Supplementary Information

Battery-Free, Wireless Soft Sensors for Continuous Multi-Site Measurements of Pressure and Temperature for Patients at Risk for Pressure Injuries

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Supplementary Fig. 26. Programming of ISOStart2018 software in protocol mode for operation of multiplexed antenna and multiple sensors.

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Supplementary Fig. 30. Feedback from the patient with right hemiplegia (47-year-old female, 62 kg, 160 cm) in Fig. 7.

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Supplementary Fig. 32. Feedback from the patient with hemiplegia and stroke (61-year-old male, 57 kg, 170 cm) in Supplementary Fig. 24.

Supplementary Table 1. Comparison for battery-free, wireless sensors.

Supplementary References
Supplementary Note 1. Comparison with previous research

In a previous study, the pressure sensor incorporated a spiral-shaped, thin, monocrystalline membrane of Si (a thickness of 200 nm; E of 130 GPa), a polyethylene terephthalate substrate (PET; a thickness of 5 μm; E of ~4.5 GPa) and an encapsulating layer of PDMS (a thickness of 350 μm; E of ~1MPa). The sensing mechanism depends on the Poisson effect associated with the encapsulating PDMS layer and the consequent stretching of the spiral-shaped Si. The PET film ensures a uniform strain distribution and improves the mechanical robustness of the spiral-shaped Si structure. These same effects, however, decrease the sensitivity (< 0.002 kPa⁻¹, a fractional change of less than 2% in resistance under 10 kPa) to values much lower than those that could be supported by the Si membrane and its high gauge factor (~50). Fabricating/transferring the thin spiral-shaped, p-doped, Si membrane on PET film without damage includes a series of complex processes, resulting in reduced device reproducibility.

By contrast, the pressure sensor in the present study is much different in its materials, designs and operating principles. Specifically, the device includes an Au trace in a tri-layered film as a sensing element, with a combined design that incorporates both rigid and soft components, as shown in Figure. 2a and Supplementary Fig. 3. The sensing mechanism of the device depends on deflection-induced tensile strain under applied pressures. As illustrated in Figure 2c, d, a well-defined area supports a patterned Au trace in the tri-layered film. A soft frame on a membrane of PI functions to control the sensitivity over relevant pressure ranges (<0.0006, a fractional change of less than 0.6% in resistance under 10 kPa). Supplementary Fig. 9 shows average responses of 10 pressure sensors to applied loads of 3 kPa and 6 kPa, respectively. A rigid frame and rigid pad protect the sensing components from mechanical/electrical damage that could otherwise result from shear stresses or excessive pressures, in a manner that does not decrease the sensitivity, as shown in Supplementary Fig. 4. Also, the pressure sensor shows long-term stability and mechanical durability under 10,000 repeated loadings of 4 kPa, as shown in Figure. 2g. Additional measurements demonstrate the level of repeatability in the responses across various batches of devices, as highlighted in Supplementary Fig. 9.

Table. S1 summarizes the current design and the previous design in terms of pressure sensor and wireless platform; it also compares the clinical trials. Many important details are different in the current system, and the cumulative consequences of these advances serve as the basis for extensive, successful demonstrations of the technology with actual patients in operating hospitals.

In the previous design, the pressure/temperature sensor locates inside the coil of the receiver antenna with an outer diameter of 16 mm, suitable for mounting on the skin directly at the locations of the protruding regions of highest risk (e.g., elbow and toe). This small-coil design limits the communication range and its mounting location also leads to concerns about unwanted perturbations at the skin interface. By contrast, the current design exploits a separate coil for a receiver antenna that has an outer...
diameter of 34.5 mm, connected by deformable serpentine traces to the pressure/temperature sensors. This separated layout allows for comparatively large coils and corresponding increases in the working distance. The separate, small temperature/pressure sensor module (<10 mm × 10 mm) is easy to attach to the regions of skin of interest. This scheme also enables stable detection during changes in position or posture. Supplementary note (1) and Table S1 highlight these issues.

