KroniKare Wound Scanner

System Description and Validation

Commercial in Confidence

Executive Summary

KroniKare Wound Scanner is an award-winning patented technology from KroniKare, with HSA (Heath Science Authority of Singapore) Class B approval as a diagnostic tool for AI-based chronic wound assessment, providing 3D wound measurement, wound tissue type classification (all 7 medically-assessed tissues) and detection of complications including ischemia, infection, undermining, and inflammation.

In a typical care setting, nurses use the KroniKare Wound Scanner to capture wound images every time the dressing is changed. These images are processed by multiple AI engines and the results are compiled into a medical report of the wound visit. A dynamic dashboard monitors the wound healing progress and also captures wound exudate conditions, limb and back ischemia and pressure point checks, and treatment (wound product). KroniKare Wound Scanner has been evaluated in Proof of Concept (PoC, Sep 2017-Jun 2018) and Proof of Value (PoV, Feb 2019-Nov 2019) studies:

The Proof of Concept (PoC) clinical study was conducted at St. Andrew's Community Hospital (11 devices on 143 patients, with 275 distinct wounds) from Sept 2017 to June 2018, and the statistical analysis in the PoC clinical study is performed by Duke-NUS Medical School.

The statistical analysis shows that KroniKare Wound Scanner performs on-par with experts (wound care specialists), while being superior to average ward nurses in detecting wound tissues and wound complications.

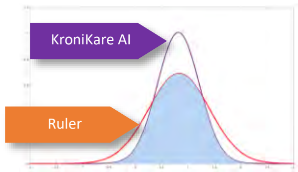
The Proof of Value (PoV), a large scale study to evaluate the performance and timesaving, was conducted across different settings from Feb 2019 to Nov 2019, featuring the acute hospital setting at Changi General Hospital (CGH), community hospital setting at St. Andrew's Community Hospital, nursing home setting at Kwong Wai Shiu Hospital (KWSH) and homecare setting at St. Luke's Hospital (SLH). In the study, 31 KroniKare Wound Scanner devices processed data from 644 patients, with 1,204 distinct wounds and 4,904 wound reports, showing similarity of KroniKare Wound Scanner size measurement, tissue analysis, and complication detection to the experts (wound care specialists).

In the Duke-NUS validated PoV report, the KroniKare Wound Scanner is shown to be on-par with physical measurement of wounds, detects similar tissue types compared to expert assessment and detects similar complications compared to expert opinion. KroniKare features a higher rate of alerts for inflammation compared to expert opinion as it employs thermal imaging.

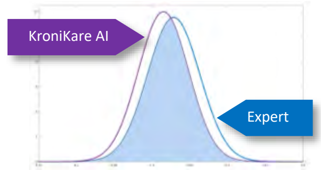
The Duke-NUS study also shows that the KroniKare Wound Scanner improves productivity savings by up to 52% in acute care setting and 80% in step-down care setting. The time and motion study shows significant savings in the clinician's time, beside additional value from digitalization, early detection of complications and efficient resource distribution.

The statistical comparisons between KroniKare AI and experts in the PoC study, shown below, indicates high matching of KroniKare Wound Scanner outputs to expert opinion (wound care specialists) in size estimation (**82% match**), tissue classification (**84% match**), and complication check (**94% match**).

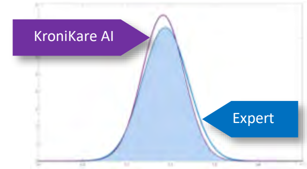
Size Estimation (KroniKare AI vs. Ruler)	Tissue Classification (7 Medically assessed tissue types)	Complication Check (Infection, Undermining, Ischemia)



82% Match
Between KroniKare AI and Ward Nurse



84% Match
Between KroniKare AI and Expert



94% Match
Between KroniKare AI and Expert

Specifically, through McNemar Tests presented below, KroniKare Wound Scanner is shown to have achieved an average accuracy of **92.6% in wound tissue classification**, and **87.8% in wound complication detection**.

MCNEMAR TEST	NECROTIC	SLOUGH	GRANULATING	EPITHELIZING
SENSITIVITY	0.909722222	0.976525822	0.93	0.973856209
SPECIFICITY	0.886486486	0.887931034	0.860465116	0.943181818
PRECISION	0.861842105	0.941176471	0.911764706	0.937106918
ACCURACY	0.896656535	0.945288754	0.902735562	0.957446809
F1	0.885135135	0.958525346	0.920792079	0.955128205

MCNEMAR TEST	NON-COMPLICATED	WOUND INFECTION	ISCHEMIA	UNDERMINING	INFLAMMATION
SENSITIVITY	0.713333333	0.930232558	0.952941176	0.913793103	0.76
SPECIFICITY	0.960893855	0.942386831	0.954918033	0.966789668	0.6875
PRECISION	0.938596491	0.85106383	0.880434783	0.85483871	0.166666667
ACCURACY	0.848024316	0.939209726	0.954407295	0.957446809	0.693009119
F1	0.810606061	0.888888889	0.915254237	0.883333333	0.273381295

In the time and motion study during the PoV study, KroniKare Wound Scanner showed **80% time saving** (saving more than **14min per wound**), even before integration with the EMR. This saving can be increased to **over 90% with EMR integration**.

Cat No.		Category	Task No.	Task	Manual Time	KroniKare Time	Saving
0	Bedside Tasks	Patient Registration	0	Entering patient Information	0	83	
1		Preparation Before Procedure	1.1	Check Case Notes/Charts	174	0	174 sec
2		Implementation of Phase I	3.7	Prepare the device/camera	30	11	19 sec
5		Implementation of Phase III	5.2	Wound image capture	72	13	59 sec
			5.3	Save the image	5	0	5 sec
			5.4	Keep phone aside	1	1	
			5.5	Wound measurement	42	10	32 sec
8	Housekeeping, Documentation, & Reporting	Housekeeping	8.2	Upload the picture into the PC	132	0	132 sec
9		Documentation and Reporting	9.1	Find patient records	10	10	
			9.2	Record and documentation	252	35	217 sec

			9.3	Update NM, NC, and SNM	156	61	95 sec
			9.4	Attach the pictures to email	78	0	78 sec
			9.5	Update INGOT system	72	72	
			9.6	Pass report to the next shift	66	0	66 sec
		Total Time in Min Per Wound			**18:10min**	**3:33min**	**14:397min**
		Timesaving per Ward per Month					**21:48hrs**
KWSH: Nursing home with long-term residents with more wounds per patient (2.85), fewer patients with wound per ward (5.13), more visits per patient per month (6.12). t = -28.2067 p = 8.22E-30							

KroniKare Wound Scanner has passed rigorous tests and have obtained Singapore Health Science Authority **(HSA) Class B** for medical devices, **CE Mark Class I with CE Mark Class II in progress**, and **ISO 13485 certification** for medical devices. These achievements have attracted local and international interest and investment from major stakeholders including Ministry of Health Holdings (MOHH/ IHiS), STEngineering (Innosparks), SGInnovate, Spark Labs Global and other VC funds. KroniKare has been featured in Singapore's National AI Strategy and multiple media, and has received grants from AI.Singapore, Enterprise Singapore, Singapore MIT Alliance in Research and Technology, Innovate UK and EUREKA GlobalStars. KroniKare has been working closely with Singapore Ministry of Health to implement nation-wide wound scanner coverage in Singapore under Smart Nursing Ward Program.

The statistical analysis report from Duke-NUS for the PoC and PoV clinical studies are presented below, followed by the system description and validation report of the KroniKare Wound Scanner.

DUKE NUS
GRADUATE MEDICAL SCHOOL SINGAPORE

29th June 2018

Centre for Quantitative Medicine,
Duke-NUS Graduate Medical School,
R63, L6, 20 College Rd,
Singapore 169856

To: Dr Hossein Nejati
KroniKare Pte Ltd

Dear Dr Nejati,

This document is in reference to the statistical analysis of KroniKare AI-based chronic wound assessment & management system for automatic size measurement, tissue classification and complication assessment.

Analysis is performed on data from 143 patients, with 275 wounds, and more than 1500 wound images, collected from 1st Sep 2017 to 1st March 2018 from St. Andrew's Community Hospital, Singapore. Analysis applied for each assessment are Paired T-Test on size measurement, McNemar Test on tissue classification and McNemar Test on complication assessment.

With regards to wound size measurement, there are no statistically significant difference between the automatic KroniKare AI system and manual measurement done by experienced nurses (considered as the gold standard). This indicates that the KroniKare AI system estimates the wound size that is statistically similar to that done by experienced wound nurse.

With regards to wound tissue classification, the KroniKare AI system shows no statistical difference to expert nurse, but statistical difference to experienced nurses. This indicates the potential of KroniKare AI system to upskill nurses to a higher level of decision making in wound tissue classification.

With regards to complication assessment, the KroniKare AI system shows no statistical difference to expert nurse, but statistical difference to experienced nurses. This indicates the potential of KroniKare AI system to upskill nurses to a higher level of decision making, and perform timely intervention in cases of detection of complication at early stages.

Details of this data analysis can be found in Sections 5 and 6 in "KroniKare Proof of Concept Trial With St. Andrew's Community Hospital June 2018"

Bibhas Charkraborty PhD
Associate Professor
Centre for Quantitative Medicine and
Programme in Health Services & Systems Research
Duke-NUS Medical School

Yours faithfully,

Dr Kenny Xu Jing
Research Fellow
Centre for Quantitative Medicine at
the Duke-NUS Medical School,
Singapore

Prof. Bibhas Chakraborty
Associate Professor and Director
Centre for Quantitative Medicine at
the Duke-NUS Medical School,
Singapore

DUKE NUS
GRADUATE MEDICAL SCHOOL SINGAPORE

11th Dec 2019
Center for Quantitative Medicine
Duke-NUS Graduate Medical School,
R63, L6, 20 College Rd,
Singapore 169856

To: Dr. Hossein Nejati
KroniKare Pte. Ltd

Dear Dr. Nejati,

This document is in reference to the statistical analysis of KroniKare Wound Scanner for AI-based chronic wound assessment in different care settings and includes automatic size measurement, tissue classification, and complication detection functionalities, as well as timesaving measurement.

Analysis is performed on data from 644 patients, with 1,204 distinct wounds, and 4,904 wound reports, from more than 15,000 images collected from Jan to Nov 2019 from four different care settings in Singapore, namely, acute care setting, Changi General Hospital, and three step-down settings, St. Andrew's Community Hospital, Kwong Wai Shiu Hospital's nursing home, and St. Luke Hospital's homecare. Analysis applied for each assessment are T-Test on size measurement, McNemar Test on tissue classification, McNemar Test on complication assessment, and T-Test on time and motion records.

1. **Wound size measurement:** There are no statistically significant difference between the automatic reports and manual reports done by experienced wound nurses at acute settings, community hospital, and nursing home.
2. **Wound tissue assessment:** KroniKare Wound Scanner reports show no statistically significant difference to expert wound nurses' opinions at all the above care settings.
3. **Wound Complication assessment**: the KroniKare Wound Scanner reports show no statistically significant difference to expert wound nurses' opinion for detection of infection, undermining, and ischemia, in acute hospital, community hospital, and nursing home. This indicates the potential of KroniKare Wound Scanner in early detection of complications that can lead to timely interventions.
4. **Time and Motion**: KroniKare Wound Scanner shows productivity saving up to 52% in acute care setting and 80% in step-down care setting for the impacted processes.

Annex A presents the summary breakdown of the findings. For details of these data analyses please refer to "KroniKare Wound Scanner: System Descriptions and Validation Dec 2019" report.

Yours faithfully,

Bibhas Charkraborty PhD
Associate Professor
Centre for Quantitative Medicine and
Programme in Health Services & Systems Research
Duke-NUS Medical School

Ms Linda Li Yun
Research Assistant
Center for Quantitative Medicine
at the Duke-NUS Medical School,
Singapore

Prof. Bibhas Chakraborty
Associate Professor and Director
Center for Quantitative Medicine
at the Duke-NUS Medical School,
Singapore

Annex A

General note: Statistical analysis shows A large **p-value** (typically ≥ 0.05) **indicate**s significant similarity, as visible for comparison of AI and expert opinion in size measurement, tissue classification, and complication assessment. A small **p-value** (typically ≤ 0.05) **indicate**s significant difference, as visible for comparison between the recorded time between manual and automatic in both acute and step-down care settings.

Table 1. Wound Size Assessment (compared against expert nurse), indicating similarity.

Item	Institution	Number of Data points	p-Values (goal: ≥0.05)		
			Length	Width	Depth
1	Changi General Hospital	207	0.669	0.929	0.138
2	St. Andrew's Comm. Hospital	310	0.994	0.165	0.160
3	Kwong Wai Shiu Hospital	98	0.102	0.105	0.093
4	St. Luke Hospital	-	-	-	-

Table 2. Wound Tissue Classification (compared against expert nurse), indicating similarity.

Item	Institution	Number of Data points	p-Value (goal: ≥0.05)			
			Nec	Slgh	Gran	Epith
1	Changi General Hospital	329	0.230	0.099	0.596	0.181
2	St. Andrew's Comm. Hospital	983	0.286	0.230	0.755	0.461
3	Kwong Wai Shiu Hospital	321	0.386	0.845	1.000	1.000
4	St. Luke Hospital	306	0.149	0.267	0.239	4.919E-20

Table 3. Wound Complication Assessment (compared against expert nurse), indicating similarity.

Item	Institution	Number of Data points	p-Value (goal: ≥0.05)				
			No complic.	Infection	Ischemia	Undermining	Inflammation
1	Changi General Hospital	271	7.431E-07	0.118	0.121	0.423	2.017E-18
2	St. Andrew's Comm. Hospital	983	0.302	0.337	0.061	0.453	3.547E-27
3	Kwong Wai Shiu Hospital	1797	0.261	0.868	0.239	0.112	0.016
4	St. Luke Hospital	306	4.426E-05	0.0002	0.302	0.181	0.016

Table 4. Time and Motion Assessment (compared against expert nurse), indicating difference.

