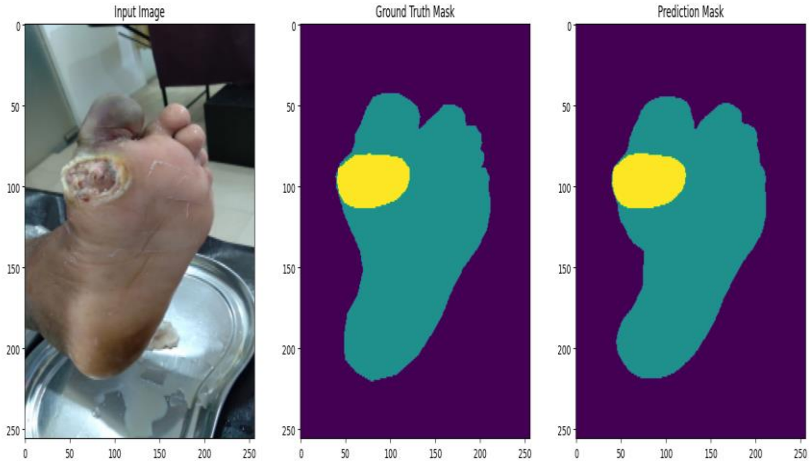

Figure 4.7: Input image, Ground truth and Prediction mask

Figure 4.8: Model output

The trained U-Net model summary, depicted in Figure 4.9, depicts the model's architecture, highlighting its layers and emphasizing its effectiveness in semantic segmentation tasks. This model architecture is critical in achieving the exceptional accuracy shown by our results.

```
Model: "wound_classification"
__________________________________________________________________________________________________
 Layer (type)                   Output Shape         Param #     Connected to
==================================================================================================
 input (InputLayer)             [(None, 256, 256, 3  0           []
                                )]

 conv2d (Conv2D)                (None, 256, 256, 32  896         ['input[0][0]']
                                )

 dropout (Dropout)              (None, 256, 256, 32  0           ['conv2d[0][0]']
                                )

 conv2d_1 (Conv2D)              (None, 256, 256, 32  9248        ['dropout[0][0]']
                                )

 max_pooling2d (MaxPooling2D)   (None, 128, 128, 32  0           ['conv2d_1[0][0]']
                                )

 conv2d_2 (Conv2D)              (None, 128, 128, 64  18496       ['max_pooling2d[0][0]']
                                )

 dropout_1 (Dropout)            (None, 128, 128, 64  0           ['conv2d_2[0][0]']
                                )

...
12/12 [==============================] - 41s 3s/step - loss: 0.0176 - accuracy: 0.9920 - recall: 0.9919 - precision: 0.9921 - val_loss: 0.3252 - val_accuracy: 0.9!
Epoch 500/500
12/12 [==============================] - 41s 3s/step - loss: 0.0175 - accuracy: 0.9917 - recall: 0.9917 - precision: 0.9918 - val_loss: 0.3304 - val_accuracy: 0.9!
Final Validation Accuracy: 95.00%
```

Figure 4.9: U-net model summary

4.1.3 Measure the identified wound areas to get the hole sizes in the insole and predict DFU criticality.

In pursuit of identifying the most optimal classification model for predicting DFU (Diabetic Foot Ulcer) criticality, a comprehensive evaluation was conducted, employing five machine learning models, namely, 'Decision Tree,' 'Random Forest,' 'XGBoost Classifier,' 'Gaussian Naïve Bayes,' and 'K-Nearest Neighbor Classifier.' The performance metrics, including accuracies and classification reports, were rigorously compared among these models. Remarkably, 'Gaussian Naïve Bayes' emerged as the model of choice due to its highest accuracy, 99.21% and the production of a confusion matrix characterized by superior precision. The accuracies and comprehensive classification reports of all five models are presented below.

```
# Model Accuracy
print("Accuracy:",metrics.accuracy_score(y_test, y_pred))

Accuracy: 0.989501312335958

# Classification Report
print(classification_report(y_test, y_pred, target_names=["0", "1"]))
cf_matrix= confusion_matrix(y_test, y_pred)
print(cf_matrix)

              precision    recall  f1-score   support

           0       0.99      0.99      0.99       171
           1       0.99      0.99      0.99       210

    accuracy                           0.99       381
   macro avg       0.99      0.99      0.99       381
weighted avg       0.99      0.99      0.99       381

[[169   2]
 [  2 208]]
```