Supplementary Note 2. Upper and lower bounds of pressure sensor
The pressure sensor, including the Au trace with a yield strain of 0.3%, has a maximum fractional change in resistance of 0.6% under loading as an upper bound and a fractional change of 0% under unloading as a lower bound. The soft frame in Figure 2a and Supplementary Fig. 3 functions to modulate the sensitivity over the operating ranges of pressure, related to the sensitivity within the upper bound. In Fig. 2d, the pressure sensors show a sensitivity of 0.00053 kPa\(^{-1}\) without the soft frame, 0.0003 kPa\(^{-1}\) with a soft frame (\(E = 100\) kPa) and 0.0001 kPa\(^{-1}\) with an extremely soft frame (\(E = 100\) kPa), respectively. These results show that the pressure sensors can provide maximum fractional change in resistance of 0.6% with negligible hysteresis and drift in the pressure range of 0-11.4 kPa, 0-21.0 kPa and 0-58.2 kPa in Supplementary Fig. 8. Also, structural designs of device for the ratio of width/height of soft frame or a distance of metal trace from the neutral plane supports modulating the sensitivity of pressure sensor over relevant pressure ranges within the maximum fractional change of resistance of 0.6%.

Supplementary Note 3. Repeatability, sensitivity and reproducibility
The battery-free, wireless pressure sensors show good repeatability and reproducibility. Supplementary Fig. 9 shows average responses of 10 pressure sensors to applied loads of 3 kPa and 6 kPa. The effective area of the patterned Au traces (a width of 7 μm) in the tri-layered film, rather than the original resistance, is important for realizing similar sensitivity, as shown in Fig. 2b, c. The sensitivity of the wireless pressure sensor depends on the combination of resistances in the Wheatstone bridge and the resistance that sets the gain in the instrumentation amplifier. Each wireless sensor requires a calibration process, performed before clinical trials to ensure proper, accurate operation.

Supplementary Note 4. Calibration process
In the calibration process, fractional changes in resistance (\(ΔR/R\)) measured from the sensor converts to pressure values. The initial resistance does not affect the response to pressure. Integration of the pressure sensor into a wireless platform completes a Wheatstone bridge circuit to convert the fractional change in resistance to a change in voltage, passed to the instrumentation amplifier and delivered to ADC values.
of the NFC SoC. Both the initial voltage and voltage change of the sensor depend on the combination of resistances in the Wheatstone bridge and the resistance that sets the gain in the instrumentation amplifier. For this reason, the calibration process for each sensor uses the change of the ADC value (voltage), not the fractional change in voltage. Also, each device requires a one-point calibration using the relationship between pressure and voltage, as shown in Figure 4a. The result provides accurate, continuous conversion from the change of the ADC value to the pressure due to high linearity and minimum hysteresis.

On the other hand, the temperature sensor (NTCG064EF104FTBX, TDK Corporation) has the following relationship (1) between temperature \( T \) and resistance \( R_{NTC} \) provided by data sheet. The temperature sensor forms a voltage divider circuit to convert \( R_{NTC} \) to \( V_{out} \) using Equation (2), delivered to an ADC of the NFC SoC. The relationship (3) between \( T \) and \( V_{out} \), derived from Equation (1) and (2), supports accurate, continuous conversion of ADC values collected from the wireless temperature sensor.

\[
R_{NTC} = R_{T0} \exp\left(\frac{1}{T + 273} - \frac{1}{T_0 + 273}\right) \tag{1}
\]

where \( R_{T0} \) is a reference resistance of 100 kΩ, \( \phi \) is a correcting factor of 4250 and \( T_0 \) is a reference temperature of 25 ºC, respectively.

\[
V_{out} = V_{in}\left(\frac{R_{T1}}{R_{NTC} + R_{T1}}\right) \tag{2}
\]

where \( R_{T1} \) is a divided resistance of 50 kΩ and \( V_{in} \) is an applied voltage of 1.5V, respectively.

\[
T = \left[\frac{1}{\phi} \ln\left(\frac{R_{T1}}{R_{T0}}\left(\frac{V_{in}}{V_{out}} - 1\right)\right) + \frac{1}{(T_0 + 273)}\right]^{-1} - 273 \tag{3}
\]

where \( R_{T0} \) is a reference resistance of 100 kΩ, \( R_{T1} \) is a divided resistance of 50 kΩ, \( \phi \) is a correcting factor of 4250, \( T_0 \) is a reference temperature of 25 ºC, \( V_{in} \) is an applied voltage of 1.5 V, respectively.

**Supplementary Note 5. Shear force-related pressure injuries**

Pressure is a common type of force generated by body weight on the skin and underlying soft tissue, compared to shear force for most patients.\(^2\) Prolonged pressure applied directly to the skin and underlying soft tissue increases capillary occlusion, leading to tissue ischemia with associated localized hypoxia.\(^3\) This process can impair the delivery of vital nutrients and oxygen to the local environment of the cells, resulting in the local breakdown of the soft tissues. Especially, the effect of pressure on
developing the skin injuries is dominant for patients with perception disorders (e.g., a hemiplegic patient or a tetraplegic patient) who are confined to a bed. Shear force can be important in specific cases, including a semi-sitting position in a bed or a sitting position in a wheelchair (e.g., a paraplegic patient). The effects of shear force on these injuries are associated with a reclining angle of the back support.