Item	Institution	Number of Data points	p-Value (goal: ≤0.05)
1	Acute Setting (Changi General Hospital)	30	0.0001
2	Step-down setting (Kwong Wai Shiu Hospital)	45	8.22E-30

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1. Burden of Chronic Wounds

Figure 1: Current wound monitoring practice is invasive, manual, time-consuming & non-scalable

1. The Problem of Chronic Wound Management

Chronic wound is a technical term for wounds that don't proceed through normal regenerative processes to closure within an expected time frame [1]. These wounds are the by-product of chronic conditions including cardio-vascular diseases, diabetes, obesity, immobility, or even aging - wounds that take on average one year to heal [2] and are as life threatening as cancer [1]. The world's rapidly aging population and the rise of chronic illnesses including diabetes are causing a sharp increase in chronic wound cases, incurring costs of over $100 billion worldwide (US >$30B, Singapore >$300M). The current wound assessment requires specialized workforce, is done manually, is invasive, subjective and based on visual inspection with large error margins (see Figure 1). On the other hand, there is a severe shortage of trained wound nurses to provide medical care, and the available experts are aging.

People suffering from chronic wounds and the cost of managing them are on the rise globally: Due to diabetes (422M), obesity (1.2B) and rapidly aging population (650M), the number of chronic wounds is increasing sharply. Chronic wounds have become a major issue of public health and economy. These wounds such as diabetic ulcers or bedsores do not heal for months or years, and are subject to high risk of infection, amputation, and death [3]. More than 52% of Singaporean patients that require home care suffer from chronic wounds [4]. 21.2% of diabetic patients develop chronic wounds, and half of these wounds develop infection. In addition, 28% of diabetic patients are in high risk of developing chronic wounds.

Shortage of manpower: Current wound monitoring practice depends heavily on manpower. According to WHO, the world will be short of 12.9 million health-care workers by 2035; By 2020, Singapore will be short of 30,000 healthcare workers (MOM). Only about 2% of nurse population are qualified wound nurses, thus it is not possible to offer adequate care to these chronic wound patients with existing practice.

Manual monitoring: Current monitoring practice is manual, invasive, time-consuming and inconsistent. Spending an average of 30min per wound, the wound nurse performs measurement with paper tapes and probes, and subjective checks (visual or by touch) for cues of complications such as infection (Figure 1). The quality of gathered information is subjective and relies on the experience of the nurse.

Data recording methods currently used is highly error-prone and non-scalable: Tracking the healing process of multiple wound sites across consecutive examinations is difficult and error-prone using subjective data. The current practice is for the nurse to use paper forms to record information at the end of the working day based on memory. Therefore, only the most highlighted cases are recorded, often with errors in measurements (44% error rate [1]) and passed to the higher medical advisor. This broken information link prevents the higher-level medical supervisors to make well-informed decisions at different levels from individual cases, to systematic comparison of treatment strategies, to legislation and healthcare planning.

With manpower shortage, and an almost completely manual practice, the wound monitoring is unscalable, thus causing delay in monitoring, leading to prolonged hospitalization, development of complications, amputation and even death [1]. Therefore, there is a pressing need for an automatic solution that reduces the risk for patients, workload for nurses and cost for hospitals. The main challenge is to develop a cost-effective, medically acceptable solution, customized for the workflow at each level that not only alleviates the problem for chronic wounds but also paves the way for advanced preventive care in chronic illnesses.

2. KroniKare Wound Scanner

2. KroniKare Wound Monitoring System

KroniKare has developed an automatic, accurate and non-invasive wound assessment system that provides different services for different user-groups. The system comprises of a front-end AI-enabled mobile app targeted at nurses at point of care, and an AI-enabled server-side targeted at higher-level decision makers. A multi-level dashboard is also provided to give different levels of access to different user groups, from nurses to the hospital administration.

The front-end module (Figure 2) replicates complete wound assessments performed by an expert wound nurse, using a combination of novel stereoscopic, thermal images and machine learning algorithms that run entirely on a normal smartphone. These assessments are:

- 3D dimension measurement: Length, width and depth of the wound, that are key indicators of wound healing progress.
- Tissue assessment: Identification of tissues on the wound bed, that help identify condition of the wound and the required treatment procedure.
- Wound complication detection: Detection of infection and undermining in wounds, usually hidden from untrained eye.
- Limb complication detection: Detection of infection and ischemia in limbs, usually hidden from untrained eye.

The automatic wound report is then sent to medical supervisors' dashboard for further evaluation and decision on treatment. To protect patient data privacy, KroniKare stores only anonymized wound data, linking with hospital's EMR only through an automatically generated random unique ID. This system is remarkably accessible, with accurate, objective, and quantifiable assessments, leading to timely diagnosis and well-informed decision-making. As KroniKare system uses both visible and thermal images, the results are robust against different skin tones and lighting conditions. In addition to reducing the workload, this system can also serve as a training companion to help upskill junior nurses. This system can be easily merged with electronic health records (Figure 3), to bridge across different care settings and seamlessly transfer complete wound related information from one setting to another (Figure 4).

The data collected by KroniKare Wound Scanner for processing and automatic report generation does not include any patient identity information. Therefore, these reports can be traced back to an individual patient only by the related healthcare institute. The individual patient data categories collected by the KroniKare Wound Scanner are:

- Patient bed no, age (bucketed if needed), race, and comorbidities
- Wound sites, and manual wound notes
- Wound images
- Automatic assessment results

Fig 2: KroniKare Wound Monitoring System – front-end runs on normal smartphone with multispectral imaging capabilities

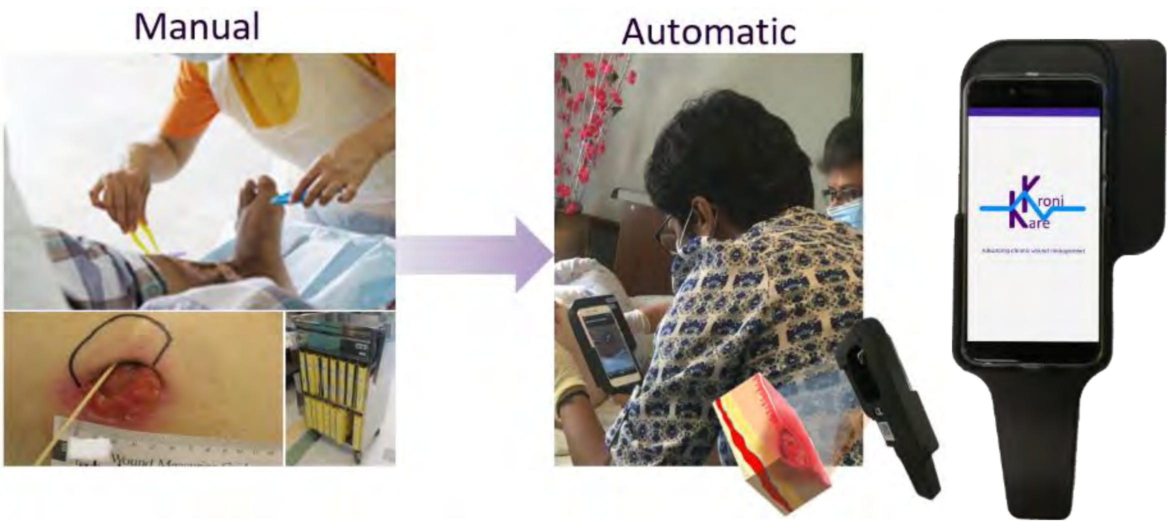


Fig 3: Overall design: Front-end used by nurses and caregivers to capture data, empowering them to be more proactive in wound care. Server generates automatic clinical reports based on AI model assessments on anonymized data, combining AI with manual notes, and allows secure integration with EMR systems. Multi-level dashboard provides full picture for experts to reach a well-informed decision.

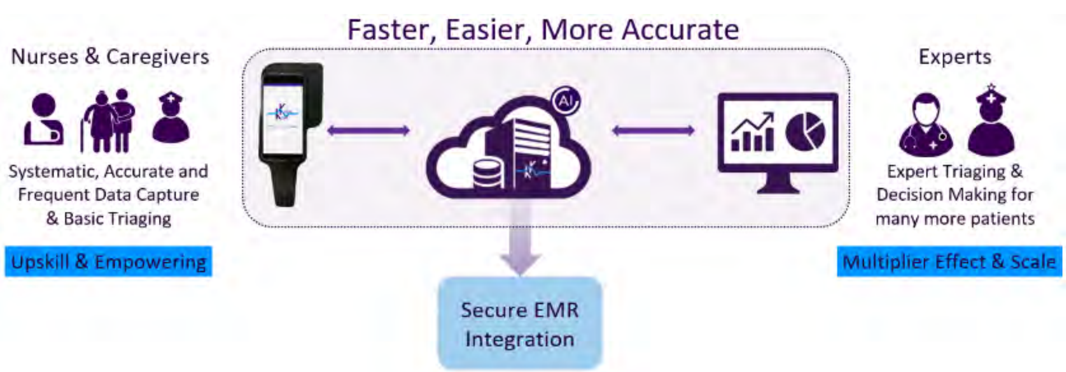
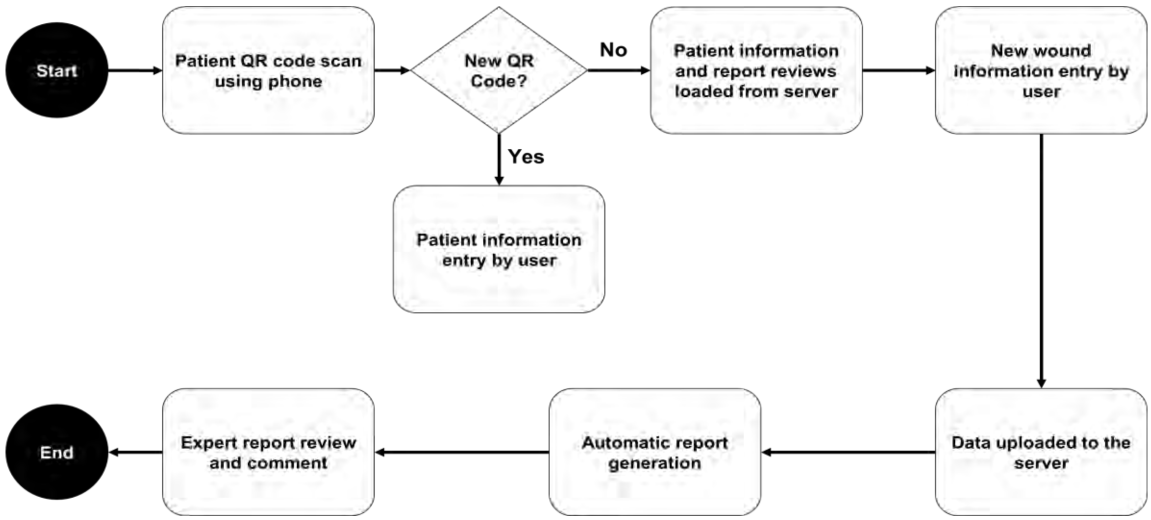


Figure 4. KroniKare can seamlessly provide services across different care settings

Figure 5: KroniKare Wound Scanner workflow for wound screening, reporting, and review.



The KroniKare Wound Scanner workflow for wound screening, reporting, and review is depicted in Figure 5.

KroniKare wound monitoring system is also realizing a missing and vital data platform that systematically collects information to be the basis of medical studies. These new studies can lead to practice modification, treatment comparison, precision medicine and preventive care, particularly for diabetic and aging population, enabling unprecedented service in personalized healthcare.

DICOM Compatibility

KroniKare Wound Scanner is DICOM compatible. Version 7 (current version) captures visible image with high-resolution (4000×3000 pixels), mid-resolution (1600×1200 pixels), and low-resolution (640×480 pixels). High-resolution images are used for high-definition displays, mid-resolution images are used for color printing, and low-resolution images are used for thumbnail display in dashboard. In addition, images captured in other wavelengths are in 640×480 pixels for display and print purposes.

Printing capabilities are available from handheld device and dashboard. Each individual report and summary reports can be exported into PDF format, which are kept under 3MB to be compatible with most EMR systems attachment limit. The capture resolutions and PDF size limit can be set per institution requirements as well.

2.1. Potential Benefits of KroniKare System

KroniKare system provides significant benefits for hospitals, in terms of productivity gain, better patient outcomes, product usage efficiency, digitalization and downstream benefits.

Multiplier Effect: Chained Manpower/ Cost Saving

Considering only the productivity gains through using KroniKare System, spending 3 minutes instead of 30 minutes per wound, estimated 45 hours per ward per month is saved in each hospital[1]. A more important benefit of using KroniKare system, however, is the multiplier effect to expand the capabilities of the currently available workforce, to serve a much larger patient population. Each patient with chronic wound in Singapore has a mean stay of 13.2 days, costing about S$10,000 per patient for direct cost and S$3,600 indirect cost per patient [2]. Multiplier effect provided by KroniKare Wound Scanner can substantially increase the reach of experts to monitor more patients in shorter amount of time and therefore lower the total cost of stay and medications.

In the current practice, wound nurse or wound care specialist needs to visit all wound patients one by one to check their condition and decide on the treatment steps. This proves to be intractable even at the hospital settings, let alone home care. By giving the power of analysis to junior nurses, KroniKare system frees the chief wound nurse's time (the most experienced wound nurse in the hospital) and allows efficient and effective work by both staff nurses, wound nurses, and the chief wound nurse. Staff nurses can now be a part of wound assessment workforce, with the key decisions made by wound nurses and wound care specialists. Wound nurses and wound care specialists can use the dashboard to view the progress of each patient and decide which patients to attend first based on patient conditions.

Using KroniKare system, the data collection is performed by junior nurses/caregivers at hospitals/homes, and the decision making is performed by the wound care specialist. This means the same team of wound care nurses can now provide care to multiple folds of patients, not only the patients at a single hospital, but potentially, patients at nursing homes and under homecare.

Better outcomes for patients

KroniKare system provides accurate and objective measurements, and the means for early detection of severe complications such as wound infection, wound undermining and limb ischemia. Detecting wound infection in early stages can lead to shorter recovery time, less medicine usage and reduction of overall costs and complications such as sepsis. Detecting early stages of limb ischemia can allow intervention by a vascular surgeon to help alleviate the problem and possibly prevention of amputation. An amputation costs S$9,000 on average in Singapore, with more severe downstream socio-economic effects including lack of mobility, increased need for social services and mental health problems [11]. Moreover, with early identification of

[1]Based on public figures from Singapore MOM and MOH in 2017

complications, faster recovery, and more accurate and efficient discharge planning would be possible. This would reduce the overall cost of chronic wound management per patient. The current average annual cost of chronic wound management per patient is estimated to more than $11,500 [12]. Moreover, because of the accessibility of KroniKare system to individuals, these benefits can be expanded across different care settings, ranging from acute and community hospitals, to nursing homes, homecare and personal care (Figure 4).

