Immediate real time visualization of tissue oxygen saturation without the need for patient contact or injectable dyes. Assess patients preoperatively, intraoperatively, postoperatively, and in clinics, to identify and track the viability of tissue in wounds or reconstructive surgery.

Based in Science, Driven by Need.

Rapid identification of healthy and at risk tissue which aids and supports surgical decisions. Begin assessing immediately. No waiting for injected dyes, set-up, or additional personnel. Simply and quickly image patients and repeat as desired. Customize your surgical procedure to your patient and assess tissue viability in all care settings.

Kent’s multispectral device provides images of deoxygenated hemoglobin, oxygenated hemoglobin, and total hemoglobin in addition to the resultant StO₂ images. These tools combined can help distinguish between arterial or venous insufficiency and guide the surgeon to corrective measures preoperatively, intraoperatively, postoperatively, and in the clinic. Ultimately, determining a skin flap has limited blood supply earlier may lead to less patient suffering and reduced healthcare costs.

Features of Kent’s Device:

- Precise assessment of tissue oxygenation compliments surgical judgement
- Rapid identification of healthy and at risk tissue supports surgical decision making
- Advanced and non-invasive technology, requires no injectable dyes or patient contact for simplified surgical workflow and lower costs
- Accurate and unlimited repeatable imaging with no concern about dye toxicity or dye oversaturation
- Mitigate risks early and identify healthy, damaged and necrotic tissue
The Kent Imaging device utilizes near infrared light to determine tissue oxygen saturation. Near infrared light penetrates ~3 millimeters into tissue making it ideal for microcirculation assessment. The strength of the Kent’s patented technology is that it provides a full view of the injured or reconstructed tissue and is completely non-invasive. The images provide two-dimensional color coded, diagnostic percent oxygen saturation values which relates directly to the viability of tissue.

Understanding the tissue is the first step to healing.

View oxygen saturation levels (StO₂) throughout the region of interest with numerical values.

The low cost and easy to use imaging device is completely non-invasive, eliminating the need for contact or the injected dyes required by other technologies. Instantly capture diagnostic insight into the availability of oxygenated blood in tissue. Providing improved decision making throughout the dynamic treatment pathway – before, during and after wound or surgical care.

Kent’s device uses light in the near-infrared (NIR) spectrum that, harmlessly, passes through the skin and is reflected off the blood supplying the tissue to determine tissue oxygen saturation, a key indicator of tissue health. The NIR light has two key features that make it useful for measuring the viability of living tissue: Firstly, NIR light is not absorbed by tissue as much as visible or ultraviolet light. Secondly, NIR light is mainly absorbed by hemoglobin and water. Most importantly, the wavelength dependent light absorption of hemoglobin differs if it is carrying oxygen from when it is not. This makes NIR light very useful in detecting oxygenated and deoxygenated blood, which conveys a comprehensive picture of tissue health and the healing capacity of wounds or surgical tissue.
Accelerated Tissue Assessment

Rapid identification of healthy and at risk tissue which aids and supports surgical decisions. Begin assessing immediately. No waiting for injected dyes, set-up, or additional personnel. Simply and quickly image patients and repeat as desired.

Capture Clinical & StO₂ Images

Toggle between both the color (clinical) and oxygen saturation (StO₂) images on the device.

Handheld & Completely Portable

Lightweight, easy to operate, battery powered device is available for use in any O.R. or treatment setting.

Export Images to EMR

Export clinical and StO₂ images in DICOM and/or JPEG format for analysis, tracking, record keeping, or insurance documentation.

No Need for Injectable Dyes

Non-invasive technology requires no injectable dyes, eliminating concerns or problems associated with dye toxicity, allergies, or reactions.

Repeatable Imaging

Assess and reassess as often as desired through worry free and unlimited successive imaging. No need to time reading of images (like ICG). Simplifies workflow and lowers costs.

Touch Screen

Large and easy to use touch screen that works with or without gloves. The 10” screen provides a 1:1 ratio colorized view of the tissue StO₂ levels and touching the image provides numerical values.

Useful in All Care Settings

Track and compare the same patient throughout their care. Assess patients from the E.R., clinic, preoperative planning, intraoperative assessment, postoperative surveillance, acute and long term care setting.

Non-Contact

Immediate imaging without patient contact or need for probes, electrodes, or gels. Assess the area of concern and surrounding tissue without the risk of contamination, pain, or incidental damage to friable tissue.
Preoperative Planning:
Establish baseline oxygenation to help plan and identify at-risk tissue before the procedure begins.

Intraoperative Assessment:
Assess surgically manipulated or altered tissue to determine flap viability.

Postoperative Surveillance:
Continued surveillance in recovery ensures tissue survival and identification of congested flaps prior to discharge.

Follow-up Visit Tracking:
Evaluate areas of concern to ensure continued positive flap health. The ability to optimize expansion by maximally filling while ensuring tissue viability throughout each visit.

In Clinic Monitoring:
Ability to assess dehisced or slow healing wounds without the need for injections or contrast.

