NZX/ASX Announcement

13 January 2025

TruScreen invited to present at WHO global AI collaboration meeting

- **TruScreen presented to a World Health Organisation (WHO) global meeting to further the use of AI technologies for screening of cervical cancer**
- **The presentation by CEO, Marty Dillon is attached for the information of stakeholders**

At the invitation of World Health Organisation (WHO) TruScreen Group Limited (NZX/ASX:TRU) presented at a WHO global AI collaboration meeting on 11 and 12 November 2024 in Edinburgh. The meeting investigated the further use of Artificial Intelligence (AI) technologies for cervical cancer screening.

TruScreen's unique AI enabled technology was the only opto-electric tissue differentiating medical device company invited to participate.

This invitation followed on from the UNITAID Report that featured TruScreen as a technology, currently in commercial use, for the primary screening of cervical cancer. After years of clinical trials, TruScreen technology received recent recognition by peak Medical Organisations and national Government agencies including:

- the Chinese Obstetricians and Gynaecologists Association (COGA),
- the Chinese Society for Colposcopy and Cervical Pathology (CSCCP),
- the Vietnam Ministry of Health National Technical List,
- COFEPRIS, the Mexican public health regulator, and
- The Russia Cervical Cancer Screening Guidelines.

TruScreen Chair, Mr Tony Ho commented:

"This WHO invitation was significant for TruScreen, and signals that, along with the recent recognition by national government agencies and peak Medical Organisations, that WHO recognises the use of TruScreen's unique AI enabled opto-electric technology to reduce the preventable deaths of women from cervical cancer.

This is particularly relevant in TruScreen's target markets – countries with limited or no cervical cancer screening programs, that resulted in high cervical cancer mortality rates. Ninety percent (90%) of cervical cancer deaths worldwide occur in these countries."

This announcement has been approved by the Board.

Ends

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About TruScreen:

TruScreen Group Limited (NZX/ASX: TRU) is a medical device company that has developed and manufactures an AI-enabled device for detecting abnormalities in the cervical tissue in real-time via measurements of the low level of optical and electrical stimuli.

TruScreen's cervical screening technology enables cervical screening, negating sampling and processing of biological tissues, failed samples, missed follow-up, discomfort, and the need for costly, specialised personnel and supporting laboratory infrastructure.

The TruScreen device, TruScreen Ultra®, is registered as a primary screening device for cervical cancer screening.

The device is CE Marked/EC certified, ISO 13485 compliant and is registered for clinical use with the TGA (Australia), MHRA (UK), NMPA (China), SFDA (Saudi Arabia), Roszdravnadzor (Russia), and COFEPRIS (Mexico). It has Ministry of Health approval for use in Vietnam, Israel, Ukraine, and the Philippines, among others and has distributors in 29 countries. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold in China.

TruScreen technology has been recognised in CSCCP's (Chinese Society for Colposcopy and Cervical Pathology) China Cervical Cancer Screening Management Guideline.

TruScreen has been recognised in a China Blue Paper "Cervical Cancer Three Stage Standardized Prevent and Treatment" published on 28 April 2023.

In Dec 2023 TruScreen technology was added to the Vietnam Ministry of Health approved National Technical List, for use in Vietnam's public and private healthcare sectors

In financial year 2024 alone, over 200,000* examinations have been performed with TruScreen device. To date, over 200 devices have been installed and used in China, Vietnam, Mexico, Zimbabwe, Russia, and Saudi Arabia. TruScreen's vision is "A world without the cervical cancer"©.

To learn more, please visit: www.truscreen.com/.

**Based on Single Use Sensor sales.*

Glossary:

Pap smear (the Papanicolaou smear) test involves gathering a sample of cells from the cervix, with a special brush. The sample is placed on a glass slide or in a bottle containing a solution to preserve the cells. Then it is sent to a laboratory for a pathologist to examine under a microscope. https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-and-procedures/pap-test

LBC (the liquid-based cytology) test, transfers a thin layer of cells, collected with a brush from the cervix, onto a slide after removing blood or mucus from the sample. The sample is preserved so other tests can be done at the same time, such as the human papillomavirus (HPV) test https://www.cancer.net/cancer-types/cervical-cancer/diagnosis

HPV (human papilloma virus) test is done on a sample of cells removed from the cervix, the same sample used for the Pap test or LBC. This sample is tested for the strains of HPV most commonly linked to cervical cancer. HPV testing may be done by itself or combined with a Pap test and/or LBC. This test may also be done on a sample of cells which a person can collect on their own. https://www.cancer.net/cancer-types/cervical-cancer/screening-and-prevention