Digitalization

Current wound records are stored in paper forms, that are costly to store, and cannot be updated or automatically searched to say the least. Using KroniKare system, all these recordings and forms would be kept in digital format, which are stored in cloud, searchable, and always updated to the latest records. Digital recording improves information flow, reduce errors, and reduces printing needs and paper usage. On average, digitalization is estimated to save over $300,000 per hospital.

Downstream Benefits

The socio-economical downstream benefits of using KroniKare cannot be fully quantified, as there are limited number of studies on the downstream benefits of proper chronic wound management. Some of the most important downstream benefits of using KroniKare system can be:

- Automatic clinical and legal documentation from admission to discharge
- Efficient & effective use of wound dressing, faster recovery, earlier discharge, free-up beds
- Upskill junior nurses, care givers, and patient self-monitoring

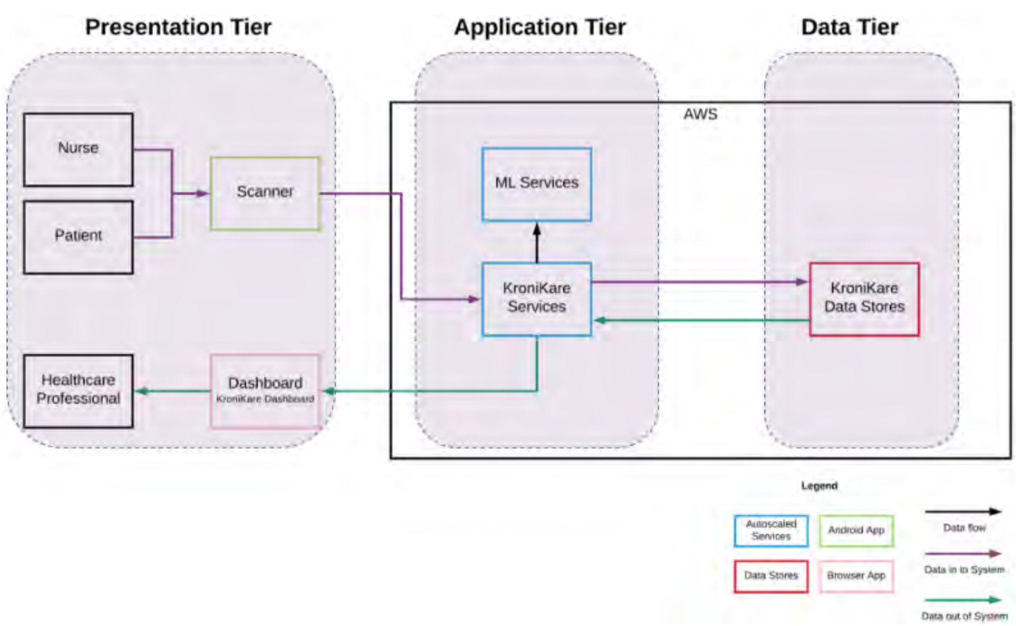
2.2. KroniKare Wound Scanner System Architecture

KroniKare Wound Scanner has a 3-Tier architecture (see Figure 6) that includes:

1. Presentation Tier to support UI for KroniKare Wound Scanner Handheld device users and expert supervision portals
2. Application Tier to support KroniKare services including AI engines, medical report generation, and statistical reporting. This tier is a processing and transition tier that does not store information.

The application tier is responsible for auto-scaling, authentication, encrypted communications, and load balancing. Auto-scaled services are located in individual private subnets. Services are accessed through the Internal Load Balancer (ILB) and subnet level Network ACLs are granted only to subnets as needed. Security Groups (firewall) for each server instance is allocated as needed and all incoming traffic from the internet are processed through a Web Application Firewall (WAF). WAF is attached to the External Load Balancer (ELB) before being forwarded to the appropriate services.

Figure 6. KroniKare can seamlessly provide services across different care settings



2.2.1. Device Preparation

Prior to the usage at each care setting, the KroniKare Wound Scanner devices should be registered and activated by KroniKare logistics team. KroniKare adopts x.509 Certification for this process. The high-level steps involved in device registration and activation is Figure 7 (Annex A).

The KroniKare Wound Scanner device then performs encryption and obfuscation of IDs as shown in Figure 8 (Annex A).

2.2.2. User Enrollment

The information for system users and changes to this information is provided by healthcare institute administration, system admin, wound care specialist or nursing manager, via written requests. All device and dashboard users are provided by the hospital before deployment and registered into KroniKare system by KroniKare Admin. User enrollment processes are illustrated in Figure 9 (Annex A).

2.2.3. Patient Enrollment

Patient data is separated via a QR Code assigned to each patient. These QR Codes are randomly generated and does not have identity information. The KroniKare Wound Scanner user (e.g. nurse, wound care specialist, nursing manager, etc.) assigns one of the QR Codes to a patient and scans the QR Code using the KroniKare Wound Scanner when visiting the patient. The QR Codes are provided by KroniKare Web-based Dashboard, or in hard and softcopies if needed.

Pseudonymization of IDs (e.g. NRIC) can also be performed by the device to allow nurses to directly scan patient NRIC, without recording any patient identity information in the records. Figure 10 (Annex A) depicts the processes involved in patient enrollment.

2.2.4. Report Retrieve and Verify

Dashboard users (Institute Administration, Wound Care Specialist, Nursing Manager, Nurse) can log into dashboard to retrieve reports and data previously sent to KroniKare servers. As Figure 11 (Annex A) illustrates, user access the dashboard and view authorized reports via the browser. The domain has been secured by SSL/TLS (i.e. https). Instead of searching through the list of wards and patients, when a specific patient report is required, the KroniKare Wound Scanner can be used to scan the respective QR Code ID to query the report on the dashboard. The reports can be exported to PDF for download, automatically sent via email, sent to EMR interface, or fetched through KroniKare Server APIs.

2.2.5. User Access Matrix

KroniKare Wound Scanner System has different base user roles with different access rights, where new specialized users can be created based on these base user roles. Table 1 (Annex A) presents the base user roles and their access right.

2.2.6. Security

All servers are accessed via SSH to Bastion host if required and all users use non-privileged accounts. SSH for Bastions are authenticated via username/password, authorized keys, and Time-based One-Time Password (TOTP). Access to servers from bastions are also limited by IP addresses. All main activities in servers and devices are logged.

2.3. KroniKare Wound Scanner Handheld

Each device provided to the clinicians is associated to related institution for security required for data protection and access control. Only clinicians registered with KroniKare server can log in to the handsets, and only clinicians with right level of access (decided by each institution) can view data and reports. Below is the general navigation through the app in 7 steps:

1. QR Code Scan: From the user's point of view, working with the app starts with scanning patient's QR code. If this is the first time the patient is enrolled to the KroniKare system, a brief information about the patient is requested (age, gender, comorbidities). KroniKare does not use or collect patient identity information, as the randomly generated QR code is unique within the KroniKare system.
2. Wound Site: Clinician indicates wound site on a body diagram (with zoom capability for smaller body parts).
3. Wound Information: Clinician inputs type, stage, and his/her own assessment of wound condition (for the sake of comparison) indicating size, tissue types, and wound/limb conditions.
4. Wound Images: Clinician captures one or more images from the wound. After each image capture, image is displayed for clinician's confirmations.
5. Wound treatment: Clinician can either input notes or capture images of the treatment products.
6. Limb/Back Images: Clinician can capture images from limbs/back of patients for complication check.
7. Additional App Functionalities: Clinicians can upload data, add wound, view image gallery and delete images, update patient information, read QR Code values, and review and modify information for a wound.

Figure 9 presents the workflow with the application and dashboard.

2.4. KroniKare Wound Scanner Storage and Dashboard

Captured information from the phones are uploaded to KroniKare's local AWS sever in Singapore, to be processed by server-side KroniKare AI engine. Users can login to KroniKare dashboard and based on their access level can view corresponding generated reports. For example, while a ward nurse can only view reports regarding respective ward, the wound care specialist or hospital administrator can view patients from all wards. The patient report page lists of all patient's visits for all of patient's wounds. The report starts with patient information and associated QR Code, followed by information input by clinician, AI evaluations, wound progress chart and site, wound images and notes (exudate, visible and thermal), limb images and notes (visible and thermal), and treatment images and notes.

The AI evaluation section is highlighted with a different color code to help differentiate from the manual assessment information.

For cases of multiple image captures from a wound or body, clinician can scroll through all captured images, and see the pictorial timeline of the wound progress.

Any complication indicated by clinician or AI are displayed with a red-colored alert icon to enhance visual attention to complications. Clinicians can print the full report into PDF or on paper or select single images to print via a wireless photo printer, provided by KroniKare team.

3. Clinical Validations

3. Clinical Validations

KroniKare Wound Scanner is validated for Proof of Concept (PoC) at St. Andrew's Community Hospital, Singapore, on data from 143 patients, led by Sister Tang Siew Yeng, followed by validation for Proof of Value (PoV) at 4 different care settings, namely, Changi General Hospital (CGH, acute setting), St. Andrew's Community Hospital (SACH, community hospital setting), Kwong Wai Shiu Hospital (KWSH, nursing home setting), and St. Luke's Hospital (SLH, homecare setting), on data from 644 patient, led by Sister Png Gek Kheng, Deputy Director at Advanced Practice Nursing/Inpatient Services/Manpower Planning at Changi General Hospital, Singapore. While the Proof of Concept study at SACH provided basic insights to the system accuracy (i.e. better than ward nurse, similar to expert wound nurse) in the community hospital setting, this Proof of Value is evaluating all system capabilities, including wound assessments (wound size measurement, tissue classification, and complication detection), presentation of wound report, aggregation of data in a single place, system usability, and immediate cost saving, over a larger population of patients.

The study design developed by Duke-NUS for comparison between KroniKare Wound Scanner system output and expert wound nurse opinions on the same wound.

3.1. Trial Objectives

Objectives of the trial were set to evaluate KroniKare system accuracy and estimate the time-savings provided by the use of this service. These objectives were:

1. **Data Collection:** Through this trial, we aimed to collect chronic wound images from at least 150 wound visits. Based on the sample size calculation, a sample size of 150 has enough statistical significance for the objectives of this trial (see tables 3 and 4 for more details). For each of these cases, the usage time is automatically captured at the app and dashboard.

2. **Performance Evaluation of KroniKare AI of AI-engine based on new data:** The collected data was used to evaluate the performance of KroniKare AI in wound dimension measurement (length, width, and depth), wound tissue classification and wound complication detection.

3. **Timesaving Estimation:** As the usage time was logged automatically for each patient visit and dashboard review, this data can then be used to measure the difference of required time for KroniKare Wound Scanner vs. manual assessments. This difference can then be used to estimate the overall timesaving at ward and hospital levels, in monthly and in yearly timescales.

A nonrandomized, blinded study was performed to determine the accuracy of the KroniKare Wound Scanner system in estimating wound size, classification of wound tissues and check on existence of complications.

Patients admitted to the hospital, clinic, or homecare with chronic wounds were admitted to the study. Excluding criteria consisted of patients with circumferential wounds, cancer wounds or surgical wounds that are stitched and closed. Additionally, if the data from manual assessment is not recorded, or the necessary images for KroniKare Wound Scanner were not captured, the respective wounds were excluded from the study (see Table 2).

Table 2. Inclusion and Exclusion Criteria

Inclusion criteria
Having at least of chronic wound
Admitted to hospital, outpatient clinic, or homecare
Written/Verbal consent
Exclusion criteria
Having circumferential wound
Having cancer wound
Having stitched wound with no visible wound area
Incomplete data from manual assessment by the clinician
Insufficient images captured necessary for KroniKare Wound Scanner

The involved clinical staff (26 in total) performed the wound assessment on the patient wound and use the application to both take required pictures and key-in their manual assessments. The required images are visible and thermal images of the wound using KroniKare Wound Scanner. All KroniKare Wound Scanners are factory calibrated and the clinicians involved in the trial are trained to use the application and dashboard to perform capturing tasks, data entry and reviewing with ease.

Activities on both device application and dashboard application are monitored and logged with timestamps to be used for usage time evaluation and audit trail. If the clinician report was incomplete, or KroniKare Wound Scanner turned off due to low battery during a wound assessment, the data from that wound was excluded from the study.

3.2. End points

As we are comparing KroniKare Wound Scanner to expert opinions, and therefore our *null hypothesis* is that KroniKare output and expert opinion are statistically different. For example, for tissue classification, the null hypothesis is:

Null hypothesis 1: The proportion of the outcome size measurements (length, width, and depth) using KroniKare AI **is different** from the proportion of corresponding size measurements by the expert.

Null hypothesis 2: The proportion of the outcome classified as Necrotic / Slough / Granulating / Epithelizing using KroniKare AI **is different** from the proportion of patients classified as the corresponding category by the expert.

Null hypothesis 3: The proportion of the outcome classified as ischemia using KroniKare AI **is different** from the proportion of patients classified as ischemia by the expert.

Null hypothesis 4: The proportion of the time spent assessing and reviewing a wound using KroniKare AI **is that same** as the proportion of the time spent assessing and reviewing a wound manually.

3.3. Statistical Analysis methods

For a 90% confidence interval (CI) and probability of marginal homogeneity using KroniKare Wound Scanner with a range of no more than ±0.5% assuming a standard deviation of 5.5%, 150 wounds were required to be controlled in this study (Table 3). With a sample size of 150, the probability is 0.900 (90% confidence) that the estimate of the standard deviation will be within 10% of the true population standard deviation. All statistical analyses were predefined in the statistical analysis plan before database lock.

For wound size measurement, each data point (wound) is processed by both evaluators (KroniKare AI and expert), and therefore we can test the similarity through two-tail T-Tests. As the claim is similarity of values from both evaluators, **a high P value can confirm this claim**. Note that in a two-tail T-Test, a high P value (here ≥0.05) indicates similarity of the two sets of values, while a low P value (here, <0.05) indicates statistically significant difference.