Figure 4.10: Decision Tree Model Results

```
# Model Accuracy
print("Accuracy:",metrics.accuracy_score(y_test, y_pred1))

Accuracy: 0.989501312335958

# Classification Report
print(classification_report(y_test, y_pred1, target_names=["0", "1"]))
cf_matrix1= confusion_matrix(y_test, y_pred1)
print(cf_matrix1)

              precision    recall  f1-score   support

           0       0.98      0.99      0.99       171
           1       1.00      0.99      0.99       210

    accuracy                           0.99       381
   macro avg       0.99      0.99      0.99       381
weighted avg       0.99      0.99      0.99       381

[[170   1]
 [  3 207]]
```

Figure 4.11: Random Forest Classifier Results

```
# Model Accuracy
print("Accuracy:",metrics.accuracy_score(y_test, y_pred3))

Accuracy: 0.9868766404199475

# Classification Report
print(classification_report(y_test, y_pred3, target_names=["0", "1"]))
cf_matrix3= confusion_matrix(y_test, y_pred3)
print(cf_matrix3)

              precision    recall  f1-score   support

           0       0.99      0.98      0.99       171
           1       0.99      0.99      0.99       210

    accuracy                           0.99       381
   macro avg       0.99      0.99      0.99       381
weighted avg       0.99      0.99      0.99       381

[[168   3]
 [  2 208]]
```

Figure 4.12: XGB Model Results

```
# Model Accuracy
print("Accuracy:",metrics.accuracy_score(y_test, y_pred3))

Accuracy: 0.9921259842519685

# Classification Report
print(classification_report(y_test, y_pred3, target_names=["0", "1"]))
cf_matrix3= confusion_matrix(y_test, y_pred3)
print(cf_matrix3)

              precision    recall  f1-score   support

           0       0.98      1.00      0.99       171
           1       1.00      0.99      0.99       210

    accuracy                           0.99       381
   macro avg       0.99      0.99      0.99       381
weighted avg       0.99      0.99      0.99       381

[[171   0]
 [  3 207]]
```

Figure 4.13: KNN Classifier Model Results

```
# Model Accuracy
print("Accuracy:",metrics.accuracy_score(y_test, y_pred2))
```

```
Accuracy: 0.9921259842519685
```

```
# Classification Report
print(classification_report(y_test, y_pred1, target_names=["0", "1"]))
cf_matrix1= confusion_matrix(y_test, y_pred1)
print(cf_matrix1)
```

```
              precision    recall  f1-score   support

           0       0.98      0.99      0.99       171
           1       1.00      0.99      0.99       210

    accuracy                           0.99       381
   macro avg       0.99      0.99      0.99       381
weighted avg       0.99      0.99      0.99       381

[[170   1]
 [  3 207]]
```

Figure 4.14: Naïve Bayes Model Results

```
# ROC_AreaUnderCurve_Score
y_score = clf.predict_proba(X_test)[:,1]
false_positive_rate, true_positive_rate, threshold = roc_curve(y_test, y_score)
print('ROC_AUC_score for GaussianNaiveBayes: ', roc_auc_score(y_test, y_score))
```

```
ROC_AUC_score for GaussianNaiveBayes:  0.9893901420217209
```

Figure 4.15: AUC of Naïve Bayes Model

The selected 'Gaussian Naïve Bayes' model exhibited an impressive ROC (Receiver Operating Characteristic) Area Under the Curve (AUC) value of 0.98939 as shown in Figure 4.15, indicative of its robust predictive capabilities. Furthermore, Figure 4.16 visually illustrates the optimal positive rate graph associated with this model.

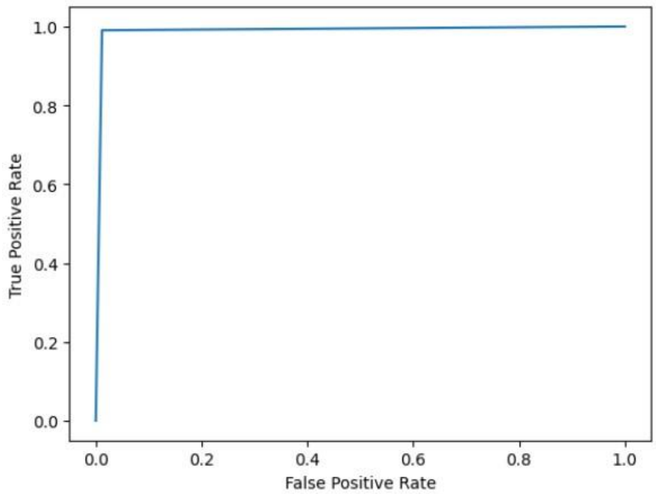

Figure 4.16: Positive rate graph of the selected model

4.1.4 Analyze the two datasets containing images of diabetic feet and identify pressure offloading areas.

Diabisole is successfully able to pinpoint unloading locations as displayed in Figure 4.17. It functions by using inputs of both actual and scanned foot images to produce a visual output after careful image processing. Offloading areas are clearly emphasized in blue in this output, while high-pressure areas and wound areas are sharply delineated in red. Healthcare practitioners can use this color-coded representation as a crucial visual aid to help them decide how best to care for patients and prevent foot ulcers.

