These injuries have the appearance of a deep bruise, and are initiated in the muscle layer next to a bony prominence, developing outwards towards the epidermis layer. Due to the etiology of DTI, it is often difficult to accurately classify DTI into any one of the 4 stages above. DTI may also develop in a relative short period of time and often deteriorates rapidly into Stage 3 and Stage 4 ulcers.

Currently, DTI is diagnosed through visual examination for purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of the underlying soft tissue. Accordingly, DTI may be difficult to detect in individuals with dark skin tones. Moreover, visual examination of DTI may also lead to misclassification under Stage 1 or Stage 2 ulcers, which does not represent the true and dangerous potential of the injury.

To treat pressure ulcers in a timely and effective manner, clinicians need to be able to identify, with precision, the presence of a DTI, and distinguish it from the early stages of ulcers. However, the current standard to detect pressure ulcers is by visual inspection, which is subjective, unreliable, untimely, and lacks specificity.

SUMMARY OF THE INVENTION

The present disclosure provides for, and includes, systems, apparatuses, and methods for detecting deep tissue injury (DTI). Disclosed herein is a method for detecting deep tissue injury (DTI) before it is visible on a patient's skin, comprising: a) obtaining a set of SEM delta values at a location on the patient's skin at a predetermined frequency; b) applying to each of the SEM delta values of the obtained set a predetermined weight; c) calculating a first average SEM delta value of the N least-recent weighted SEM delta values; d) calculating a second average SEM delta value of the M most-recent weighted SEM delta values; e) comparing the difference between the first average and the second average SEM delta value with a predetermined threshold value; and f) determining that there is DTI at the location on the patient's skin when the difference is greater than the predetermined threshold value. In an embodiment, the set of obtained SEM delta values comprises at least five SEM delta values each taken one day apart. In an embodiment, the predetermined weights are in the range of 0 to 2. In an embodiment, the predetermined weights monotonically increase with time. In an embodiment, N>M. In an embodiment, N is 4 and M is 2. In an embodiment, the predetermined threshold value is a real number in the range of 0 to 1. In an embodiment, the most recent SEM delta value is obtained by linear extrapolation of the K most-recent SEM delta values. In an embodiment, K is 3. In an embodiment, the predetermined threshold is 0.7. In an embodiment, the location on the patient's skin is selected from the group consisting of the back of the head, the sacrum, the shoulder, the elbow, the lower back, the tailbone, the buttock, the hip, the inner knee, the heel, and a combination thereof.

Disclosed herein is a computer-implemented method for training a neural network for detection of deep tissue injury (DTI) before the injury is visible on a patient's skin,

comprising: a) for each patient in a first plurality of patients who have been diagnosed with a DTI, obtaining a first set of sub-epidermal moisture (SEM) delta values at a location on the patient's skin at a predetermined frequency before and up to the formation of the DTI; b) for each patient in a second plurality of patients who have not been diagnosed with a DTI, obtaining a second set of SEM delta values at the same location on the patient's skin at the predetermined frequency; c) applying a set of weights to each of the SEM delta values of the first and second set of obtained SEM delta values; d) creating a training set comprising the first set of weighted SEM delta values and the second set of weighted SEM delta values of all patients in the first and second plurality of patients; and e) training the neural network using the training set. In an embodiment, the trained neural network outputs a set of optimized weights, comprising an optimized weight for each timepoint before the formation of a DTI, and where the optimized weights monotonically increase with time. In an embodiment, the method further comprises the steps of: a) for each patient in the first and second plurality of patients, i) calculating a first average SEM delta value of the N least-recent weighted SEM delta values in the set of SEM delta values; ii) calculating a second average SEM delta value of the M most-recent weighted SEM delta values in the set of SEM delta values; iii) calculating a difference value between the first average and the second average SEM delta value; and iv) comparing the difference between the first average and the second average SEM delta value with a threshold value; b) creating a training set comprising a first set of difference values in the first plurality of patients and a second set of difference values in the second plurality of patients; and c) training the neural network using the training set. In an embodiment, the predetermined frequency is once a day. In an embodiment, the first and second set of SEM delta values comprises at least six SEM delta values each taken one day apart. In an embodiment, N+M = 6. In an embodiment, N=4 and M=2. In an embodiment, the location on the patient's skin is selected from the group consisting of the back of the head, the sacrum, the shoulder, the elbow, the lower back, the tailbone, the buttock, the hip, the inner knee, the heel, and a combination thereof.