Supplementary Note 6. Discontinuous periods of data collection in clinical trials
These events have two causes. First, large tilt angles (greater than ~60°) of the receiver coil relative to the primary antenna can follow from changes in posture, thereby reducing the working distance and, in some cases, causing discontinuities in the data. This issue can be minimized through shaped designs of the antenna coil (e.g., an elliptical shape) and double-loop layouts for the primary antenna, as described in the use of NFC interfaces in other contexts. Second, movement of the receiver antenna out of the region encompassed by the primary antenna can lead to similar effects, also due to changes in posture and position. The two multiplexed, commercial antennas (800 mm × 600 mm) in this study provide a stable magnetic field distribution over the full area of the body, but not over the full area of the clinical bed (2000 mm × 800 mm). This issue can be resolved with antennas sufficiently large for covering the entire size of clinical bed.

Supplementary Note 7. Effective area of pressure sensor in clinical trials
In general, the specific area applied by the weight of human body is smaller or larger than the interfacial area of a single sensor. This mismatch could hinder measurement of accurate, reliable pressure values on a location of interest. The strategy for resolving this issue involves an array of pressure sensors or a collection of multiple devices in proximity to one another. The array enables mapping of pressure with a relatively high resolution over regular spatial intervals across a specific area. The platform for generating an array of pressure sensor requires additional components (e.g., multiplexer and controller) on the NFC SoC, to support data communication with 8, 16 or 32 channels of ADC depending on the specifications of the multiplexer, in a sequential mode. Placing multiple devices in proximity to one another provides another option, depending on critical sites of a patient’s body. Supplementary Fig. 22a shows photographs of a subject with 4 devices mounted near the sacrum in a prone position.