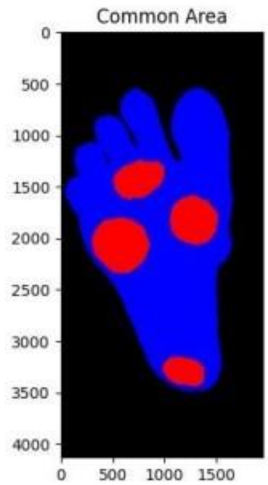

Figure 4.17: System identifies offloading area.

By carefully locating offloading areas based on the distribution of pixels within the photos, the computer uses pixel analysis to identify them. The treatment given to patients is improved by careful analysis that guarantees precise identification and enables proper assessment of pressure redistribution.

```
'blue_pixcel_count': 2892240}
```

Figure 4.18: System calculates offloading area in pixels.

4.2 Research Findings

The research findings in the field of wound detection and measurement, high-pressure area identification, severity measurement, and offloading area identification have been achieved through the utilization of cutting-edge technologies. While other models and methodologies exist for these tasks, the chosen models have been proven to be exceptionally effective.

Wound Area Detection and Measurement: The U-Net image segmentation model implemented with TensorFlow stands out as the best choice for wound area detection and measurement. Other approaches such as traditional image processing techniques may lack the robustness and accuracy required for intricate medical image analysis.

High-Pressure Area Detection: Using U-Net image segmentation in TensorFlow to detect high-pressure areas represented by red color zones is highly effective. Alternatives like thresholding or simple color-based methods may not capture nuanced pressure variations as comprehensively.

Severity Measurement: Pixel distribution analysis with TensorFlow and OpenCV offers a robust approach to measuring wound severity. While other statistical or histogram-based methods may be used, they may not provide the detailed information necessary for accurate severity assessment.

Offloading Area Identification: Tabular classification using a random forest model from Scikit-learn is an ideal choice for identifying offloading areas. Although neural networks could be considered, random forest excels in handling structured data like tabular information.

While these models have demonstrated their excellence in their respective tasks, it's important to acknowledge that alternative technologies and approaches exist. For instance, deep learning models like Mask R-CNN or Faster R-CNN could be explored for wound area detection, and object detection models might be considered for high-pressure area identification. In severity measurement, deep learning-based methods might also provide competitive results. Additionally, for offloading area identification, neural networks or gradient boosting algorithms could be alternative options.

However, the selected models have proven to be not only effective but also reliable and efficient for their specific tasks. The decision to use them is driven by their track record in medical image analysis, precision, and suitability for the given tasks, ensuring robust research findings in the realm of diabetic wound management.

4.3 Discussion

Our innovative web application, 'DiabiSole,' represents a groundbreaking solution for the challenging task of managing diabetic foot ulcers (DFUs). It is specifically designed to aid prosthetic and orthotic surgeons in customizing insoles for diabetic shoes, a process that traditionally relied on manual methods. Unlike existing approaches, 'DiabiSole' automates the customization process, making it faster, more efficient, and remarkably precise. It introduces a paradigm shift by addressing key aspects of DFU management, such as wound detection, high-pressure area identification, offloading area identification, and wound severity prediction.

Wound Area Detection and Measurement: The application accurately identifies and measures diabetic foot wounds, enabling precise customization of insoles. This innovation minimizes complications and treatment delays, improving patient outcomes.
High-Pressure Area Detection and Measurement: 'DiabiSole' identifies areas of the foot that are susceptible to future wounds due to high pressure. This proactive approach empowers healthcare professionals to take preventive measures, reducing the likelihood of complications and recurring DFUs.
Identification of Offloading Areas: The application assists in identifying areas where pressure needs to be redistributed on the foot. This not only enhances patient comfort but also contributes to overall well-being.
Wound Severity Detection: 'DiabiSole' aids healthcare professionals in assessing wound criticality, enabling them to tailor treatment plans to the specific needs of each patient. This personalized approach aligns with our overarching goal of improving patient outcomes.