Disclosed herein is a computer-implemented method for training a neural network for detection of deep tissue injury (DTI) before the injury is visible on a patient's skin, comprising: a) for each patient in a first plurality of patients who experience a DTI, obtaining a first set of sub-epidermal moisture (SEM) delta values at a location on the patient's skin at a predetermined frequency before and up to the formation of the DTI; b) for each patient in a second plurality of patients who do not experience a DTI, obtaining a second set of SEM delta values at the same location on the patient's skin at the predetermined frequency; c) applying a set of weights to each of the SEM delta values of the first and second set of obtained SEM delta values; d) for each patient in the first and second plurality of patients, i) calculating a first average SEM delta value of the N least-recent weighted SEM delta values in the set of SEM delta values; ii) calculating a second average SEM delta value

of the M most-recent weighted SEM delta values in the set of SEM delta values; iii) calculating a difference value between the first average and the second average SEM delta value; and iv) comparing the difference between the first average and the second average SEM delta value with a threshold value; e) creating a training set comprising a first set of difference values in the first plurality of patients and a second set of difference values in the second plurality of patients; and f) training the neural network using the training set. In an embodiment, the trained neural network outputs a) a set of optimized weights, comprising an optimized weight for each timepoint before the formation of a DTI, where the optimized weights monotonically increase with time; b) an optimized threshold; c) the value of N; and d) the value of M. In an embodiment, the predetermined frequency is once a day. In an embodiment, the first and second set of SEM delta values comprises at least six SEM delta values each taken one day apart. In an embodiment, N + M = 6. In an embodiment, N = 4 and M = 2. In an embodiment, the location on the patient's skin is selected from the group consisting of the back of the head, the sacrum, the shoulder, the elbow, the lower back, the tailbone, the buttock, the hip, the inner knee, the heel, and a combination thereof. In an embodiment, the set of optimized weights and the optimized threshold are used to predict the occurrence of deep tissue injury.

The present disclosure provides for, and includes, a non-transitory computer readable medium for identifying DTI tissue. The non-transitory computer readable medium may comprise instructions stored thereon, that when executed on a processor, may perform the steps of: a) obtaining a set of SEM delta values at a location on the patient's skin at a predetermined frequency; b) applying to each of the SEM delta values of the obtained set a predetermined weight; c) calculating a first average SEM delta value of the N least-recent weighted SEM delta values; d) calculating a second average SEM delta value of the M most-recent weighted SEM delta values; e) comparing the difference between the first average and the second average SEM delta value with a predetermined threshold value; and f) determining that there is DTI at the location on the patient's skin when the difference is greater than the predetermined threshold value. In an embodiment, the set of obtained SEM delta values comprises at least five SEM delta values each taken one day apart. In an embodiment, the predetermined weights are in the range of 0 to 2. In an embodiment, the predetermined weights monotonically increase with time. In an embodiment, N>M. In an embodiment, N is 4 and M is 2. In an embodiment, the predetermined threshold value is a real number in the range of 0 to 1. In an embodiment, the most recent SEM delta value is obtained by linear extrapolation of the K most-recent SEM delta values. In an embodiment, K is 3. In an embodiment, the predetermined threshold is 0.7. In an embodiment, the location on the patient's skin is selected from the group consisting of the back of the head, the sacrum, the shoulder, the elbow, the lower back, the tailbone, the buttock, the hip, the inner knee, the heel, and a combination thereof.