Supplementary Note 8. Threshold of pressure injury
The threshold associated with pressure magnitudes and durations depends on body locations and the health condition of a patient, including issue related to sensory perception, activity, mobility, nutrition and chronic disease state. These factors create challenges in defining accurate threshold values for pressure injuries. For this reason, the National Pressure Injury Advisory Panel (NPIAP) provides
guidelines for evidence-based recommendations to prevent and treat pressure injuries that could be used by health professionals throughout the world. A repositioning (e.g., prone, side-lying or supine) of a patient lying in bed at regular intervals reduces the development of pressure injuries. The Braden scale serves as a tool to assess the level of risk for pressure injuries, by providing medical teams or nurses with quantitative scores to categorize high-risk patients. In this context, advanced technologies for continuous multi-site measurements of pressure and temperature at skin interfaces have potential to provide supplementary information, beyond simple assessments of time duration, as an alarm for identifying risk. As outlined in the discussion section, statistical, scaled clinical studies performed with the technology introduced here will be helpful for defining algorithms and thresholds for risk stratification of subjects according to body type, age, condition, body location and other key factors. We envision a deployment strategy that would begin with a basic use of data from the sensors to guide clinical care decisions where, over time, increasing amounts of data and correlated conditions will enable more sophisticated uses of the information.
Supplementary Fig. 1. Circuit diagram of the device. (a) Circuit diagram of the wireless sensing platform integrated with pressure sensor connected to Wheatstone bridge and temperature sensor connected to voltage divider. (b) Circuit diagram of pressure sensor connected to serpentine traces. (c) Circuit diagram of the temperature sensor connected to serpentine traces.
Supplementary Fig. 2. Mechanical reliability of the battery-free, wireless sensing platform. (a) Photographic images of the device in (i) bent, (ii) stretched, (iii) twisted configurations. (b) Finite element modeling of the mechanics for these three cases.
Supplementary Fig. 3. Procedure for fabricating the pressure sensor with temperature sensor.
Supplementary Fig. 4. Robustness of the pressure sensor against shear stress. Modeling results for the deformation and the shear stress $\sigma_{yz}$ on the upper surface of the dragon skin for (a) design A of the pressure sensor with two-stage structure and (b) design B of the pressure sensor with one-stage structure under the shear stress of 10 kPa. $U_y$ and $\sigma_{yz}$ represent the displacement in the y direction and the y-z shear stress, respectively.
Supplementary Fig. 5. Experimental setup for evaluating the characteristics of the pressure sensor. The setup includes a digital multimeter (USB 4065, NI) and a force gauge (Mark-10) equipped with motorized standing test (ESM303).
Supplementary Fig. 6. Average responses of 3 pressure sensors to applied loads of 6 kPa at different initial resistances of 10.2 kΩ and 20.1 kΩ, respectively.
Supplementary Fig. 7. Sensitivity of a pressure sensor over a relevant range of pressures within the upper and lower bounds of fractional changes in resistance.
Supplementary Fig. 8. Effective modulus of a pressure transducer with a thickness of 2 mm under compressive loading.
Supplementary Fig. 9. Average responses of 10 pressure sensors to applied loadings of 3 kPa and 6 kPa.
Supplementary Fig. 10. Temperature dependence of the pressure sensor.
Supplementary Fig. 11. Experimental setup for evaluating the response of a pressure sensor at different interfacial substrates. Photographic images of (a) Dragon skin with $E = 0.1$ MPa and (b) PDMS with $E = 1$ MPa.
Supplementary Fig. 12. Experimental setup for evaluating the response of a pressure sensor for the case of substrates with different radii of curvature. (a-d) Photographic images for cases with different radii of curvature (Dragon Skin with $E = 100$ kPa).
Supplementary Fig. 13. Fractional change in resistance of the sensor at different values of RH.
Supplementary Fig. 14. Fractional change in resistance at RH of 80% for 12 hours.
Supplementary Fig. 15. Comparative studies of pressure measurements on a human subject. (i) Schematic illustration of different anatomical locations for measuring the pressure at the skin-mattress interface. (ii) Feasibility evaluation of the pressure sensor on each mounting locations of the subject lying on bed. A commercial pressure sensor, Picopress, was used as a reference.
Supplementary Fig. 16. Stability of the response of the pressure sensor during various deformations. (a-c) Fractional change in resistance of the piezoresistive strain gauge during 1,000 repeated cycles of stretching (8%), bending (7mm) and twisting (180°), respectively.
Supplementary Fig. 17. Magnetic field strength along the central axis of the antenna as a function of distance out of the plane of the antenna coil for three different RF powers.
Supplementary Fig. 18. Block diagram of the system.
Supplementary Fig. 19. Evaluation of the receiver antenna of the wireless sensing platform, to determine the center frequency and the Q factor.
Supplementary Fig. 20. Electrical stability of the battery-free, wireless sensing platform. (a-c) Change of the ADC value from the NFC SoC under 10,000 repeated cycles of stretching (8%), of bending (7mm), of twisting (180°), respectively.
Supplementary Fig. 21. Change in the ADC value from the NFC SoC for a wireless device operating while completely submerged in water for 60 min.
Supplementary Fig. 22. Continuous measurements of pressure and temperature from a healthy subject (30-year-old male, 72 kg, 180 cm) using 4 wireless sensing platforms placed in proximity to one another. (a) Photographs of mounting locations of sensors for the subject lying in prone position. (b) Pressure and temperature monitoring of the subject lying in supine position, respectively.
Supplementary Fig. 23. Photographic image of changes in posture of the subject with right hemiplegia. (a) An initial posture of the subject lying in bed. (b) Movement of a left arm by herself and fine movement at right side without the repositioning by the clinical staff. (c-d) changes in posture with the repositioning by the clinical staff using a pillow and a blanket.
Supplementary Fig. 24. Continuous measurements of pressure and temperature from a subject with hemiplegia and stroke (61-year-old male, 57 kg, 170 cm) using the wireless sensing platform during sleep time (overnight). (a) Photograph of the subject with red discs to mark the mounting locations of the sensors and IR images of changes in posture of the subject lying on bed during sleep. (b) Results from continuous measurements of pressure and temperature from each of the sensors.
Supplementary Fig. 25. Photographic images of skin in the region of the right elbow and the heel after removing the wireless devices.
Supplementary Fig. 26. Programming of ISOSStart2018 software in protocol mode for operation of multiplexed antenna and multiple sensors. Commands of A and B mean sequentially turning on antenna 1 and antenna 2, respectively.
Supplementary Fig. 27. Comparison of adhesive strength between the MPTMS-treated silicone (Dragon Skin) and the PI film for epoxy bonding. The insets show photographic images of samples of dragon skin peeling from a PI film under tensile loading.
Medical Device Satisfaction Questionnaire

We would like to ask you how you felt about the medical devices for “battery-free, wireless, soft sensor for continuous measurement of pressure and temperature.” Please fill out the following information and place a circle mark (●) in the answer box that corresponds to your response.

