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NZX/ASX Announcement

12 November 2024.

TruScreen – Key Markets Update

Highlights

- **Unit sales of Single Use Sensors (SUS) to China exceeded 6 months budget by >55%**
- **World Health Organisation (WHO) invites TruScreen to present at its global (by invitation only) AI cervical cancer screening conference in Edinburgh**
- **Indonesia product registration completed**
- **Uzbekistan product registration commenced to enable evaluation of TruScreen for national screening program**
- **TruScreen included in Russian Cervical Cancer Screening Guideline**
- **UNITAID features TruScreen in its Cervical Cancer Screening Landscape report**
- **Summary of published study reports in 2024 including new report by leading research journal, Germany's Stringer Nature**

TruScreen Group Limited (NZX/ASX:TRU) is pleased to provide an update of its key markets and target markets.

Global recognition by national Governments and NGOs

Following recent inclusions in UNITAID and Russian screening guidelines *TruScreen is now included in guidelines published by the World Health Organisation (WHO), UNITAID (including the Clinton Health Access Initiative and Australia's Daffodil Foundation), The Chinese Obstetricians and Gynaecologists Association (COGA), the China Society for Colposcopy and Cervical Pathology (CSCCP), Cofepris public health approval in Mexico, the Vietnam Hospital national Technical List and the Russia Cervical Cancer Screening Guideline.*

WHO invites TruScreen to present at (by invitation only) an AI cervical cancer screening conference at Edinburgh

TruScreen CEO Marty Dillon is to present at the World Health Organisation conference in November at Edinburgh to further the use of Artificial Intelligence (AI) tools for visualization of the cervix for cervical screening and treatment. The WHO invitation recognises the advancement and adoption of TruScreen AI enabled technology by several national government's screening guidelines, notably China, Vietnam, Mexico and Russia.

Global Markets

China continues to be TruScreen's key focus, but exciting opportunities are emerging from other markets outlined below.



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China

Number of Women of Screening Age: 476,599,793*

- **Strong SUS Sales:** Consumable sales (SUS) in China reached 90,720 units in the first half of FY2025, exceeding budget by 55.6%.
- **Software Upgrade:** We have completed documentation for China's NMPA registration variations, enabling software upgrade on Chinese devices. The upgrade will improve the user experience for doctors and clinicians and will extend the device's in-use service interval.
- **Private Sector Expansion:** Building on success in the public hospital system, our distributor Beijing Siweixiangtai Tech Ltd. Co (SWXT) is targeting the growing China private health sector.

In Jiangsu province, after the initial installation of TruScreen in the Affiliated hospital of Nantong University, eight further private hospitals have confirmed the adoption of the TruScreen technology, with an estimated monthly SUS usage of 300-500 per device per month. This is more than twice the current average SUS usage per device per month in China. Jiangsu Province, with a population of 85 million is a key growth market for TruScreen and SWXT. The successful market expansion program will continue to other populous provinces of Zhejiang and Guangdong.

Vietnam

Number of Women of Screening Age: 35,887,201*

- **Ho Chi Minh City Screening Program:** TruScreen is selected as the exclusive screening method for a city-wide program in Ho Chi Minh City, commencing in early 2025. The decision by the Ho Chi Minh City Public Health Association (HPHA) is based on the success of smaller-scale programs conducted by our distributor GHS. CEO, Marty Dillon and Head of Commercial, Dr. Jerry Tan will meet with the Chair of the HPHA on 15 November to implement the program and conclude the agreement between TruScreen, HPHA and GHS.
- **Public Hospital Adoption:** With the streamlined public hospital approval process, four major public hospitals in Vietnam have obtained procurement approval and are in the process of installing TruScreen for their cervical cancer screening programs. Two more hospitals are expected to follow shortly.
- **Austrade Collaboration:** TruScreen and GHS, are working with Austrade to engage with Hanoi based sub-distributors to focus on the north of Vietnam as a key expansion market. A social media campaign is also being developed to increase awareness of women of Ho Chi Minh City and Hanoi on the need for cervical cancer screening.



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Mexico

Number of Women of Screening Age: 45,983,174*

- **Public Sector Focus:** Distributor Sunbird is actively engaging with the newly elected government officials to introduce TruScreen to the public sector.