The present disclosure provides for, and includes, a non-transitory computer readable medium for identifying DTI tissue. The non-transitory computer readable medium may comprise instructions stored thereon, that when executed on a processor, may perform the steps of: a) for each patient in a first plurality of patients who have been diagnosed with a DTI, obtaining a first set of sub-epidermal moisture (SEM) delta values at a location on the patient's skin at a predetermined frequency before and up to the formation of the DTI; b) for each patient in a second plurality of patients who have not been diagnosed with a DTI, obtaining a second set of SEM delta values at the same location on the patient's skin at the predetermined frequency; c) applying a set of weights to each of the SEM delta values of the first and second set of obtained SEM delta values; d) creating a training set comprising the first set of weighted SEM delta values and the second set of weighted SEM delta values of all patients in the first and second plurality of patients; and e) training the neural network using the training set. In an embodiment, the trained neural network outputs a set of optimized weights, comprising an optimized weight for each timepoint before the formation of a DTI, and where the optimized weights monotonically increase with time. In an embodiment, the method further comprises the steps of: a) for each patient in the first and second plurality of patients, i) calculating a first average SEM delta value of the N least-recent weighted SEM delta values in the set of SEM delta values; ii) calculating a second average SEM delta value of the M most-recent weighted SEM delta values in the set of SEM delta values; iii) calculating a difference value between the first average and the second average SEM delta value; and iv) comparing the difference between the first average and the second average SEM delta value with a threshold value; b) creating a training set comprising a first set of difference values in the first plurality of patients and a second set of difference values in the second plurality of patients; and c) training the neural network using the training set. In an embodiment, the predetermined frequency is once a day. In an embodiment, the first and second set of SEM delta values comprises at least six SEM delta values each taken one day apart. In an embodiment, N+M = 6. In an embodiment, N=4 and M=2. In an embodiment, the location on the patient's skin is selected from the group consisting of the back of the head, the sacrum, the shoulder, the elbow, the lower back, the tailbone, the buttock, the hip, the inner knee, the heel, and a combination thereof.

The present disclosure provides for, and includes, a non-transitory computer readable medium for identifying DTI tissue. The non-transitory computer readable medium may comprise instructions stored thereon, that when executed on a processor, may perform the steps of: a) for each patient in a first plurality of patients who experience a DTI, obtaining a first set of sub-epidermal moisture (SEM) delta values at a location on the patient's skin at a predetermined frequency before and up to the formation of the DTI; b) for each patient in a second plurality of patients who do not experience a DTI, obtaining a second set of SEM delta values at the same location on the patient's skin at the predetermined frequency; c)

applying a set of weights to each of the SEM delta values of the first and second set of obtained SEM delta values; d) for each patient in the first and second plurality of patients, i) calculating a first average SEM delta value of the N least-recent weighted SEM delta values in the set of SEM delta values; ii) calculating a second average SEM delta value of the M most-recent weighted SEM delta values in the set of SEM delta values; iii) calculating a difference value between the first average and the second average SEM delta value; and iv) comparing the difference between the first average and the second average SEM delta value with a threshold value; e) creating a training set comprising a first set of difference values in the first plurality of patients and a second set of difference values in the second plurality of patients; and f) training the neural network using the training set. In an embodiment, the trained neural network outputs a) a set of optimized weights, comprising an optimized weight for each timepoint before the formation of a DTI, where the optimized weights monotonically increase with time; b) an optimized threshold; c) the value of N; and d) the value of M. In an embodiment, the predetermined frequency is once a day. In an embodiment, the first and second set of SEM delta values comprises at least six SEM delta values each taken one day apart. In an embodiment, N + M = 6. In an embodiment, N = 4 and M = 2. In an embodiment, the location on the patient's skin is selected from the group consisting of the back of the head, the sacrum, the shoulder, the elbow, the lower back, the tailbone, the buttock, the hip, the inner knee, the heel, and a combination thereof. In an embodiment, the set of optimized weights and the optimized threshold are used to predict the occurrence of deep tissue injury.