For tissue classification, for each data point (wound) we have categorical data (tissue labels) from both evaluators (KroniKare AI and expert). Therefore, we can test the similarity claim through McNamara's test. Here again, **a high P value (≥0.05) can confirm similarity** between KroniKare AI and expert, while a low P value (<0.05) would reject the claim.

For complication check, for each data point (wound) we have categorical data (complication labels) from both evaluators (KroniKare AI and expert). Here again application of McNamara's test, resulting in **a high P value (≥0.05) can confirm similarity** between KroniKare AI and expert, while a low P value (<0.05) would reject the claim.

In summary:

- For **size measurements**: we apply **Two-Tail T-Tests**, hoping for **P≥0.05** that indicates similarity between physical measurements and AI-based measurements.
- For **tissue classification**: we apply **McNemar's Test**, hoping for **P≥0.05** that indicates similarity between tissue types detected by AI and tissue types detected by expert.
- For **complication checks**: we apply **McNemar's Test**, hoping for **P≥0.05** that indicates similarity between complications detected by AI and complications detected by expert.

3.4. Trial Approach

At Changi General Hospital (CGH), 28 wards, Medical Intensive Care Unit (MICU), and outpatient clinics, and homecare use a total of 10 KroniKare Wound Scanner in this trial. At St. Andrew's Community Hospital (SACH), 10 wards, outpatient clinic, and homecare use a total of 11 KroniKare Wound Scanner in this trial. At Kwong Wai Shiu Hospital (KWSH), 8 wards and homecare use a total of 5 KroniKare Wound Scanner in this trial. At St Luke's Hospital (SLH), the homecare team uses a total of 5 KroniKare Wound Scanner in this trial.

Trained clinicians used the KroniKare App to capture information for each wound case. Each patient was randomly associated with an automatically generated QR code to de-identify patient from clinical information. The clinical information included both clinician's manual assessment, and captured information and images that is used by KroniKare AI engines:

- Patient information:
    - Age, gender, race, comorbidities
    - Limited information for clinicians to better identify the patient: last four characters of IC, and bed number.
- Wound information:
    - Site, type, stage
    - Exudate condition
    - Manual wound assessment based on clinician's opinion: size, tissue composition, wound complications, limb/back complications, peri-wound condition, and other notes such as smell.
    - Wound image(s)
- Treatment information:
    - Image or notes on the treatment used for each wound
- Body images:
    - Images from limb or back to detect possible complications

3.5. Training

KroniKare team trained clinicians in 2 to 5 sessions in separate days (depending on the size of the clinical teams) in each hospital, providing application training and handholding to 36 key opinion leaders in wound care at Changi General Hospital (CGH), St. Andrew's Community Hospital (SACH), Kwong Wai Shiu Hospital (KWSH), and St. Luke's Hospital (SLH) (see Table 5). Clinical teams involved were from departments of Advanced Practice Nurse Development, Specialty Nursing, Nursing Management, Community Nursing, Nursing Home, and Homecare. Figures 13 illustrates some of the images from the training sessions. During the trial, KroniKare team provided technical and training support, training manuals (in hardcopy and softcopy), handholding, and technical support for the users.

Table 5: Key Opinion Leaders at CGH, SACH, KWSH, and SLH involved in the trial

SITE	CLINICIANS
CHANGI GENERAL HOSPITAL	21 clinicians led by Sister Png Gek Kheng
ST. ANDREW'S COMMUNITY HOSPITAL	10 clinicians led by Sister Siew Yeng Tang
KWONG WAI SHIU HOSPITAL	5 clinicians led by Sister Serene Tan
ST. LUKE'S HOSPITAL	5 clinicians led by Sister Yvonne Lau

3.6. Achievements

Over the course of the trial, the following achievements have been made:

Data Collection: Using the KroniKare phone app, a diverse set of data was collected including wound information (visible and thermal images at each visit) and treatment information (notes or images regarding wound care products used for each wound): 644 patients assessed, 1,204 distinct wound cases assessed, and 4,904 automatic wound reports generated.

KroniKare AI Evaluation: The collected data enabled fair comparison of KroniKare AI and manual assessment and supported the similarity of KroniKare AI output to wound care experts.

Timesaving Estimation: Through logging usage of the application and web-based dashboard, we could reach an estimation of timesaving that KroniKare Wound Scanner could present. This estimation indicates when the clinical staff are trained and comfortable with the application, this service can save about 24 hours per month per ward, from the workload of the clinical staff.

3.7. Data

In this section we describe the data collection protocol and statistical methods applied to measure performance of KroniKare Wound Scanner for different aspects of wound assessment.

3.7.1. Data collection protocol

The clinician-provided data is captured through a mobile application, collecting wound size measured manually, list of wound tissues based on the opinion of the nurse, and if the nurse suspects ischemia.

Based on the images captured by the application, the AI generates the estimated wound size, list of automatically detected tissue classes, and indication of if the AI model has "suspected" high risk of ischemia complication.

The clinician captures images (visible and thermal) from the wound, and then continues with the traditional assessment methods:

- Size measurement with paper ruler and probe,
- Tissue classification based on visual inspection, and
- Check for ischemia based on visual inspection and feeling the temperature of tissues around the wound with hand)

The AI model uses the images captured to estimate the same quantities:

- Size measurement by applying point matching and triangulation on two visible images, captured at the same time from slightly different angles,
- Tissue classification by applying deep learning segmentation and classification model on one or more visible images of the wound bed,
- Ischemia complication check by applying deep learning segmentation and classification model on one or more visible-thermal image pairs of the wound.

Figure 13. Pictures from KroniKare Wound Scanner training sessions at different care settings.

Changi General Hospital

St. Andrew's Community Hospital

Kwong Wai Shiu Hospital

The study is double blind but not randomized, i.e. the same patients are assessed by both the nurse and the AI model, but the nurse does not see the AI output at the time of assessment, and the AI does not receive nurse-provided data as a part of its inputs.

The final report of the same patients with all the images captured (both visible and thermal) are then presented to the wound care specialist for expert opinion. The expert is also blind to the nurse and AI results, at the time of providing an opinion.

3.7.2. Data Statistics

The data used for the statistical analysis are entered by nurses and uploaded directly from the devices. The data captured wound information from patient at different hospital sections, including wards, Medical Intensive Care Unit (MICU), Outpatients Clinic and Homecare.

The entire dataset is comprised of 644 patients (316 male, 328 females, with average age of 77.4), 1,204 wounds, of which 4,904 reports are generated (from more than 15,000 images). Samples used in the following statistical tests are the ones without null or all zero values.

The data points contain a wide variety of chronic wounds including:

- Ulcers (e.g. venous ulcer, arterial ulcer, pressure ulcer, diabetic foot ulcer and callous wound, ...)
- Surgical wounds
- Traumatic Laceration Wound
- Eczema
- Gout Wound
- Skin Tear
- Gangrenous Wound
- Graft Wound
- Incisional Wound
- Drainage Site Wound
- Abrasion Wound
- Amputated Wound
- Incontinence-associated Dermatitis (IAD)
- Lateral Malleolus Wound
- Fistula Wound
- Laceration Wound
- Over-granulated Wound (e.g. due to tracheostomy)
- Trauma Wound
- Excoriation Wound
- Eschar Wound

3.8. Statistical Analysis Results

In this section we present statistical analysis and the respective results on size measurement, tissue classification, and complication assessment, comparing KroniKare AI and expert measurement and opinions.

Using data collected from all 4 sites, size measurements by KroniKare AI were compared to expert measurements for the data points collected from all sites, using two-tailed t-testes on length, width and depth. Wound tissue type classification and wound complication detection output from KroniKare AI were also compared to respective expert opinions using McNemar's test.

It should be noted that we can only compare the two evaluators (KroniKare AI and expert), when both evaluators' data is present. There are cases where the expert has not entered any values to the respective fields, or due to not capturing respective images, the KroniKare AI has not generated any output. In total, there are 207 samples that contained length and width from both evaluators, 149 samples that contained depth from both evaluators, and 329 samples that contained tissue classes from both evaluators, and 271 samples that contained complications from both evaluators.

The statistical tests applied (see Statistical Analysis Appendix) were to **confirm similarity of KroniKare AI outputs to expert opinion** for wound size measurement (length, width and depth), tissue classification and complication assessment. This indicates potential of KroniKare system to upskill nurses to a higher level of decision making and perform timely interventions in case of detection of a complication at early stages.

With accuracy of the KroniKare Wound Scanner established, we would like to compare the time required for manual wound assessment and monitoring, to using automated wound assessment and report generation by this service. This aspect is evaluated in the next section.

The goals of these trial were to collect data, evaluate KroniKare Wound Scanner performance (in wound size measurement, tissue analysis, and wound complication detection), and estimate the timesaving provided by this service. With data from 644 patients, with 1,204 wounds, and 4,904 automatic wound reports, our statistical analysis supports the similarity of KroniKare Wound Scanner performance to expert's opinion in all three aspects of wound assessment:

- KroniKare Wound Scanner **wound measurement** is on-par with physical (manual) wound measurement
- KroniKare Wound Scanner **tissue classification** is comparable to wound care specialist opinions
- KroniKare Wound Scanner **complication detection** for detection of infection, undermining, and ischemia is comparable to wound care specialist opinion.

For the detailed analysis please refer to Annex B.

4. Timesaving

4. Usage and Time Saving

We performed usage analysis in each of the sites, and two time and motion studies for acute care setting and step-down care setting.

KroniKare Wound Scanner devices have been used extensively by the KOL at clinical sites as our usage statistics illustrates. The 31 sets of KroniKare Wound Scanner have been used extensively by the KOLs at clinical sites. The system usage shows that wound care is a round-the-clock work almost at all different settings. Although the workload is distributed throughout the day, this workload is not evenly distributed, mostly aggregated between 8am to 12am (4 hours in the morning).

Our timesaving analysis shows substantial timesaving (and therefore cost saving) via KroniKare Wound Scanner, measured to be more than 52% in the acute care setting and 80% in the step-down care setting. This saving does not factor in different time-value between ward nurse and wound care specialist, nor does it include the additional value to the device due to its accuracy in automatic documentation of the wound, and detection of complications that may lead to better treatment, faster recovery and prevention of complications.

Figures 14 to 17 illustrate the average distribution of wound care workload in a typical day at Changi General Hospital (CGH), St. Andrew's Community Hospital (SACH), Kwong Wai Shiu Hospital (KWSH), and St. Luke's Hospital (SLH).

Figure 14. Average distribution of wound care workload over 24 hours at CGH (round-the-clock work, peak workload 10am). 73.94% of workload is performed from 8am to 12pm.

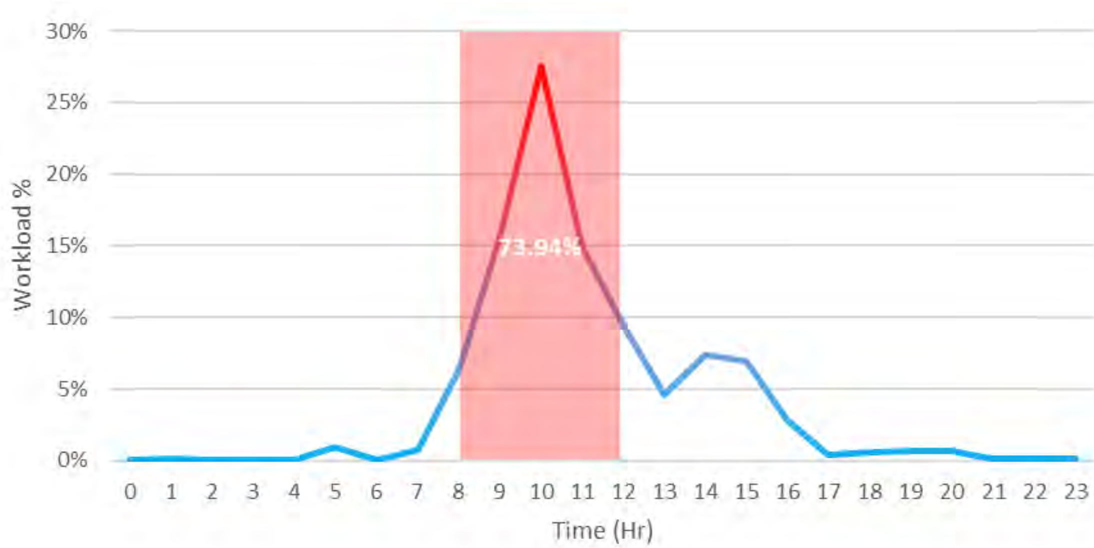


Figure 15. Average distribution of wound care workload over 24 hours at SACH (Start of work 5am, end of work 11pm, peak workload 10am). 72.79% of workload is performed from 8am to 12pm.

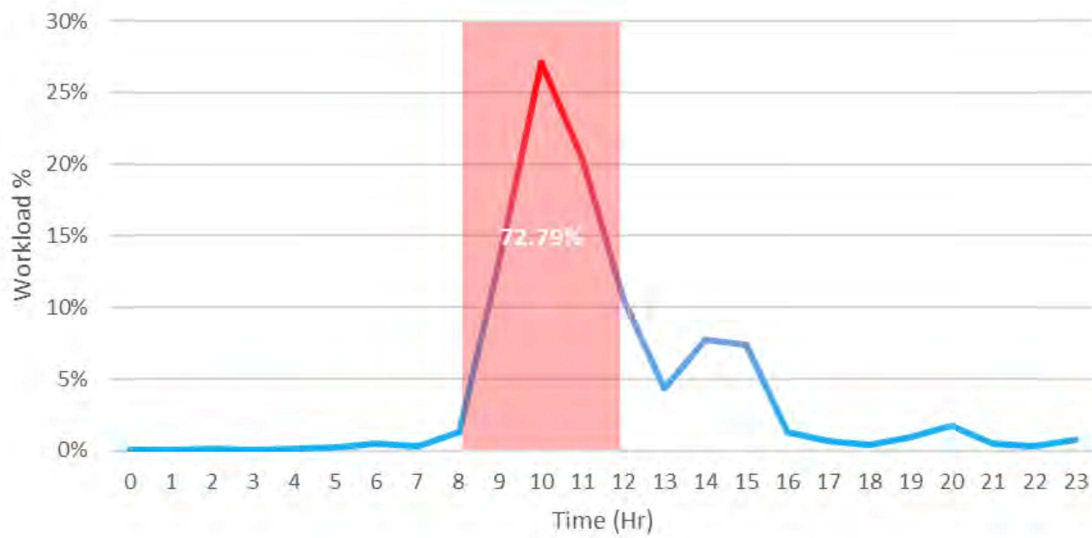


Figure 16. Average distribution of wound care workload over 24 hours at KWSH (Start of work 6am, end of work 10pm, peak workload 9am). 82.68% of workload is performed from 8am to 12pm.