Sensitivity* and *specificity mathematically describe the accuracy of a test which reports the presence or absence of a condition. If individuals who have the condition are considered "positive" and those who don't are considered "negative", then sensitivity is a measure of how well a test can identify true positives and specificity is a measure of how well a test can identify true negatives:

- **Sensitivity** (true positive rate) is the probability of a positive test result, conditioned on the individual truly being positive.
- **Specificity** (true negative rate) is the probability of a negative test result, conditioned on the individual truly being negative (Sensitivity and specificity – Wikipedia).

For more information about the cervical cancer and cervical cancer screening in New Zealand and Australia, please see useful links:

New Zealand: National Cervical Screening Programme | National Screening Unit (nsu.govt.nz)

Australia: Cervical cancer | Causes, Symptoms & Treatments | Cancer Council

TruScreen

Reproducibility of Test Result & Test-Retest Reproducibility

11 November, 2024

About **TruScreen Technology**

TruScreen

Handheld device

Single Use Sensor (SUS)

Intelligent Cradle

Primary cervical cancer screening device for detection of pre-cancerous and cancerous cervical tissue via an AI generated Algorithm

What is the TRU System and how does it work? The TRU system consists of a handheld device (HHD), intelligent cradle and a single-use-sensor (SUS).

TruScreen Regulatory Approvals

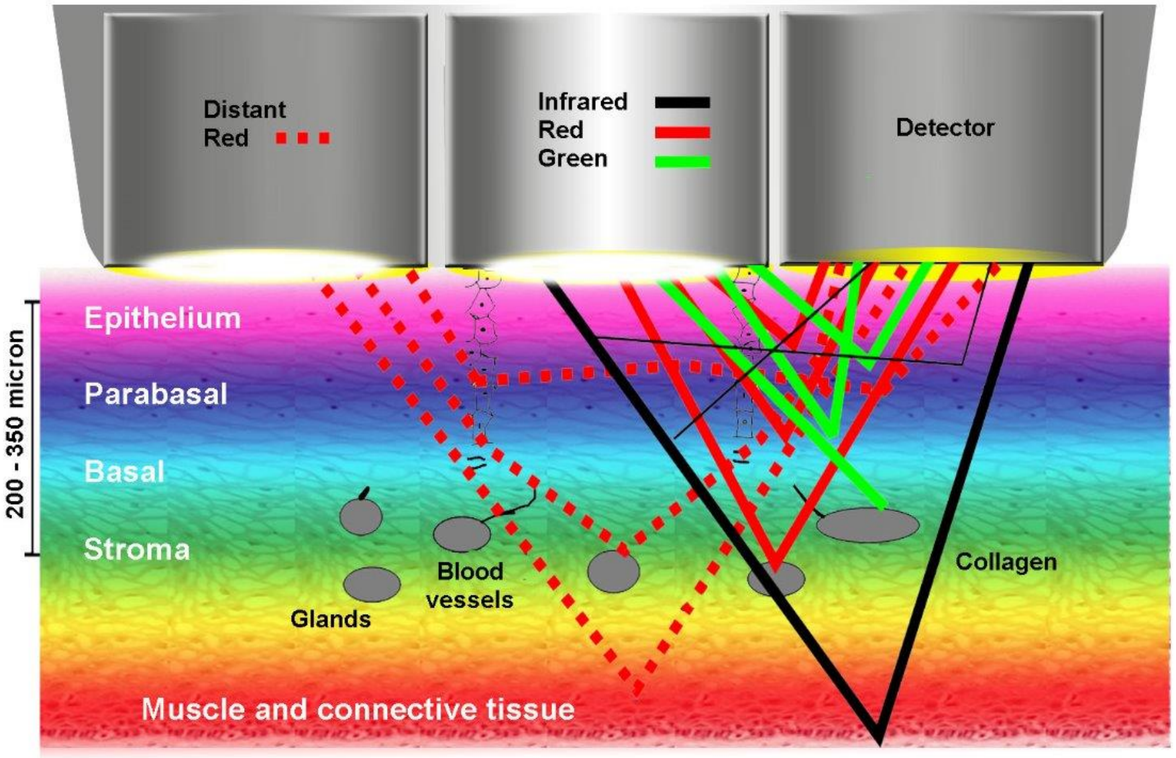
International Quality Accreditation:

- ISO 13485
- ISO 60601-1-2
- CE Mark

International Approvals:

- CE Mark, European Union
- NMPA, China
- TGA, Australia
- MHRA, UK
- SFDA, Saudi Arabia
- Roszdravnadzor, Russia
- COFEPRIS, Mexico
- WAND New Zealand
- Zimbabwe Ministry of Health
- IEAKI Indonesia
- Vietnam Ministry of Health

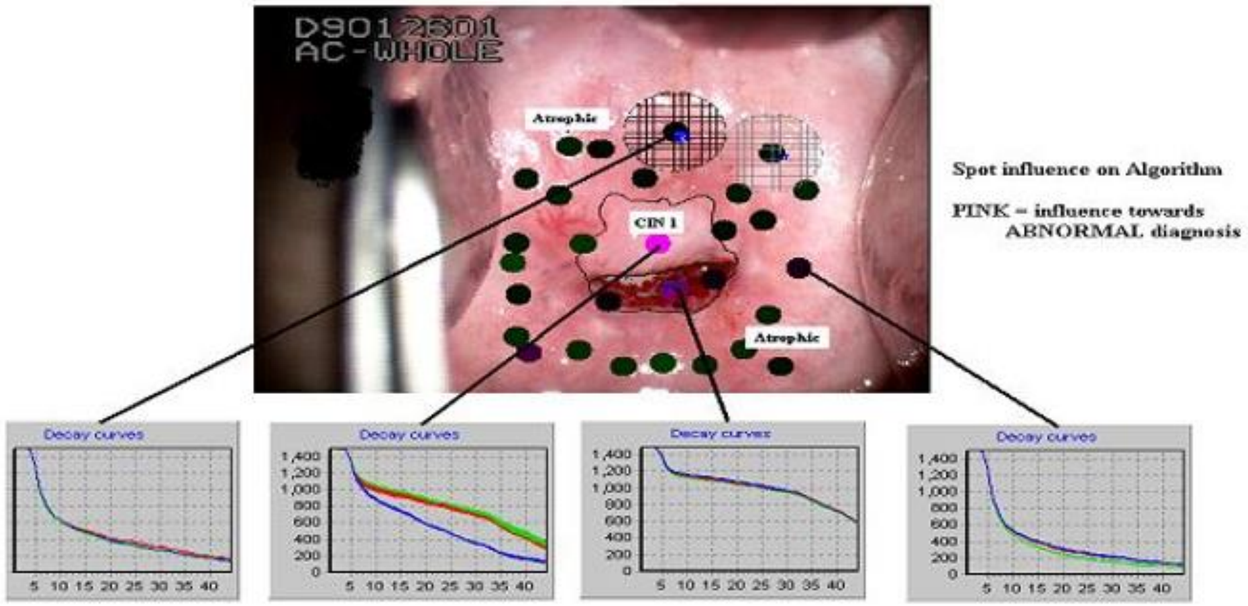
Optical Tissue Differentiation



TruScreen measures the scattering and diffuse reflection of Distant Red, Red, Infrared and Green light.

TruScreen detects changes in sub-surface tissue that are not visible in visual inspection or collected in a Pap Smear sample.

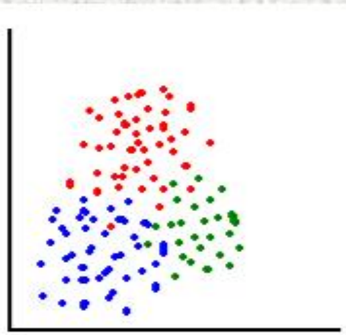
Electrical Tissue Differentiation



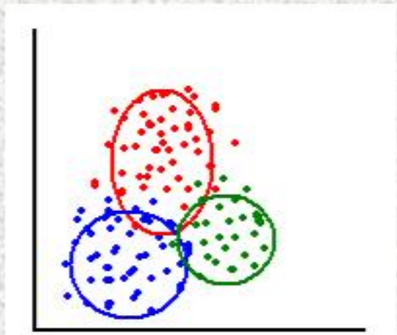
Squamous tissue acts as a battery and stores, for a brief period, electrical charge.

TruScreen stimulates the cervix with low voltage multi pulse stimulation (0.78 V) and then measures the voltage decay of the tissue.