A first aspect of the present disclosure provides a computer-implemented method for predicting deep tissue injury (DTI), the method comprising: receiving, via an input device, a plurality of sub-epidermal moisture (SEM) delta values associated with a patient; automatically inputting, via a processor, the plurality of SEM delta values into a trained model to receive a probability value, where the model is configured to predict a probability value corresponding to a future occurrence of the patient developing DTI, where the model is trained based on a set of training data comprising SEM delta data from a set of patients; and outputting, via an output device, a prediction of the future occurrence of the patient developing DTI based on the probability value. In an embodiment, training the model comprises the steps of: receiving, via an input device, a set of training data comprising: 1) a plurality of sub-epidermal moisture (SEM) delta values associated with a set of patients, and 2) a threshold value, where each patient in the set of patients has a known deep tissue injury (DTI) status, where the threshold value is a number between 0 and 1; automatically inputting, via a processor, the training data into an optimization algorithm to receive a plurality of optimal weight values; and automatically updating, via a processor, the model with the plurality of optimal weight values. In an embodiment, the optimization algorithm is configured to: generate a plurality of increasing random numbers between 0 and 2 as a

plurality of weight values; input the training data and the plurality of weight values into the model to receive a set of predicted deep tissue injury (DTI) statuses associated with the set of patients; compare the predicted DTI statuses with the known DTI statuses associated with the set of patients; calculate a true positive rate (TPR) and a false positive rate (FPR) based on the comparison, where the TPR is calculated as percentage of patients in the set of patients whose predicted DTI status matches their known DTI status, and the FPR is calculated as percentage of patients in the set of patients whose predicted DTI status does not match their known DTI status; repeat steps a) to d) for a predetermined number of times as the number of iterations; identify optimal TPR and FPR from all calculated TPRs and FPRs from the iterations; and output the plurality of optimal weight values associated with the identified optimal TPR and FPR. In an embodiment, the plurality of SEM delta values comprises the SEM delta readings from a predetermined number of days before the day of predicting deep tissue injury (DTI). In an embodiment, identifying optimal TPR and FPR comprises minimizing the objective function of 1-TPR+FPR and satisfying the constraint of TPR>>FPR. In an embodiment, the input device is a SEM scanner. In an embodiment, the SEM scanner is connected to a computer by cable or by wireless technology. In an embodiment, the DTI occurs at a location selected from the group consisting of the back of the head, the sacrum, the shoulder, the elbow, the lower back, the tailbone, the buttock, the hip, the inner knee, the heel, and a combination thereof.

A second aspect of the present disclosure provides a method for assessing risk of deep tissue injury (DTI) of a patient, the method comprising: obtaining a plurality of sub-epidermal moisture (SEM) delta values associated with a patient; inputting the plurality of SEM delta values into a trained model to receive a probability value, where the model is configured to predict a probability value corresponding to future occurrence of the patient developing DTI, where the model is trained based on a set of training data comprising SEM delta data of a set of patients; outputting a prediction of future DTI occurrence likelihood of the patient based on the probability value; and assessing risk of the patient developing DTI based on the predicted future DTI occurrence likelihood. In an embodiment, the predicted future occurrence is categorized as no DTI, low likelihood of DTI, high likelihood of DTI, or suspected DTI. In an embodiment, the method further comprises selecting an intervention for the patient based on the assessed risk of DTI. In an embodiment, the intervention comprises at least one of: reducing pressure, repositioning the patient, changing the patient's support surface, providing a low-friction padded mattress, providing a silicon pad, providing a heel boot, cleaning and dressing wounds, removing damaged tissue, applying a topical cream, applying a barrier cream, applying neuro-muscular stimulation, drug administration, and surgery. In an embodiment, the DTI occurs at a location selected from the group consisting of the back of the head, the sacrum, the shoulder, the elbow, the lower back, the tailbone, the buttock, the hip, the inner knee, the heel, and a combination thereof. In an embodiment, the

method further comprises generating or updating a report from performing the method. In an embodiment, the method further comprises transmitting the report to the patient or a clinician. In an embodiment, the method further comprises storing the report on a non-transitory computer readable storage medium. In an embodiment, the method further comprises displaying the report on a computer display.