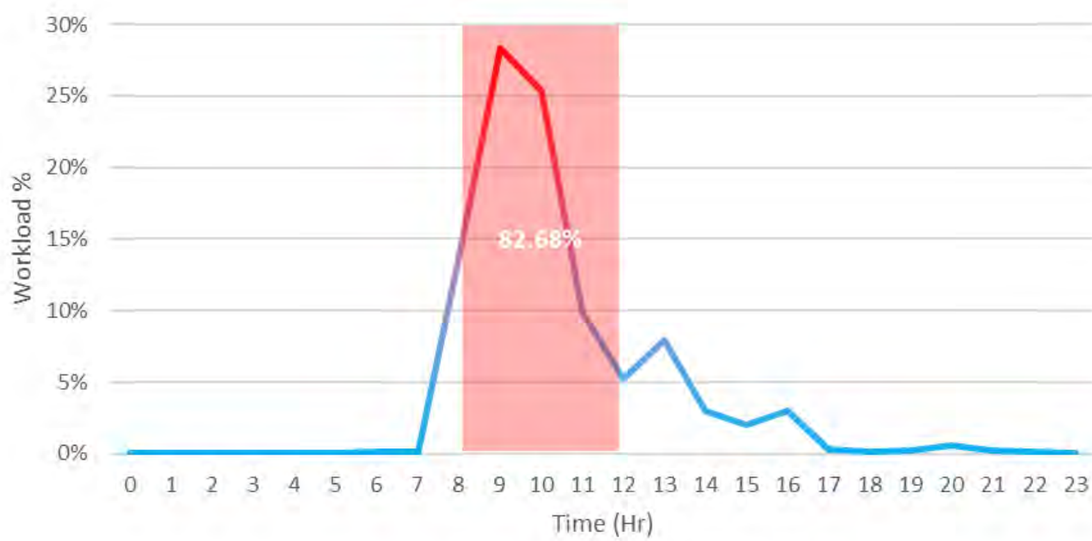


Figure 17. Average distribution of wound care workload over 24 hours at SLH (Work starts at 5am and end at 10pm, peaking at 10am). 78.66% of work is performed from 8am to 12pm.

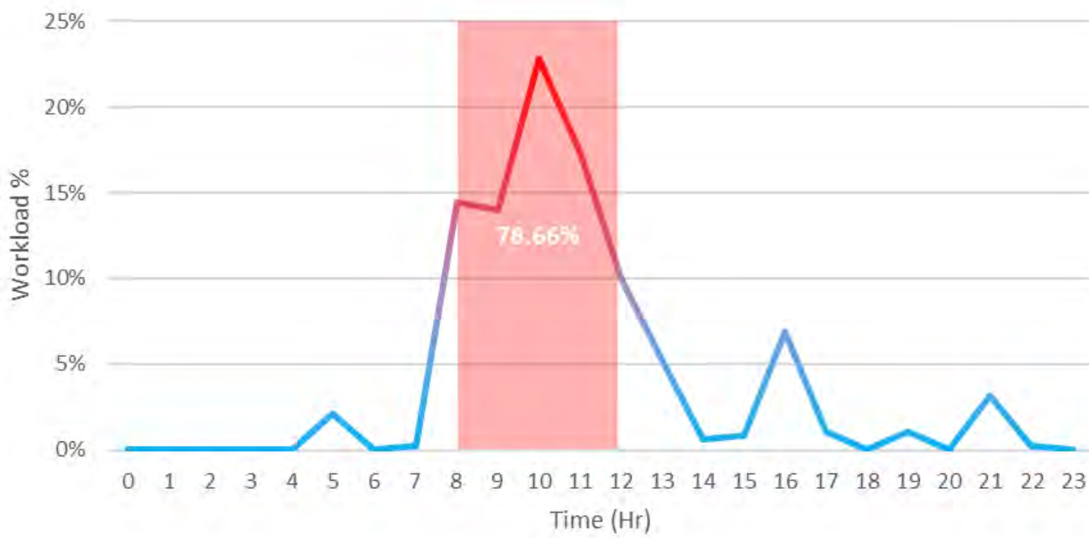


Table 23 illustrates the identified 12 distinct processes involved in chronic wound care in this acute setting, two of which highlighted and measured for comparison between manual and automatic processes. We used average measured time required for each section of manual wound assessment from **30 manually measured data points** to compare to average measured time for corresponding sections of KroniKare Wound Scanner system logs from **30 automatically measured data points**, to reach the estimation of timesaving by KroniKare Wound Scanner at each step for each patient and each ward, and per month, and per year.

Using average time saving we measure the cost saving using KroniKare Wound Scanner, only based on the timesaving aspect. It should be noted that timesaving for higher-level clinicians, administration, patient transportation (for outpatient clinics), and clinician transportation (for homecare) is not included in this calculation, and accounting for these additional timesaving aspects could substantially increase the timesaving and cost saving estimations.

Table 24 illustrates T-Test results, mean, and standard deviation differences between manual and automatic (KWS) in wound measurement and photography, indicating manual process is 0.74 min faster than KWS. This is due to the fact that at CGH, nurses used the device full functionality and captured additional images from the exudate, treatment product, and limb images (in addition to wound images). These additional images allow documentation of the full status of the wound, which is not available in manual process. Therefore the 0.74min additional time adds valuable data for well-informed decisions when viewing the automatically generated reports.

Table 23. Time spent on manual processes of wound care (30.5 min in total). Highlighted processes (wound measurement and photography and wound information documentation) were timed and measured for comparison between manual and automatic timings.

Standard Wound Care Steps	Average Time Spent (Mins)	% Spent
Checking of case file to preparation of requisites	7.1	23.4
Approaching patient till completion of bed side prep	2.1	7.1
Removing dressing and exposing wound	2.4	7.8
Measurement of wound and wound photography	2.0	6.5
Measurement of wound undermining	0.4	1.2
Measurement of wound tunneling	0.3	0.9
Covering wound	1.5	4.9
Shift patient back to original position	1.6	5.3
Documentation of wound information	9.0	29.8
Electronic documentation of nurse notes	2.1	6.8
Electronic documentation of charging	0.7	2.2
Speaking to ward nurses on treatment	1.3	4.2

Table 24. Average time difference between manual and automatic for wound measurement and photography (t = -2.6013, p = 0.1114).

	OBSERVATION	MEAN(MIN)	STANDARD DEVIATION	[95% CONFIDENCE INTERVAL]	
MANUAL	30	1.95	1.72	1.31	2.59
AUTOMATIC	30	2.69	1.79	2.02	3.35

Table 25. Average time difference between manual and automatic for wound information documentation (t = 7.0976, p=0.0001).

	OBSERVATION	MEAN(MIN)	STANDARD DEVIATION	95% CONFIDENCE INTERVAL	
MANUAL	30	9.01	4.83	7.21	10.81
AUTOMATIC	30	2.54	1.27	2.07	3.02

Table 25 presents the T-Test results, mean, and standard deviation differences between manual and automatic (KWS) processes in wound information documentation. This comparison shows a clear advantage of using KWS, saving on average 6.47min per wound documentation.

Following the time and motion study at the acute setting, we conducted a similar time and motion study at step-down care at Kwong Wai Shiu Hospital. Once again, we started by identifying all the processes involved in wound care, and then comparing the affected processes by KroniKare Wound Scanner. As presented in Table 26, the complete wound care consists of 9 categories of tasks, namely, (1) preparation before the procedure, (2) preparation prior to the start of the procedure, (3) implementation of phase I, (4) implementation of phase II, (5) implementation of phase III, (6) implementation of phase IV, (7) end of implementation, (8) housekeeping, and (9) documentation and reporting.

Table 26 (Annex C) also presents the average time in manual practice for each task, indicating the process time (P/T: normal time for a task to be performed), additional delay time (D/T: additional time needed in cases of issues with a task), and the likelihood of a task being completed in the process time (i.e. not delayed by any issues). Table 27 (Annex C) represents possible issues related to each task that can prolong that task. Some tasks such as transferring the medication or trolley, however, could not be affected by the KroniKare Wound Scanner. The affected tasks which are used in the time and motion study comparison, are highlighted in Table 28 (Annex C).

We used average measured time required for each section of manual wound assessment from **45 manually measured data points** to compare to average measured time for corresponding sections of KroniKare Wound Scanner system logs from **45 automatically measured data points**, to reach the estimation of timesaving by KroniKare Wound Scanner at each step for each patient and each ward, per month and per year.

Using average time saving and the average nurse salary from Singapore Ministry of Manpower, we measure the cost saving using KroniKare Wound Scanner, only based on the timesaving aspect. It should be noted that timesaving for higher-level clinicians, administration, patient transportation (for outpatient clinics), and clinician transportation (for homecare) is not included in this calculation, and accounting for these additional timesaving aspects could substantially increase the timesaving and cost saving estimations.

Measured timesaving for acute care setting and step-down care setting are presented in Table 29 and Table 30 respectively, showing **52% saving** (9.6hrs per ward per month) at acute care setting and **80% saving** (21.8hrs per ward per month) at step-down care setting. It is important to note that 52% saving at acute hospital is despite the different number of images captures between manual and automatic methods. While **in the manual method, only 1 imag**e was captured per wound, in the automatic method **using KroniKare Wound Scanner, at least 3 images** were captured per wound, including wound visible image, wound 3D image, wound thermal image, wound exudate image, limb thermal image, and wound treatment image.

This timesaving translates into ability of the current workforce of the healthcare institution to provide service to a larger number of patients (in Singapore each patient with chronic wound has S$10,000 direct cost and $3,600 indirect cost [2] for public hospitals). It should be noted that this saving does not include the additional value to the device due to its accuracy in automatic documentation of the wound, and detection of complications, that may lead to better treatment, faster recovery and prevention of complications.

4.1. Wound Type Differences in Different Settings

Based on the data gathered from each of the settings, we could compare differences between different care settings in the wound parameters. These comparisons can confirm the assumptions on the chronic wound care services provided by each care setting. Differences on the wound treated at these setting indicate that the acute setting manages larger and more complex wounds, while the community hospital setting has the highest number of patients with chronic wounds, but these wounds seem less complicated. Finally, nursing home and homecare settings seem to deal with patients that are more at-risk of limb ischemia.

These differences between different care settings have led to differences in the customized software (on-device and dashboard) for each of these settings, provided by KroniKare Wound Scanner systems. These differences can be used for better planning for each of these care settings for efficient resource allocation, legislation and incentives.

All above indicate potential of KroniKare system to not only provide accurate assessment of the wounds, but also save time and manpower, and collect valuable real-time data from different care settings to help management at every level. KroniKare can upskill junior nurses to a higher level of decision making and allow performing timely interventions by wound nurses and wound care specialists in case of detection of a complication at early stages, and lead to substantially higher downstream savings of time, cost and livelihoods.

Table 29. 52% Timesaving with KroniKare Wound Scanner in acute care setting (CGH).

Cat No.		Category	Task No.	Task	Manual Time	KroniKare Time	Saving
0	Bedside Tasks	Patient Registration	0	Scan Patient	117 (only 1 image capture per wound)	162 [1] (at least 3 images captured per wound)	-45 [1]
1		Preparation Before Procedure	1	Check wound site(s)			
2		Implementation of Phase I	2	Enter information for wound(s)			
5		Implementation of Phase III	3	Capture wound image(s)			
			4	Wound measurement(s)			
			5	Capture thermal image(s)			
8	Housekeeping, Documentation, & Reporting	Housekeeping	6	Find patient records	541	153	388
9		Documentation and Reporting	7	Update records, notes			
			8	Update measurement charts			
			9	Upload images			
			10	Update person in charge			
			11	Review reports			
		Total Time in Min Per Wound			**10:58min**	**5:15min**	**5:43min**
		Timesaving per Ward per Month					**9.6hrs**

CGH: Acute hospital, more complicated wounds, more dynamic environment with fewer wounds per patient (2.1), more patients with wound per ward (9.2), fewer visits per patient per month (5.2). (t = 4.0311, p=0.0001)

[1] Wound image capture: in manual timing, only 1 image was captured per wound, while in KroniKare timing, at least 3 images were captured per wound including wound visible image, wound 3D image, wound thermal image, wound exudate image, limb thermal image, and wound treatment image.

Table 30. 80% Timesaving with KroniKare Wound Scanner in step-down care setting (KWSH)

Cat No.		Category	Task No.	Task	Manual Time	KroniKare Time	Saving
0	Bedside Tasks	Patient Registration	0	Entering patient Information	0	83	
1		Preparation Before Procedure	1.1	Check Case Notes/Charts	174	0	174 sec
2		Implementation of Phase I	3.7	Prepare the device/camera	30	11	19 sec
5		Implementation of Phase III	5.2	Wound image capture	72	13	59 sec
			5.3	Save the image	5	0	5 sec
			5.4	Keep phone aside	1	1	
			5.5	Wound measurement	42	10	32 sec
8	Housekeeping, Documentation, & Reporting	Housekeeping	8.2	Upload the picture into the PC	132	0	132 sec
9		Documentation and Reporting	9.1	Find patient records	10	10	
			9.2	Record and documentation	252	35	217 sec
			9.3	Update NM, NC, and SNM	156	61	95 sec
			9.4	Attach the pictures to email	78	0	78 sec
			9.5	Update INGOT system	72	72	
			9.6	Pass report to the next shift	66	0	66 sec
		Total Time in Min Per Wound			**18:10min**	**3:33min**	**14:397min**
		Timesaving per Ward per Month					**21:48hrs**

KWSH: Nursing home with long-term residents with more wounds per patient (2.85), fewer patients with wound per ward (5.13), more visits per patient per month (6.12). t = -28.2067 p = 8.22E-30

5. Awards & Media Coverage

5. Awards and Media Coverage

KroniKare's works in healthcare has not been hidden from the eyes of stakeholders and media. Showing potential to disrupt the cost, time and to improve accuracy in chronic wound care, KroniKare has been awarded in different stages, including winning the 1st prize in Accenture HealthTech Challenge in APAC region in 2017 (Figure 18), and placed among the top 9 in the Global Accenture HealthTech Challenge in San Francisco from 700 medtech startups across the globe. In 2018, after only 1.5 years from its incorporation, KroniKare won the Bronze Award at SG:D Tech Blazer Awards in the Most Promising Category, among 331 entries (Figure 19). In 2019, KroniKare was selected in the finalists' group, among 700 companies in the World Artificial Intelligence Conference (Figure 20).