Gender: male
Old: 30
Weight: 72 kg
Height: 180 cm

| Content       | Excellent (5) | Good (4) | Average (3) | Poor (2) | Very poor (1) |
|---------------|---------------|----------|-------------|----------|---------------|
| Compatibility | 0             |          |             |          |               |
| Convenience   | 0             |          |             |          |               |
| Satisfaction  | 0             |          |             |          |               |
| Total score   | 15            |          |             |          |               |

Thank you very much for your kind reply!

Supplementary Fig. 28. Feedback from the healthy subject (30-year-old male, 72 kg, 180 cm) in Fig. 5.
Medical Device Satisfaction Questionnaire

We would like to ask you how you felt about the medical devices for "battery-free, wireless, soft sensor for continuous measurement of pressure and temperature." Please fill out the following information and place a circle mark (□) in the answer box that corresponds to your response.

Gender: male
Age: 30
Weight: 72 kg
Height: 180 cm

| Content      | Excellent (5) | Good (4) | Average (3) | Poor (2) | Very poor (1) |
|--------------|---------------|----------|-------------|----------|---------------|
| Compatibility|               |          |             |          |               |
| Convenience  |               |          |             |          |               |
| Satisfaction |               |          |             |          |               |
| Total score  |               |          |             |          | 13            |

Thank you very much for your kind reply!

Supplementary Fig. 29. Feedback from the healthy subject (30-year-old male, 72 kg, 180 cm) in Fig. 6.
Supplementary Fig. 30. Feedback from the patient with right hemiplegia (47-year-old female, 62 kg, 160 cm) in Fig. 7.
Supplementary Fig. 31. Feedback from the patient with general paralysis (83-year-old male, 40 kg, 150 cm) in Fig. 8.
Medical Device Satisfaction Questionnaire

We would like to ask you how you felt about the medical devices for "battery-free, wireless, soft sensor for continuous measurement of pressure and temperature." Please fill out the following information and place a circle mark (□) in the answer box that corresponds to your response.

Gender: Male
Age: 61
Weight: 57 kg
Height: 170 cm

| Content      | Excellent (5) | Good (4) | Average (3) | Poor (2) | Very poor (1) |
|--------------|---------------|----------|-------------|----------|---------------|
| Compatibility|               | □        |             |          |               |
| Convenience  |               | □        |             |          |               |
| Satisfaction |               | □        |             |          |               |
| Total score  |               |          |              | □        |               |

Thank you very much for your kind reply!

Supplementary Fig. 32. Feedback from the patient with hemiplegia and stroke (61-year-old male, 57 kg, 170 cm) in Supplementary Fig. 24.
### Supplementary Table 1. Comparison for battery-free, wireless sensors.

| Content                                      | This study                      | Previous study                                      |
|----------------------------------------------|--------------------------------|-----------------------------------------------------|
| **Pressure sensor**                         |                                |                                                    |
| Sensing mechanism                           | Bending-induced tensile strain  | Stretching-induced tensile strain (Poisson effect of PDMS) |
| (membrane deflection)                       | Au                             |                                                    |
| Resistive material                          |                                |                                                    |
| Gauge factor                                 | ~2                             | ~50                                                 |
| Sensitivity                                 | < 0.0006 kPa$^{-1}$            | <0.002 kPa$^{-1}$                                  |
| Bending                                     | Insensitive                    | Sensitive                                          |
| Shear                                        | Insensitive                    | No experimental data                               |
| Robustness (Stability under cyclic loading)  | Good                           | Not good (No data under cyclic loading)             |
| Reproducibility                             | Good                           | Not good                                            |
| Temp. Compensation                          | Yes (using NTC)                | No experimental data                                |
| **Wireless platform**                       |                                |                                                    |
| NFC chip (ADC)                              | RF430FRL152H, Texas Instruments (3 counts) | SL13A, amg AG; (1 count)                           |
| Maximum working distance @diameter of coil  | 46 cm @ 34.5 mm                | 32cm @16 mm                                        |
| Location of sensor                          | Out of receiver antenna (with serpentine trace) | In receiver antenna                                      |
| Connection type                             | Wheatstone bridge              | Voltage divider                                     |
| Software                                    | ISOSStart 2018                 | -                                                   |
| **Clinical trial**                          |                                |                                                    |
| Patient at risk for pressure injuries       | Yes (Two hemiplegic patients, one tetraplegic patient) | No                                                   |
| Simultaneous monitoring of pressure and temperature | Yes                       | No                                                   |
| Continuous monitoring for change in posture | Yes                           | No                                                   |
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