No Need for Injectable Dye or Leads
Preoperative Planning:
Establish baseline oxygenation to help plan and identify at risk tissue before the procedure begins.

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In Clinic Monitoring:
Ability to assess dehisced or slow healing wounds without the need for injections or contrast.

Wound Clinic:
Evaluate wound healing progression, adequate debridement, graft acceptance, and effects of Hyperbaric Oxygen Therapy.

Applications:
- Penetrating Trauma
- Emergent Deglovings
- Breast Reconstruction
- Colorectal Surgery
- Cardiac Evaluation
- Wound Assessment
- Hyperbaric Oxygen Valuation
- Vascular Surgery
- Podiatry
- Diabetic Ulcers
- Limb Salvage
- Flap Monitoring
- Surgical Wound Dehiscence
- Adverse Event Evaluation
- Ischemic Bowel
- Plastic Surgery
- Abdominal Wall Repair
- .... Anywhere Soft Tissue Viability is Critical to Patient Outcomes

No Need for Injectable Dye or Leads, No Patient Contact
Portable to be Used in Any Department or Care Setting
**Competitive Overview**

### Rapid Tissue Assessment
- Begin assessing immediately
- No waiting for anesthesia or a peripheral line for dye injection, set-up or additional personnel
- Instantly capture tissue oxygen saturation
- Assess image, interpret, and utilize clinical information regardless of care setting

### Ease of Use
- Provides clear oxygen saturation values as opposed to percentages of fluorescence
- Battery operated, handheld - no cords or tethers
- Compact footprint to save floor space in the O.R.
- No per use disposables, fees, or costs
- No need to time the reading of images or wait for dye perfusion to see results

### Improved Safety
- Unlimited imaging without concern of dye toxicity, allergies, or reactions
- Eliminate the risk of needle sticks and sharps
- Easy to follow prompts and intuitive operations
- Repeatable, objective data to support clinical

### Non-Invasive
- No need for injectable dyes
- No contact with the patient
- Assess and reassess as often as required
- Monitor and assess patients throughout the care

<table>
<thead>
<tr>
<th>Technology</th>
<th>Capital Cost</th>
<th>Per Use Fee</th>
<th>Time from start to Results</th>
<th>No Disposable</th>
<th>Non Contact</th>
<th>Handheld/Cordless</th>
<th>Regional View</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kent Imaging</td>
<td>&lt;$30,000</td>
<td>$0</td>
<td>&lt;1 minute</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>ICG FLUORESCENCE</td>
<td>$50,000 - 250,000</td>
<td>$500 - 1,800</td>
<td>&gt;10 minutes</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>✓</td>
</tr>
<tr>
<td>TCOM</td>
<td>$30,000+</td>
<td>$50-100</td>
<td>&gt;60 minutes</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
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</tbody>
</table>

One Time Capital Purchase or Monthly Subscription Fee ONLY
NO Per Patient or Per Use Fees
# Flap Viability

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICG</td>
<td>87.5%</td>
<td>87.4%</td>
</tr>
<tr>
<td>NIR</td>
<td>90.6%</td>
<td>85.6%</td>
</tr>
</tbody>
</table>

"Excellent concurrence between perfusion and hemoglobin oxygenation imaging of the flap."


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# Kent Imaging Vs. TCOM

**Figure 1: TC0$_2$ vs. NIR (Kent)**

The relationship between TC0$_2$ and NIR spectroscopy was defined as $y=0.93x+5.35$ with a correlation coefficient=0.92 and r$^2$ =0.84. TC0$_2$ calculated saturation% NIR saturation%.

"The Kent imaging device provides an excellent assessment of tissue viability. It’s easy to use and minimizes disruption of patient flow. We are able to obtain data equivalent to traditional technologies, such as TCOM without the need for disposables and there is no contact with the patient or patient’s wound bed. This device is fast easy and extremely cost effective in our very cost sensitive wound center”

- Dr. Robert Bowen, M.D. University Healthcare, Berkeley Medical Center

Current Handheld Device FDA 510(k) Clearance

Previous Stand Based Device FDA 510(k) Clearance
Health Canada License #99281

**Medical Device Licence**

**Licence Number:** 99281

**First Issue Date:** 2017/06/07

**Device Class/Classe de l'instrument:** 2

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

**Licence Name/Nom de l'homologation:**
KENT CAMERA MULTISPECTRAL IMAGING DEVICE

**Licence Type/Type d'homologation:**
System / Système

**Manufacturer Name & Address/Nom du fabricant & adresse**

KENT IMAGING, INC.

604 - 16TH AVENUE SW
CALGARY, ALBERTA
CANADA
T2R 0S9

Kimby Barkley - Interim Director, Medical Devices Bureau/Directrice interim, Bureau des matériaux médicaux

Application Number:

Numéro de la demande: 268649

Manufacturer ID:

Identificateur du fabricant: 131830


For additional safety information and complete instructions for use, please refer to the User Manual.