KroniKare team has also had the honor to present to VIPs including presentation of the system to Deputy Prime Minister Heng Swee Keat at Changi General Hospital in 2018 (Figure 21), presentation of KroniKare AI systems to Minister S. Iswaran at AI.Singapore 2019 (Figure 22), and presentation to Deputy Prime Minister Heng Swee Keat and Minister Dr. Vivian Balakrishnan at SWITCH Exhibition 2019, during the announcement of Singapore National AI Strategy where KroniKare has been featured for Healthcare (Figure 23). Minister Dr. Vivian Balakrishnan announced Singapore's National AI Strategy during Smart City Expo World Congress in Barcelona in Nov 2019, in which KroniKare Wound Scanner is featured indicating the support from IHiS, HSA, CGH, SACH and KWSH, where integration to Next Generation EMR (NGEMR) is handled by IHiS for nation-wide integration (Figure 24). See Annex D for details. KroniKare has also been featured in speeches by Minister S. Iswaran at the Innovfest Unbound on 5th June 2018, Minister Gan Kim Yong's speech for MOH Workplace Seminar 2018 on 27th April 2018, and Minister Dr. Amy Khor's speech at NIKKEI X NUS Enterprise Digitalization Forum 2018.

KroniKare's works have been covered extensively by various media channels, having been featured in the news in 2017, 2018, and 2019, including Channel News Asia, Channel 5, Channel 8, Channel U, The Strait Times, The Business Times, Infocomm Media Development Authority (IMDA), Asia Pacific Medtech Forum, Tech in Asia, The Edge, e27, Berita Harian, Lianhe Wanbao, Zaobao, SWITCH, Innovfest, Echelon and SGInnovate. Some of these articles are presented in Figure 25.

Figure 18. KroniKare team winning the 1st prize in Accenture Health Tech Challenge APAC region in 2017.

Figure 19. KroniKare team winning the Bronze Award in SG:D Tech Blazer Awards in 2018.

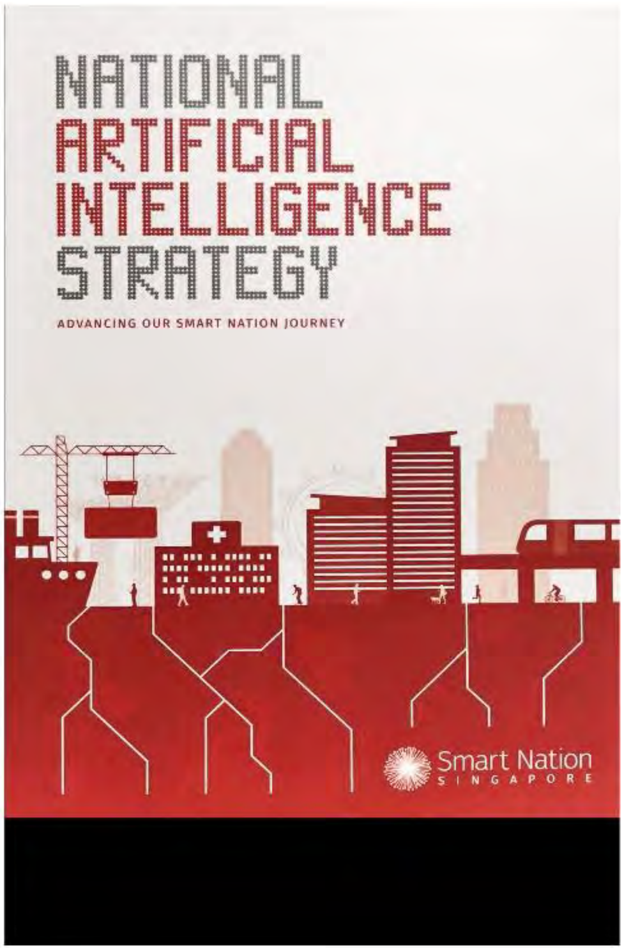
Figure 20. KroniKare team, finalist in World Artificial Intelligence Conference 2019 among 700 companies.

Figure 21. KroniKare team presenting to Deputy Prime Minister Heng Swee Keat at Changi General Hospital in 2018.

Figure 22. KroniKare team presenting to Minister S. Iswaran at AI.Singapore in 2019.

Figure 23. Presentation to Deputy Prime Minister Heng Swee Keat and Minister Vivian Balakrishna during SWITCH Exhibition in 2019.

Figure 24. Singapore National AI Strategy booklet, announced in Nov 2019 by Minister Dr. Vivian Balakrishnan in Smart City Expo World Congress in Barcelona, where KroniKare is featured for its application of AI in healthcare, mentioning the support from IHiS, HSA, CGH, SACH, and KWSH, and integration to Next Generation EMR (NGEMR) by IHiS.



From 100 Experiments to Scaling Startups

Automatic Assessment of Chronic Wounds in Diabetic and Elderly Patients

Chronic wounds are a common clinical problem in hospitals. AI Singapore worked with a local start-up, KroniKare, to develop a Computer Vision system on an AI-driven mobile and web platform to capture, analyse and diagnose chronic wound conditions. This enables healthcare institutions to better triage patients and allocate resources for wound management, resulting in improved patient outcomes in terms of early detection and faster intervention for major wound complications.

Following the successful Proof of Concept study with AI Singapore, Integrated Health Information Systems (IHiS) facilitated the scaling, validation, regulatory approval, and planned deployment of Kronikare's solution. The Health Sciences Authority (HSA) provided scientific and regulatory advice and the device underwent HSA's priority review scheme to obtain regulatory approval.

Kronikare has now deployed its scanner in St Andrew's Community Hospital and a nursing home at Kwong Wai Shiu Hospital. It has also completed operational trials at Changi General Hospital with promising results. IHiS continues to work with companies like Kronikare to support the integration of the results into the clinical Electronic Medical Record systems.

A nurse can use KroniKare Wound Scanner to capture an image of the wound for full assessment and documentation under 30 seconds at a patient's bedside.

Uploaded data vectors are automatically compiled into medical reports for monitoring wound progress and prioritising serious cases using a tablet.

Figure 25. Example of articles in the media outlets on KroniKare Wound Scanner in The Strait Times, The Business Times, and Zaobao.

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Appendix

User access roles and processes in KroniKare Wound Scanner System.

Table 1. User Access Roles for KroniKare Wound Scanner System

Role	Capture Data	Upload Data	Change Phone Password	Add/Remove Nurse Phone User	View Patient Report in Associated Ward	View Patient Report of All Wards	View Statistical Reports	Add Dashboard User	Change Dashboard Password	Add Ward	Patient Transfer
Institute Administrator						×	×				×
System Administrator			×	×	×	×	×	×	×	×	×
Medical Supervisor	×	×	×		×	×	×				×
Wound Care Specialist	×	×	×		×	×	×				×
Nursing Manager	×	×			×						×
Supervising Nurse	×	×			×	×					
Nurse	×	×									
KroniKare System Administrator			×	×	×	×	×	×	×	×	×

Table 1 (Cont.). User Access Roles for KroniKare Wound Scanner System.

Role	Nurse Transfer	Report Verification	Edit Report	Add Photo to Report	Remove Photo from Report	View Phone Log	View System Log	System Backup	Phone Lock	Remote Phone Data Wipe
Institute Administrator	×	×								
System Administrator	×									
Medical Supervisor	×	×	×	×	×					
Wound Care Specialist	×	×	×	×	×					
Nursing Manager	×									
Supervising Nurse										
Nurse										
KroniKare System Administrator	×		×	×	×	×	×	×	×	×

Statistical analysis by Duke-NUS on KroniKare Wound Scanner performance compared to expert wound nurses for 3D size measurement, wound tissue classification, and wound complication detection.

For descriptive purposes, mean, standard deviation, median, minimum, and maximum values are presented for continuous variables, and number and percentages are presented for categorical variables.

Table 3. Sample size required for Two-Sided Relative Error Confidence Intervals

Target Confidence Level	**Actual Confidence Level**	**Sample Size (no. of wound reports)**	Relative Error
0.900	0.900	150	0.095

Confidence Level is the proportion of standard deviation estimates that will be within the relative error of the true standard deviation.
Target Confidence Level is the value of the confidence level that is entered into the procedure.
Actual Confidence Level is the value of the confidence level that is obtained from the procedure.
Sample Size (N) is the size of the sample drawn from the population.
Relative Error is the distance from the true standard deviation as a proportion of the true standard deviation.

Marginal Homogeneity Calculation

The marginal homogeneity is stablished using the McNemar's test. McNemar's test is to assess if proportions of the outcome differ by variable 1 (e.g. tissues detected by clinicians) and variable 2 (e.g. tissues detected by KroniKare Wound Scanner). The McNemar's test is an appropriate statistical analysis when the purpose of research is to assess if proportions of the outcome differ for paired samples. For this research question, the dichotomous variables are variable 1 and variable 2. McNemar's test is often used because of its ability to detect subtle differences in a single sample at two times. It is applied to a 2 x 2 contingency table. The assumptions of McNemar's test for significance will be analyzed prior to analysis [11, 12].

The test is applied to a 2 × 2 contingency table, which tabulates the outcomes of two tests on a sample of n subjects, described in Table 4.

The null hypothesis of marginal homogeneity states that the two marginal probabilities for each outcome are the same, i.e. pa + pb = pa + pc and pc + pd = pb + pd.

Table 4. Construction of McNemar's test for detection of one tissue type

	Detected by KroniKare	**Undetected by KroniKare**	**Row total**
Detected by Clinicians	*a*	*b*	*a* + *b*
Undetected by Clinicians	*c*	*d*	*c* + *d*
Column total	*a* + *c*	*b* + *d*	*n*

Thus, the null and alternative hypotheses are [6]:

$$H_0 : p_b = p_c$$
$$H_1 : p_b \neq p_c$$

Here pa, etc., denote the theoretical probability of occurrences in cells with the corresponding label. The McNemar test statistic is:

$$\chi^2 = \frac{(b-c)^2}{b+c}$$

Under the null hypothesis, with a sufficiently large number of discordant (cells b and c), χ^2 has a chi-squared distribution with 1 degree of freedom. If the χ^2 result is significant, this provides sufficient evidence to reject the null hypothesis, in favor of the alternative hypothesis that pb ≠ pc, which would mean that the marginal proportions are significantly different from each other.

The primary end point and other continuous variables were tested using the Wilcoxon signed rank test. The relation between two continuous variables were expressed by the Pearson correlation coefficient. For graphical purposes, the parameters measured by the clinicians, KroniKare Wound Scanner, and wound care specialist we demonstrated using Bland-Altman plots, against the averages of each two groups. Random effects and residual covariance structure were determined using Akaike information criterion. All tests were two tailed and conducted at the 0.05 significance level.

Performing statistical analysis, we intended to test the similarity of KroniKare AI outputs to expert opinion. With the aim for on parity with the expert opinion, we seek establishing similarity between values provided by KroniKare AI, and respected values assessed by the expert. We compare three main aspects, namely, wound size estimation, wound tissue classification, and complication detection. The gold standard for size estimation is physical measurement by ruler, performed by clinicians. Gold standards for tissue classification and complication detection are expert opinions.

Table 6: Two Tail T-Test Results for Wound Length at CGH

	Manual Length	*Automatic Length*
Mean	5.770048309	5.729777889
Variance	14.95142864	13.7025425
Observations	207	207
Pearson Correlation	0.936698139	
df	206	
t Stat	0.427207148	
P(T<=t) two-tail	0.669674641	
t Critical two-tail	1.971546669	

Table 7: Two Tail T-Test Results for Wound Width at CGH

	Manual Width	*Automatic Width*
Mean	3.601449275	3.606637391
Variance	5.332570705	4.97469708
Observations	207	207
Pearson Correlation	0.931021125	
df	206	
t Stat	-0.088166789	
P(T<=t) two-tail	0.929829763	
t Critical two-tail	1.971546669	

Table 8: Two Tail T-Test Results for Wound Depth at CGH

	Manual Depth	*Automatic Depth*
Mean	0.675167785	0.711156936
Variance	1.173500816	0.954494306
Observations	149	149
Pearson Correlation	0.964237022	
df	148	
t Stat	-1.489386654	
P(T<=t) two-tail	0.138513491	
t Critical two-tail	1.976122494	

Table 9: Two Tail T-Test Results for Wound Length at SACH

	Manual Length	*Automatic Length*
Mean	4.790712905	4.791125237
Variance	15.41675633	14.84506678
Observations	310	310
Pearson Correlation	0.966348272	
df	309	
t Stat	-0.007175741	
P(T<=t) two-tail	0.994279267	
t Critical two-tail	1.967670885	

Table 10: Two Tail T-Test Results for Wound Width at SACH

	Manual Width	*Automatic Width*
Mean	2.61616129	2.667627475
Variance	4.155524698	4.289890111
Observations	310	310
Pearson Correlation	0.949686401	
df	309	
t Stat	-1.388453975	
P(T<=t) two-tail	0.165998929	
t Critical two-tail	1.967670885	

Table 11: Two Tail T-Test Results for Wound Depth at SACH

	Manual Depth	*Automatic Depth*
Mean	0.573394493	0.434459307
Variance	3.253482416	0.798550706
Observations	218	218
Pearson Correlation	0.598038402	
df	217	
t Stat	1.407504034	
P(T<=t) two-tail	0.160708786	
t Critical two-tail	1.970956301	

Table 12: Two Tail T-Test Results for Wound Length at KWSH

	Manual Length	*Automatic Length*
Mean	3.889796	4.016296602
Variance	9.018864	10.34184947
Observations	98	98
Pearson Correlation	0.972491	
df	97	
t Stat	-1.64918	
P(T<=t) two-tail	0.102345	
t Critical two-tail	1.984723	

Table 13: Two Tail T-Test Results for Wound Width at KWSH

	Manual Width	*Automatic Width*
Mean	2.654082	2.580847194
Variance	4.149932	3.606441319
Observations	98	98
Pearson Correlation	0.976969	
df	97	
t Stat	1.632311	
P(T<=t) two-tail	0.105856	
t Critical two-tail	1.984723	

Table 14: Two Tail T-Test Results for Wound Depth at KWSH

	Manual Depth	*Automatic Depth*
Mean	0.36949	0.469705279
Variance	0.444586	0.149695795
Observations	98	98
Pearson Correlation	0.489691	
df	97	
t Stat	-1.69736	
P(T<=t) two-tail	0.092835	
t Critical two-tail	1.984723	

Table 15. CGH Tissue Classification McNemar Test results on KroniKare AI vs. expert.