Two projects are being pursued by Sunbird S.A de C.V for sales expansion:

- **Mobile checkup units in Mexico City:** (with a potential for up to 20 devices to be installed with strong SUS pull through over a two-year period.) TruScreen is also being considered as an 'opto-electronic' screening technology to enable the delivery of a mobile cervical cancer screening program to the women of Mexico City and surrounds.
- **Leveraging the government's focus on AI in medicine** to highlight TruScreen's AI capabilities.

In addition, Sunbird has commenced a series of cervical cancer screening webinars to increase sales to gynaecologists in the private health sector in Mexico.

Uzbekistan

Number of Women of Screening Age: 11,617,411*

- **National Screening Program:** TruScreen continues to work with the Ministry of Health in Uzbekistan to develop a national cervical cancer screening program. Product registration of the TruScreen Cervical Cancer Screening Device is in progress and is a pre-requisite for a pilot screening program in Tashkent to commence in Q1 CY2025. A successful completion of the pilot is expected to result in 14 primary healthcare clinics in Tashkent adopting the TruScreen's technology. The next stage is to extend cervical screening programs to Uzbekistan nationally.

Indonesia

Number of Women of Screening Age: 95,961,293*

- **Registration Complete:** TruScreen has successfully completed product registration in Indonesia. TruScreen is collaborating with Austrade to connect with distributors and key stakeholders in the public and private hospital sectors. Training with a key stakeholder's team is scheduled for December, with commercial sales expected to begin in Q1 CY2025.

Zimbabwe

Number of Women of Screening Age: 5,152,773

- **Ministry of Health Re-Validation:** The Zimbabwe Ministry of Health is expected to complete its periodic re-validation of TruScreen in December. Thereafter tenders would be called for national screening in metropolitan and regional Zimbabwe.



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Thailand, Malaysia and Singapore

Number of Women of Screening Age: 38,391,281

- **Distribution Agreement Signed:** TruScreen has appointed Intega Pte Ltd- a Singapore based medical technology distributor, to market and distribute the TruScreen Cervical Cancer Screening Device and SUS in Singapore, Malaysia, and Thailand. The partnership marks a significant milestone for TruScreen as it completes a continuous vertical East Asian market, from Indonesia in the south, north through ASEAN (Association of South East Asian Nations) region, then Vietnam and China in the north. ASEAN is the fastest growing economic regional bloc in Asia.

Jordan, Palestine and Rwanda

Number of Women of Screening Age: approx. 8,849,008

- Sadaf Medical, TruScreen's distributor in Jordan, Palestine and Rwanda has recently featured TruScreen in seminars and trade shows in all three countries. The first TruScreen devices are expected to be installed in Jordan and Rwanda by December, and in Palestine in Q1 CY2025.

TruScreen in Jordan





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TruScreen in Rwanda



Recent global publications

During 2024, TruScreen was recognised in the following global publications.

- ✓ TruScreen study in Saudi Arabia outperforms traditional Pap Smear tests. (See *NZX/ASX announcement 5 August 2024*)
- ✓ TruScreen selected by UNITAID, an agency of the World Health Organisation (WHO) and included in its Technology Landscape Report to its member nations. (see *NZX/ASX announcement 03 October 2024*)
- ✓ TruScreen was selected as one of six global companies, from a cohort of 580 companies, that will have an impact on global women's health. The evaluation was conducted by Austrian based StartUs Insights. (See *NZX/ASX announcement 29 October 2024*)
- ✓ Report published by leading research journal, Germany's Springer Nature concluded that TruScreen cervical cancer screening results were comparable and even better (for patients with type 3 TZ) than conventional LBC (Liquid based Cytology). (See *NZX/ASX announcement 11 November 2024*)

Looking Ahead

TruScreen CEO Martin Dillon commented *“TruScreen is at the turning point of its commercialisation phase. Sales have been increasing as markets and medical key opinion leaders become more aware of the advantages that TruScreen brings to cervical cancer screening. Recent developments, such as the increased recognition by WHO, NGO’s, government guidelines, and the invitations to develop public screening programs in Ho Chi Minh City and Uzbekistan indicate that TruScreen technology is now at a point where adoption of our unique technology will accelerate, and sales will grow at a higher rate.”*

*All population figures are for women aged 15-64 years as detailed in the World Fact Book : <https://www.cia.gov/the-world-factbook/>

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 23 countries. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold in China, with the "Made in China" registration.

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, by COGA (*Chinese Obstetricians and Gynaecologists Association*).

In financial year 2023 alone, over 140000¹ 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/.

¹Based on Single Use Sensor sales.



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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](#)