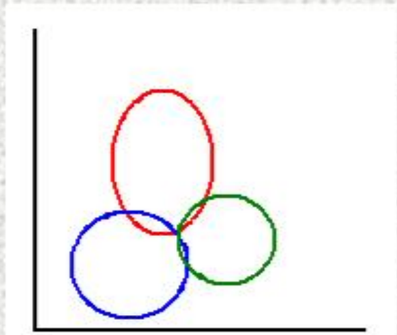
Algorithm and a Repeatable Result



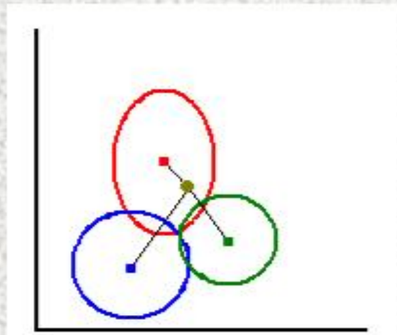
Data
Raw data is converted into features. In unsupervised clustering the data is not labelled.



Training
The training algorithms identify clusters in the data.



Model
The description (parameters) of each cluster is used as the model of the data.



Execution
New data is classified by its relative membership in each cluster, e.g. 70%, 10%, 20% (anti-clockwise from top).

TruScreen Algorithm

Developed by PLT/CSIRO / University of Sydney

- The Algorithm Team were led by Geoff Mckellar and Stephen Gould at PLT and David McMichael at the CSIRO, and a PLT team led by Victor Skladnev developed the ‘probe’ and signal processing technology.

- Algorithm development utilised mathematical techniques including PCA, mixture models, clustering/vector quantization, SVM, neural network, logistic classifiers.

- Mixture models and logistic classifier gave the best performance

TruScreen Algorithm

- The Algorithm D2.03G was then ‘frozen’ and provided that the TruScreen Device is in ‘spec’ and the users follow the IFU then a reproducible/repeatable result is assured

- This has been clinically verified in trials involving more than 40,000 women, in multiple settings and across multiple ethnicities

Improvements using
  - Feature engineering (e.g. add Fourier transform based features)
  - Support Vector Machine
  - Random Forest
  - Sparse expectation–maximization (EM) algorithm
  - Monte Carlo method

Showed no improvement on the TEST database, even though they showed improvement on the development database.

Reproducibility of TRU Result

The TruScreen Algorithm is fixed and processes data using the same 'cluster' definitions for every patient:

But**:**

<u>Equipment and People vary</u> thus the control of the quality of input date is essential:

Equipment Variability to be stabilised:

- Handpiece parameters
- SUS Parameters
- Ageing effect on both
- Start UP Self Check – Electrical and Optical
- OTP Test
- SUS Fit test – Electrical
- SCS at 20 Tests (Gain/Drive Current)
- Probing Pattern

Human Variability to be stabilised

- Follow the IFU
  - Contraindications
  - Patient Preparation
  - Probing Pattern
- TRAINING

CREATE a DEVICE AGNOSTIC SOLUTION

Reproducible Results Require Reproducible Equipment and Reproducible Users

Reproducibility of an Algorithm

The use of AI to enable an algorithm to 'self-improve' raises many questions.

- If an Algorithm is constantly 'improving' how is it clinically verified and validated.
- If the Algorithm is 'improved' via input data, how is the input equipment controlled so that the input data is constant, and not compromised by variable background 'noise'
- Light Source, cameras etc. As these age and the intensity and colour of the background light changes, how does the equipment compensate for these variations?

Self Learning Algorithms are meant to be Self Improving

BUT

If Poor Data enters the learning process will the Algorithm learn 'bad habits'

And

Become less accurate rather than more accurate.

Reproducibility of an Algorithm

- As cameras change, how does the algorithm compensate or adjust to the differing optics of the new camera?
- Solarscan lessons….perfect colour and prefect light for melanoma screening
- If the Algorithm is ‘improved’ via input data, how is the human element controlled so that the input data is constant, and not compromised -
  - User training and technician training

What is a Gold Standard

If the AI inputs are measured against a database of classifications derived from ‘Gold Standard’ diagnoses, how Gold is that Standard?

Subjective analyses of images, laboratory handling failures, poor sample collection and processing can all devalue the Gold in any standard.

What is a Gold Standard

- Colposcopy
- Histology
- HPV DNA
- All have human input…..
- Lessons from around the world show that a ‘suspicious’ mind will guard against blind trust

Thus Reproducible Results Require not just Reproducible Equipment and Reproducible Users, **but an unvarying Gold Standard**