MCNEMAR TEST	NECROTIC	SLOUGH	GRANULATING	EPITHELIZING
NONPRESENT TO PRESENT	21	13	18	10
PRESENT TO NONPRESENT	13	5	14	4
CHI-SQAURE	1.441176471	2.722222222	0.28125	1.785714286
ALPHA	0.05	0.05	0.05	0.05
CRITICAL VALUE	3.841459	3.841459	3.841459	3.84146
P VALUE	0.229949057	0.098960154	0.595883091	0.181449208
SENSITIVITY	0.909722222	0.976525822	0.93	0.973856209
SPECIFICITY	0.886486486	0.887931034	0.860465116	0.943181818
PRECISION	0.861842105	0.941176471	0.911764706	0.937106918
ACCURACY	0.896656535	0.945288754	0.902735562	0.957446809
F1	0.885135135	0.958525346	0.920792079	0.955128205

Table 16. SACH Tissue Classification McNemar Test results on KroniKare AI vs. expert.

MCNEMAR TEST	NECROTIC	SLOUGH	GRANULATING	EPITHELIZING
NONPRESENT TO PRESENT	14	21	22	26
PRESENT TO NONPRESENT	8	13	19	20
CHI-SQAURE	1.136363636	1.441176471	0.097560976	0.543478261
ALPHA	0.05	0.05	0.05	0.05
CRITICAL VALUE	3.841459	3.841459	3.841459	3.84146
P VALUE	0.286422023	0.229949057	0.754776427	0.460994786
SENSITIVITY	0.978947368	0.976491863	0.968490879	0.963099631
SPECIFICITY	0.977011494	0.951834862	0.943005181	0.941834452
PRECISION	0.96373057	0.962566845	0.96369637	0.952554745
ACCURACY	0.977755308	0.96562184	0.958543984	0.953488372
F1 SCORE	0.971279373	0.969479354	0.966087676	0.957798165

Table 17. KWSH Tissue Classification McNemar Test results on KroniKare AI vs. expert.

MCNEMAR TEST	NECROTIC	SLOUGH	GRANULATING	EPITHELIZING
NONPRESENT TO PRESENT	8	14	9	21
PRESENT TO NONPRESENT	4	12	8	20
CHI-SQAURE	0.75	0.038461538	0	0
ALPHA	0.05	0.05	0.05	0.05
CRITICAL VALUE	3.841459	3.841459	3.841459	3.84146
P VALUE	0.386476231	0.844519267	1	1
SENSITIVITY	0.943661972	0.939393939	0.971326165	0.914893617
SPECIFICITY	0.968	0.886178862	0.785714286	0.755813953
PRECISION	0.893333333	0.93	0.967857143	0.911016949
ACCURACY	0.962616822	0.919003115	0.947040498	0.872274143
F1 SCORE	0.917808219	0.934673367	0.969588551	0.912951168

Table 18. SLH Tissue Classification: McNemar Test results on KroniKare AI vs. expert.

MCNEMAR TEST	NECROTIC	SLOUGH	GRANULATING	EPITHELIZING
NONPRESENT TO PRESENT	9	4	12	86
PRESENT TO NONPRESENT	3	9	6	0
CHI-SQAURE	2.083333333	1.230769231	1.388888889	0
ALPHA	0.05	0.05	0.05	0.05
CRITICAL VALUE	3.841459	3.841459	3.841459	3.84146
P VALUE	0.148914673	0.267257493	0.238592829	4.91873E-20
SENSITIVITY	0.85	0.909090909	0.9375	1
SPECIFICITY	0.91	0.80952381	0.785714286	0.156862745
PRECISION	0.653846154	0.957446809	0.882352941	0.173076923
ACCURACY	0.9	0.891666667	0.85	0.283333333
F1 SCORE	0.739130435	0.932642487	0.909090909	0.295081967

Table 19. CGH Complication Assessment: McNemar Test results on KroniKare AI vs. expert.

MCNEMAR TEST	NON-COMPLICATED	WOUND INFECTION	ISCHEMIA	UNDERMINING	INFLAMMATION
NONPRESENT TO PRESENT	7	14	11	9	95
PRESENT TO NONPRESENT	43	6	4	5	6
CHI-SQAURE	24.5	2.45	2.4	0.642857143	76.67326733
ALPHA	0.05	0.05	0.05	0.05	0.05
CRITICAL VALUE	3.841458821	3.841458821	3.841458821	3.841458821	3.841458821
P VALUE	7.43098E-07	0.117524868	0.12133525	0.422678074	2.01715E-18
SENSITIVITY	0.713333333	0.930232558	0.952941176	0.913793103	0.76
SPECIFICITY	0.960893855	0.942386831	0.954918033	0.966789668	0.6875
PRECISION	0.938596491	0.85106383	0.880434783	0.85483871	0.166666667
ACCURACY	0.848024316	0.939209726	0.954407295	0.957446809	0.693009119
F1	0.810606061	0.888888889	0.915254237	0.883333333	0.273381295

Table 20. SACH Complication Assessment: McNemar Test results on KroniKare AI vs. expert.

MCNEMAR TEST	NON-COMPLICATED	WOUND INFECTION	ISCHEMIA	UNDERMINING	INFLAMMATION
NONPRESENT TO PRESENT	19	23	27	10	172
PRESENT TO NONPRESENT	27	16	14	6	21
CHI-SQAURE	1.065217391	0.923076923	3.512195122	0.5625	116.5803109
ALPHA	0.05	0.05	0.05	0.05	0.05
CRITICAL VALUE	3.841458821	3.841458821	3.841458821	3.841458821	3.841458821
P VALUE	0.302028228	0.336668368	0.060918691	0.453254705	3.5472E-27
SENSITIVITY	0.945674044	0.946843854	0.947169811	0.954887218	0.873493976
SPECIFICITY	0.96090535	0.96627566	0.962395543	0.988235294	0.789473684
PRECISION	0.961145194	0.925324675	0.902877698	0.927007299	0.457413249
ACCURACY	0.953204476	0.960325534	0.958290946	0.983723296	0.803662258
F1 SCORE	0.953346856	0.935960591	0.924493554	0.940740741	0.600414079

Table 21. KWSH Complication Assessment: McNemar Test results on KroniKare AI vs. expert.

MCNEMAR TEST	NON-COMPLICATED	WOUND INFECTION	ISCHEMIA	UNDERMINING	INFLAMMATION
NONPRESENT TO PRESENT	45	19	12	11	10
PRESENT TO NONPRESENT	34	17	6	21	1
CHI-SQAURE	1.265822785	0.027777778	1.388888889	2.53125	5.818181818
ALPHA	0.05	0.05	0.05	0.05	0.05
CRITICAL VALUE	3.841458821	3.841458821	3.841458821	3.841458821	3.841458821
P VALUE	0.260551788	0.867632335	0.238592829	0.111611768	0.015861333
SENSITIVITY	0.980209546	0.392857143	0.769230769	0.993781798	0.857142857
SPECIFICITY	0.430379747	0.989259469	0.993224167	0.388888889	0.696969697
PRECISION	0.973973395	0.366666667	0.625	0.982192543	0.375
ACCURACY	0.956037841	0.979966611	0.989983306	0.304347826	0.725
F1 SCORE	0.97708152	0.379310345	0.689655172	0.993781798	0.52173913

Table 22. SLH Complication Assessment: McNemar Test results on KroniKare AI vs. expert.

MCNEMAR TEST	NON-COMPLICATED	WOUND INFECTION	ISCHEMIA	UNDERMINING	INFLAMMATION
NONPRESENT TO PRESENT	9	21	10	10	10
PRESENT TO NONPRESENT	33	2	5	4	1
CHI-SQAURE	16.68085106	14.08695652	1.066666667	1.785714286	5.818181818
ALPHA	0.05	0.05	0.05	0.05	0.05
CRITICAL VALUE	3.841458821	3.841458821	3.841458821	3.841458821	3.841458821
P VALUE	4.42252E-05	0.00017455	0.301699582	0.181449208	0.015861333
SENSITIVITY	0.791208791	0	0.921875	0.966101695	0.857142857
SPECIFICITY	0.927419355	0.930921053	0.949238579	0.946808511	0.696969697
PRECISION	0.941176471	0	0.855072464	0.919354839	0.375
ACCURACY	0.846405229	0.924836601	0.942528736	0.954248366	0.725
F1 SCORE	0.859701493	0	0.887218045	0.94214876	0.52173913

Size Measurement: KroniKare AI vs. Expert T-Test Results

The values of size measurements from both evaluators (KroniKare AI and expert) are in numerical values for length, width and depth of each wound.

Two Tail T-Tests on manual vs. automatic size estimations are applied on length, width, and depth (Hypothesized Mean Difference = 0 for all tests). Tables 6 to 8 (Annex B), respectively, illustrate results of T-Tests on measured wound length, width, and depth on 207 CGH samples per measurement per evaluator for length and width, and 149 CGH samples per measurement per evaluator for depth. All these tests results show high P values, which indicate similarity of values provided by the two evaluators (KroniKare AI and expert).

Tables 9 to 11 (Annex B), respectively, illustrate results of T-Tests on measured wound length, width, and depth on 310 SACH samples per measurement per evaluator for length and width, and 149 SACH samples per measurement per evaluator for depth. All these tests results show high P values, which indicate similarity of values provided by the two evaluators (KroniKare AI and expert).

Tables 12 to 14 (Annex B), respectively, illustrate results of T-Tests on measured wound length, width, and depth on 98 KWSH samples per measurement per evaluator for length and width, and depth. All these tests results show high P values, which indicate similarity of values provided by the two evaluators (KroniKare AI and expert).

Tissue Classification: KroniKare AI vs. Expert McNemar's Test Results

The values of tissue classification are in binary (1: presence of a particular tissue type, 0: absence of a particular tissue type) categorical form. McNemar test are applied on KroniKare AI detection of presence of a tissue type vs. expert opinion, both on the same wound images. As the data types are categorical, we could also employ other well-known performance measures in machine learning including sensitivity, specificity, precision, accuracy, and F1 scores. These let us shed light on the performance of the system in its closeness to the expert opinion. We regard 80% (0.8) an acceptable performance for these measures.

Results of applying McNemar test results on tissue type evaluations for KroniKare AI and expert at CGH on 329 data points are presented in Table 15 (Annex B). All these tests results show high P values and high-performance indicators (sensitivity, specificity, precision, accuracy, and F1 scores), which indicate similarity of tissue labels provided by the two evaluators (KroniKare AI and expert).

Results of applying McNemar test results on tissue type evaluations for KroniKare AI and expert at SACH on 983 data points are presented in Table 16 (Annex B). All these tests results show high P values and high-performance indicators (sensitivity, specificity, precision, accuracy, and F1 scores), which indicate similarity of tissue labels provided by the two evaluators (KroniKare AI and expert).

Results of applying McNemar test results on tissue type evaluations for KroniKare AI and expert at KWSH on 321 data points are presented in Table 17 (Annex B). All these tests results show high P values and high-performance indicators (sensitivity, specificity, precision, accuracy, and F1 scores), which indicate similarity of tissue labels provided by the two evaluators (KroniKare AI and expert).

Results of applying McNemar test results on tissue type evaluations for KroniKare AI and expert at SLH on 306 data points are presented in Table 18 (Annex B). All these tests results show high P values and high-performance indicators (sensitivity, specificity, precision, accuracy, and F1 scores), which indicate similarity of tissue labels provided by the two evaluators (KroniKare AI and expert).

Complication Assessment: KroniKare AI vs. Expert McNemar's Test Results

The values of complication assessment from both evaluators (KroniKare AI and expert) are in binary (1: presence of complication, 0: absence of complication) categorical form. McNemar test are applied on KroniKare AI complication presence detection vs. expert opinion, both on the same wound images.

Table 19 (Annex B) presents results of applying McNemar test results on 271 data points from CGH on conditions detection by expert and KroniKare AI. All these tests results show high P values except for the inflammation detection. The higher rate of inflammation alert from KroniKare Wound Scanner may be due to the use of thermal images to detect inflammation (opposed to the visual cues and touch in the manual process). This difference in rate of detection of inflammation has cause the rate of non-complicated cases to be different. The rest of the complications are similarly labeled by the two evaluators (KroniKare AI and expert).

Table 20 (Annex B) presents results of applying McNemar test results on 983 data points from SACH on conditions detection by expert and KroniKare AI. All tests results show high P values except for inflammation detection (similar to CGH). This indicate similarity of complication labels provided by the two evaluators (KroniKare AI and expert) in detecting infection, ischemia and undermining.

Table 21 (Annex B) presents results of applying McNemar test results on 1797 data points from KWSH on conditions detection by expert and KroniKare AI. All these tests results show high P values except for inflammation detection (similar to CGH). This indicate similarity of complication labels provided by the two evaluators (KroniKare AI and expert) in detecting infection, ischemia and undermining.

Table 22 (Annex B) presents results of applying McNemar test results on 306 data points from SLH on conditions detection by expert and KroniKare AI. All these tests results show high P values except for inflammation detection (similar to CGH). This indicate similarity of complication labels provided by the two evaluators (KroniKare AI and expert) in detecting infection, ischemia and undermining.

Conclusion of Statistical Analysis Results

The statistical tests applied (see Statistical Analysis Appendix) were to **confirm similarity of KroniKare AI outputs to expert opinion** for wound size measurement (length, width, and depth), tissue classification, and complication assessment. This indicates potential of KroniKare system to upskill nurses to a higher level of decision making and perform timely interventions in case of detection of a complication at early stages.

With accuracy of the KroniKare Wound Scanner established, we would like to compare the time required for manual wound assessment and monitoring, to using automated wound assessment and report generation by this service. This aspect is evaluated in the next section.