The thorough testing of 'DiabiSole' confirmed its robust performance across both functional and non-functional aspects. To further enhance user experience and the application's capabilities, we have designed intuitive and user-friendly interfaces for smoother navigation.

Our future work aims to expand 'DiabiSole' by incorporating the generation of 3D models for custom insoles. This groundbreaking advancement will allow users to visualize the final customized insole before the actual customization process takes place. By tailoring each design to the unique needs of individual patients, we expect 'DiabiSole' to deliver even more personalized solutions for DFU management. Moreover, our plans include training the system on a larger dataset to increase its accuracy, ensuring that it continues to provide unparalleled support to healthcare professionals and patients alike. These advancements hold great promise for significantly improving diabetic foot ulcer management, translating into enhanced patient outcomes.

5 CONCLUSION

In conclusion, our innovative web application, “DiabiSole,” has filled an important gap in the field of diabetic foot care, specifically addressing the challenges associated with diabetic foot ulcers (DFUs) in Sri Lanka. “DiabiSole” stands out for its capability to automate the identification of callus areas, determine optimal hole sizes for pressure relief, and predict DFU criticality. It fills a significant gap in the literature by thoroughly addressing the strategic placement of holes in insoles, a critical aspect of DFU management that had previously been overlooked.

While our research has yielded promising results and represents a significant advancement, it is important to acknowledge that the current version of “DiabiSole” is limited in its representation of results, primarily delivering them in a 2D format. As we look ahead, our commitment lies in expanding the application to incorporate 3D modeling capabilities, allowing users to visualize customized insoles tailored to their specific needs. This advancement aims to provide an even more personalized and precise solution for DFU management, further elevating the quality of care delivered to patients.

In summary, 'Diabisole' stands as a pioneering achievement at the intersection of healthcare and technology. By bridging the gap in insole customization, it has the potential to reduce the risk of complications, and amputations, and improve patient outcomes. We are dedicated to advancing 'Diabisole' further, with the ultimate goal of making diabetic foot care more accessible, effective, and personalized for patients in Sri Lanka and beyond.

6 BUDGET & BUDGET JUSTIFICATION

Table 6.1: Budget plan per month

Component	Amount (Rs.)
Travelling fee for the data gathering	2500.00
Internet charges (the development and technical information learning)	3000.00
Stationary	2000.00
Total	**7500.00**

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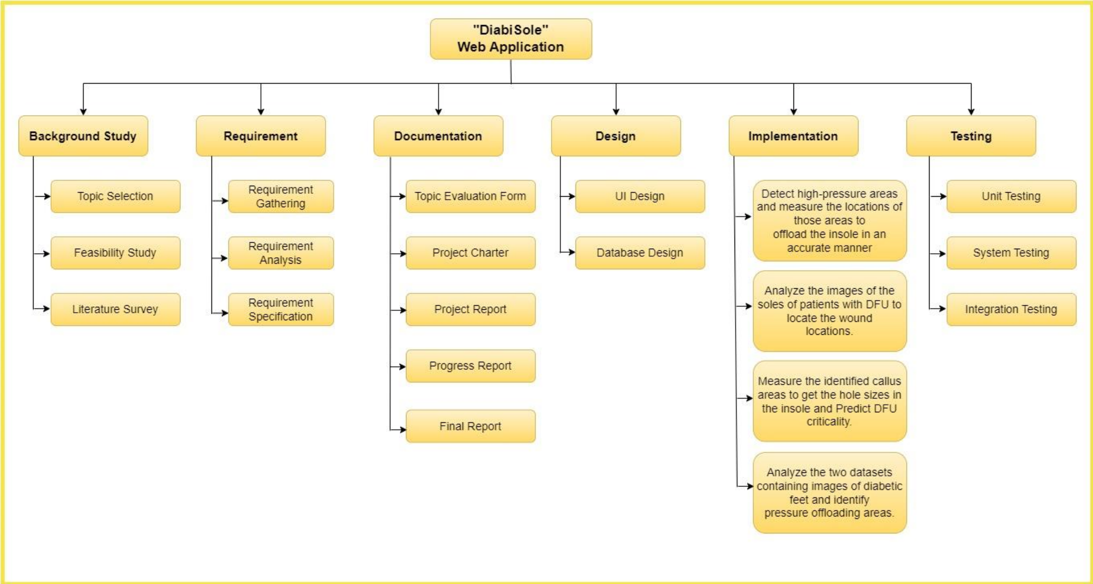
APPENDICES