Disclosed herein is a non-transitory computer-readable storage medium comprising one or more programs for execution by one or more processors of a device, the one or more programs comprising instructions which, when executed by the one or more processors, cause the device to perform the method of any one of the preceding embodiments. In an embodiment, the non-transitory computer-readable storage medium further comprises a report generated from performing the method of any one of the preceding embodiments.

Disclosed herein is an electronic device, comprising: one or more processors; a memory; and one or more programs, where the one or more programs comprises instructions which, when executed by the one or more processors, cause the device to perform the method of any one of the preceding embodiments. In an embodiment, the electronic device further comprises one or more displays to present a report generated from performing the method of any one of the preceding embodiments.

A third aspect of the present disclosure provides a system for predicting deep tissue injury (DTI), including: a) a Sub-Epidermal Moisture (SEM) scanner configured to make SEM measurements; b) a processor electronically coupled to the SEM scanner and configured to receive the SEM measurements; and c) a non-transitory computer readable media that is electronically coupled to the processor and comprises instructions stored thereon that, when executed on the processor, performs the steps of: i) calculating a plurality of SEM delta values from the SEM measurements, ii) automatically inputting, via a processor, the plurality of SEM delta values into a trained model to receive a probability value, wherein the trained model is configured to predict a probability value corresponding to a future occurrence of the patient developing DTI, and wherein the trained model is trained based on a set of training data comprising a plurality of SEM delta values associated with a set of patients; iii) outputting, via an output device, a prediction of the future occurrence of the patient developing DTI based on the probability value.

A fourth aspect of the present disclosure provides a system for assessing risk of deep tissue injury (DTI), including: a) a Sub-Epidermal Moisture (SEM) scanner configured to make SEM measurements; b) a processor electronically coupled to the SEM scanner and configured to receive the SEM measurements; and c) a non-transitory computer readable media that is electronically coupled to the processor and comprises instructions stored thereon that, when executed on the processor, performs the steps of: i) calculating a plurality of SEM delta values from the SEM measurements, ii) automatically inputting, via the processor, the plurality of SEM delta values into a trained model to receive a probability

value, wherein the trained model is configured to predict a probability value corresponding to a future occurrence of the patient developing DTI, and wherein the trained model is trained based on a set of training data comprising a plurality of SEM delta values associated with a set of patients; d) outputting, via an output device, a likelihood of future occurrence of DTI based on the probability value.

BRIEF DESCRIPTION OF THE FIGURES

Some aspects of the disclosure are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and are for purposes of illustrative discussion of embodiments of the disclosure. In this regard, the description, taken with the drawings, make apparent to those skilled in the art how aspects of the disclosure may be practiced.

FIG. 1A: An example apparatus according to the present disclosure, comprising one coaxial electrode.

FIG. 1B: An illustration of an example method using an example apparatus according to the present disclosure to measure SEM delta values, in order to detect potential DTIs.

FIG. 2A: Sample SEM delta values taken from patients who were diagnosed with DTIs (left) and patients who were not diagnosed with DTIs (right).

FIG. 2B: An illustration of an example method for detecting DTIs according to the present disclosure.

FIG. 3: Sample SEM delta values taken from patients.

FIG. 4: Example ways of dividing data for processing.

FIG. 5A: A flowchart illustrating an example method for predicting DTI according to the present disclosure.

FIG. 5B: A flowchart illustrating an example method for optimizing weights according to the present disclosure.

FIG. 6: Sample optimized weights and threshold according to the present disclosure.

FIG. 7: Example method for predicting formation of DTIs according to the present disclosure.

FIG. 8: Results of example prediction and detection methods according to the present disclosure.

FIG. 9: An example system in accordance with an aspect of the present disclosure.