The goals of these trial were to collect data, evaluate KroniKare Wound Scanner performance (in wound size measurement, tissue analysis, and wound complication detection), and estimate the timesaving provided by this service. With data from 644 patients, with 1,204 wounds, and 4,904 automatic wound reports (from more than 15,000 images), our statistical analysis supports the similarity of KroniKare Wound Scanner performance to expert's opinion in all three aspects of wound size, wound tissues, and wound complications:

- KroniKare Wound Scanner **wound measurement** is on-par with physical (manual) wound measurement
- KroniKare Wound Scanner **tissue classification** is comparable to wound care specialist opinions
- KroniKare Wound Scanner **complication detection** for detection of infection, undermining, and ischemia is comparable to wound care specialist opinion.

Table 26. Complete wound care tasks performed and their average time in step-down care (Kwong Wai Shiu Hospital). P/T: process time, D/T: additional delay time, %: likelihood of task performed within process time (P/T).

Cat No.	Category	Cat P/T	Cat D/T	Cat %	Cat Overall Time	Task No.	Task	Task P/T	Task D/T	Task %	Task Overall Time
0	Patient Registration	0	0	100	0	0	Entering patient Information	0	0	100	0
1	Preparation Before Procedure	240	300	63	351	1.1	Check Case Notes/Previous Wound Chart	120	180	70	174
						1.2	Collect & Prepare Requisite	120	120	90	132
2	Preparation Prior to Start the Procedure	200	0	100	200	2.1	Clean dressing trolley	30	0	100	30
						2.2	Wash hand	60	0	100	60
						2.3	Don Apron	20	0	100	20
						2.4	Push trolley with requisite to resident	30	0	100	30
						2.5	Prepare environment (e.g. turn fan off and light on)	10	0	100	10
						2.6	Prepare resident	20	0	100	20
						2.7	Expose the outing if needed	30	0	100	30
3	Implementation of Phase I	220	3720	56	1856.8	3.1	Perform Hand Hygiene	60	0	100	60
						3.2	Open the dressing set	30	0	100	30
						3.3	Pour solution	5	0	100	5
						3.4	Open the wound product	30	120	70	66
						3.5	Prepare the trash bag	5	0	100	5
						3.6	Perform hand rub	60	0	100	60
						3.7	Take out the phone and switch on camera mode	30	1800	80	390
4	Implementation of Phase II	575	0	100	575	4.1	Perform hand rub	60	0	100	60
						4.2	Remove old dressing	60	0	100	60
						4.3	Perform hand rub	60	0	100	60
						4.4	Prepare the soaked cotton ball	15	0	100	15
						4.5	Clean the wound thoroughly	300	0	100	300
						4.6	Damp dry the wound if needed	60	0	100	60
						4.7	Ask resident if any pain felt	5	0	100	5
5	Implementation of Phase III	126	180	54	208.8	5.1	Perform hand rub	60	60	60	84
						5.2	Take out the camera and take picture	60	120	90	72
						5.3	Save the image	5	0	100	5
						5.4	Keep phone aside	1	0	100	1
						5.5	Measure the wound using ruler	30	60	80	42
6	Implementation of Phase IV	270	180	64	334.8	6.1	Perform hand rub	60	120	80	84
						6.2	Place the wound product	60	0	100	60
						6.3	Cover the wound and secure it	120	0	100	120
7	End of Implementation	230	0	100	230	7.1	Dress back the clothing if needed	60	0	100	60
						7.2	Readjust resident's bed	30	0	100	30
						7.3	Turn the light off and fan on	10	0	100	10
						7.4	Clear the used dressing set	30	0	100	30
						7.5	Throw the trash bag into bin	10	0	100	10
						7.6	Clean trolley	30	0	100	30
						7.7	Perform hand washing	60	0	100	60
8	Housekeeping	210	180	72	260.4	8.1	Return the unused dressing product back the storage	60	0	100	60
						8.2	Upload the picture into the computer	120	120	90	132
						8.3	Disinfect the phone	30	60	80	42
9	Documentation and Reporting	490	540	78	608.8	9.1	Take out dressing chart	10	60	100	10
						9.2	Record and documentation	180	180	60	252
						9.3	Email NM, NC, and SNM on the update of the wound	120	120	70	156
						9.4	Attach the pictures from the computer to the email	60	60	70	78
						9.5	Update INGOT system	60	60	80	72
						9.6	Pass report to the next shift	60	60	90	66
	Total Process Time (Sec)	2561	5100	76.33	4625.6						
	Total Process Time (Min)	42.68	85.00	76.33	77.09						

Table 27. Possible issues that may delay each task during chronic wound care at Kwong Wai Shiu Hospital.

Cat No.	Category	Task No.	Task	Issue
0	Patient Registration	0	Entering patient Information	
1	Preparation Before Procedure	1.1	Check Case Notes/Previous Wound Chart	Incorrect wound charting from previous recording
		1.2	Collect & Prepare Requisite	Incomplete collection of requisites
2	Preparation Prior to Start the Procedure	2.1	Clean dressing trolley	
		2.2	Wash hand	
		2.3	Don Apron	
		2.4	Push trolley with requisite to resident	
		2.5	Prepare environment (e.g. turn fan off, light on)	
		2.6	Prepare resident	
		2.7	Expose the outing if needed	
3	Implementation of Phase I	3.1	Perform Hand Hygiene	
		3.2	Open the dressing set	
		3.3	Pour solution	
		3.4	Open the wound product	Opening the wrong dressing product
		3.5	Prepare the trash bag	
		3.6	Perform hand rub	
		3.7	Take out the phone and switch on camera mode	Phone in no/low battery mode
4	Implementation of Phase II	4.1	Perform hand rub	
		4.2	Remove old dressing	
		4.3	Perform hand rub	
		4.4	Prepare the soaked cotton ball	
		4.5	Clean the wound thoroughly	
		4.6	Damp dry the wound if needed	
		4.7	Ask resident if any pain felt	
5	Implementation of Phase III	5.1	Perform hand rub	Forgot to perform hand rub
		5.2	Take out the camera and take picture	Retake picture due to wrong position or unclear photo
		5.3	Save the image	
		5.4	Keep phone aside	
		5.5	Measure the wound using ruler	Unsure how to measure, measure wrongly
6	Implementation of Phase IV	6.1	Perform hand rub	Forgot to perform hand rub
		6.2	Place the wound product	
		6.3	Cover the wound and secure it	
7	End of Implementation	7.1	Dress back the clothing if needed	
		7.2	Readjust resident's bed	
		7.3	Turn the light off and fan on	
		7.4	Clear the used dressing set	
		7.5	Throw the trash bag into bin	
		7.6	Clean trolley	
		7.7	Perform hand washing	
8	Housekeeping	8.1	Return the unused dressing product back the storage	
		8.2	Upload the picture into the computer	Unable to recall which photo belongs to which wound
		8.3	Disinfect the phone	Forgot to disinfect
9	Documentation and Reporting	9.1	Take out dressing chart	
		9.2	Record and documentation	Wrong interpretation of wound, incomplete documentation, missing information, completely forgotten to document
		9.3	Email NM, NC, and SNM on the update of the wound	Wrong interpretation of wound, incomplete documentation, missing information, completely forgotten to document
		9.4	Attach the pictures from the computer to the email	Forgotten to send email or update wound
		9.5	Update INGOT system	
		9.6	Pass report to the next shift	Did not update the white board or diary book on the next changing date

Table 28. Tasks impacted by KroniKare Wound Scanner at Kwong Wai Shiu Hospital.

Cat No.	Category	Cat P/T	Cat D/T	Cat %	Overall Time	Task No.	Task	Task P/T	Task D/T	Task %	Task Overall Time
0	Patient Registration	0	0	100	0	0	Entering patient Information	0	0	100	0
1	Preparation Before Procedure	240	300	63	351	1.1	Check Case Notes/Previous Wound Chart	120	180	70	174
						1.2	Collect & Prepare Requisite	120	120	90	132
2	Preparation Prior to the Procedure	200	0	100	200	2.1	Clean dressing trolley	30	0	100	30
						2.2	Wash hand	60	0	100	60
						2.3	Don Apon	20	0	100	20
						2.4	Push trolley with requisite to resident	30	0	100	30
						2.5	Prepare environment (e.g. turn fan off and light on)	10	0	100	10
						2.6	Prepare resident	20	0	100	20
						2.7	Expose the outing if needed	30	0	100	30
3	Implementation of Phase I	220	3720	56	1856.8	3.1	Perform Hand Hygiene	60	0	100	60
						3.2	Open the dressing set	30	0	100	30
						3.3	Pour solution	5	0	100	5
						3.4	Open the wound product	30	120	70	66
						3.5	Prepare the trash bag	5	0	100	5
						3.6	Perform hand rub	60	0	100	60
						3.7	Take out the phone and switch on camera mode	30	0	100	30
4	Implementation of Phase II	575	0	100	575	4.1	Perform hand rub	60	0	100	60
						4.2	Remove old dressing	60	0	100	60
						4.3	Perform hand rub	60	0	100	60
						4.4	Prepare the soaked cotton ball	15	0	100	15
						4.5	Clean the wound thoroughly	300	0	100	300
						4.6	Damp dry the wound if needed	60	0	100	60
						4.7	Ask resident if any pain felt	5	0	100	5
5	Implementation of Phase III	126	180	54	208.8	5.1	Perform hand rub	60	60	60	84
						5.2	Take out the camera and take picture	60	120	90	72
						5.3	Save the image	5	0	100	5
						5.4	Keep phone aside	1	0	100	1
						5.5	Measure the wound using ruler	30	60	80	42
6	Implementation of Phase IV	270	180	64	334.8	6.1	Perform hand rub	60	120	80	84
						6.2	Place the wound product	60	0	100	60
						6.3	Cover the wound and secure it	120	0	100	120
7	End of Implementation	230	0	100	230	7.1	Dress back the clothing if needed	60	0	100	60
						7.2	Readjust resident's bed	30	0	100	30
						7.3	Turn the light off and fan on	10	0	100	10
						7.4	Clear the used dressing set	30	0	100	30
						7.5	Throw the trash bag into bin	10	0	100	10
						7.6	Clean trolley	30	0	100	30
						7.7	Perform hand washing	60	0	100	60
8	Housekeeping	210	180	72	260.4	8.1	Return the unused dressing product back the storage	60	0	100	60
						8.2	Upload the picture into the computer	120	120	90	132
						8.3	Disinfect the phone	30	60	80	42
9	Documentation and Reporting	490	540	78	608.8	9.1	Take out dressing chart	10	60	100	10
						9.2	Record and documentation	180	180	60	252
						9.3	Email NM, NC, and SNM on the update of the wound	120	120	70	156
						9.4	Attach the pictures from the computer to the email	60	60	70	78
						9.5	Update INGOT system on the wound if it is a new pressure ulcer	60	60	80	72
						9.6	Pass report to the next shift	60	60	90	66
	Total Time in Min	42.7	85	76.3	77.1						

Annex D

Patent, certificates for HSA Class B and ISO 13485 for medical device manufacturer.

REPUBLIC OF SINGAPORE
THE PATENT ACT (CHAPTER 221)
CERTIFICATE ISSUED UNDER SECTION 35

I HEREBY CERTIFY that under the provisions of the Patent Act, a patent has been granted in respect of an invention having the following particulars:

TITLE	:	SYSTEM AND METHOD FOR FACILITATING ANALYSIS OF A WOUND IN A TARGET SUBJECT
APPLICATION NUMBER / PATENT NUMBER	:	11201808517T
DATE OF FILING	:	17 OCTOBER 2017
PRIORITY DATA	:	-
NAME OF INVENTOR(S)	:	NEJATI, HOSSEIN
NAME(S) AND ADDRESS(ES) OF PROPRIETOR(S) OF PATENT	:	KRONIKARE PTE LTD 71 AYER RAJAH CRESCENT #04-12 SINGAPORE 139951
DATE OF GRANT	:	30 NOVEMBER 2018

DATED THIS 30 TH DAY OF NOVEMBER 2018

INTELLECTUAL PROPERTY OFFICE OF SINGAPORE
REPUBLIC OF SINGAPORE

Daren Tang Heng Shim
Registrar of Patents
Singapore

HSA Health Sciences Authority

Singapore Integrity · Ser

To be the leading innovative authority protecting and advancing national health a

PUBLIC ENQUIRY - SINGAPORE MEDICAL DEVICE REGISTER (SMDR)

Device Info

Device Name:	**KroniKare KroniKare Wound Scanner** [Kronikare Pte ltd]
Description:	KroniKare Wound Scanner is a diagnostic tool for AI-based chronic wound assessment, providing wound measurement, wound tissue type classification (all 7 medically-assessed tissues) and ischemia detection, as well as triaging alerts for infection, undermining, and inflammation, to complement the information provided to experts for final decisions and diagnosis. KroniKare Wound Scanner is intended for use on chronic wounds by trained users who are competent in using the application and the results should be interpreted by experts. Experts are clinical staff familiar with chronic wound assessment and management, including wound nurses, wound care specialists, and vascular surgeons.
Medical Specialty Area:	Radiology / Imaging
Medical Device Class:	Class B medical device
Device Registration No:	DE0503713
Registration Date:	08/10/2019

FDA U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

12/31/2018

Audrey Swearingen, Regulatory Affairs Manager
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, TX 78746
UNITED STATES

Dear Audrey Swearingen:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: Q182466
Received: 12/31/2018
Applicant: KroniKare Pte Limited
Device: KroniKare Mobile Wound Assessment Device

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: KroniKare Pte Ltd
#03-19
75 Ayer Rajah Crescent
Singapore 139953

Holds Certificate No: **MD 717232**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

> Design, manufacture, import, export, storage and distribution of KroniKare wound scanner for assessment and management of chronic wounds.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-10-28 Effective Date: 2019-10-28
Latest Revision Date: 2019-10-28 Expiry Date: 2022-10-27

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KroniKare Pte Ltd
75 Ayer Rajah Crescent | #03-19 | Singapore 139953
T: (65) 6906 3790

Stevenage Bioscience Catalyst, SG1 2FX | UK

Salarpuria, No. 4-22, Tower-1, Hosur Rd,
Koramangala | BENGALURU Bengalore | Karanataka | India

E: info@kronikare.ai
www.KroniKare.ai