Appendix – A: Application logo



Appendix – B: Work breakdown chart

To whom it may concern, 15 March 2023

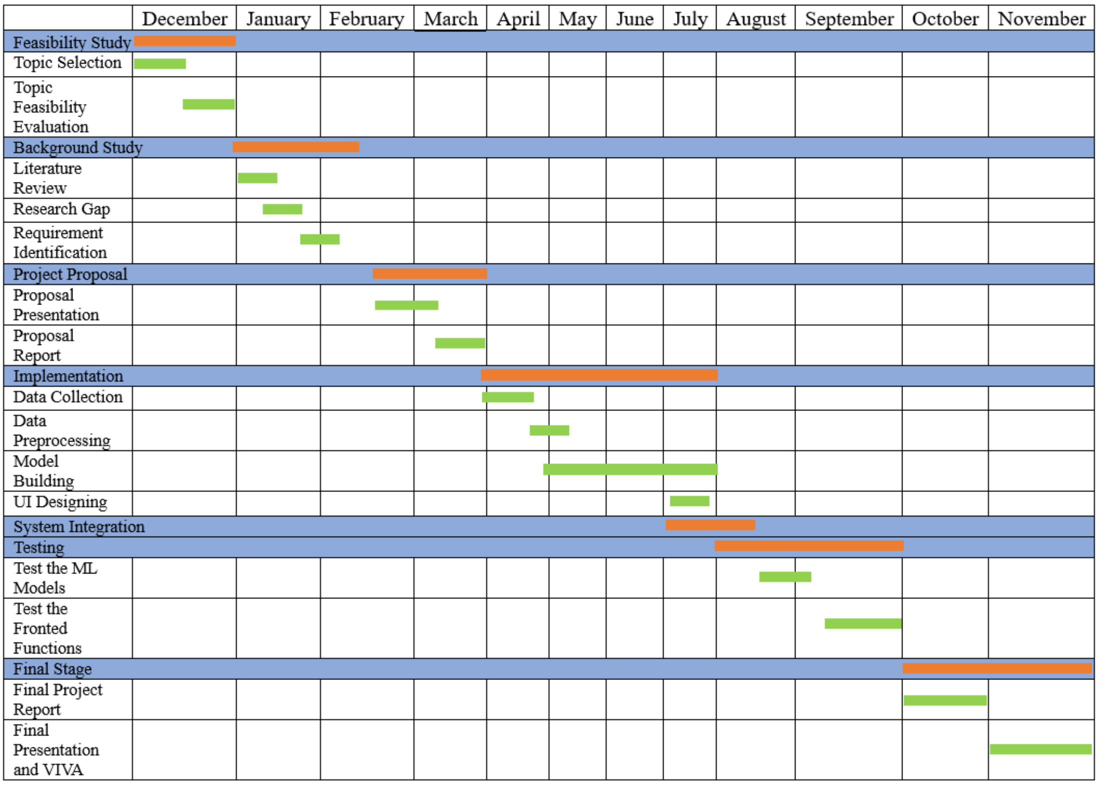
"DiabiSole – Optimizing Diabetic Foot Care through Machine Learning and Image Processing" research project which is conducted by the Ariyasinghe P.A.D.N.I. [IT20033828], Dahanayake U.S. [IT20043650], Samarasinghe S.A.K.S. [IT20206246] and Samarakoon S.M.D.H. [IT20457952]4th year students at Sri Lanka Institute of Information Technology under supervision of Ms. Jenny Krishara.

This is to certify that for the above-mentioned research project, I will be providing the medical consultation for all the medical related aspects in this project. I hereby confirm that as an external supervisor of the project, I will be offering my consultation and all the datasets that they require as a medical officer throughout this project.

Thank you.

Dr. Piumika De Silva

Appendix – C: External supervisor (Consultant Doctor) letter



Appendix – D: Gantt chart

To whom it may concern,

I have personally gone through the web application DIABISOLE: Optimizing Diabetic Foot Care Through Machine Learning and Image Processing which is implemented by the students Ariyasinghe P.A.D.N.I., Dahanayake U.S., Samarasinghe S.A.K.S. and Samarakoon S.M.D.H can recommend this web application for podiatrists who are responsible in Diabetic foot care with customizing insoles.

Thank you.

……………………………………………

Dr. Piumika De Silva

Kings Hospital

Colombo 05

Appendix – E: External supervisor’s Recommendation letter