

## Unique Device Identification Webinar 14

Invited guest speakers from Zebra Technologies will present on the UK Scan4Safety pilot



**Michelle van Wijk**  
UDI Project Manager, TGA



**Brett Newstead**  
Zebra Technologies Corporation



# Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past, present and emerging.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

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# Agenda

## **Project Update**

Special Invited Guest Presentation - Brett Newstead from Zebra

Questions and Answers



# Sandpit Update (as at 17 October 2022)

	<b>Registrations</b> <b>364</b> (from a mix of sponsors, manufacturers, software providers, healthcare and TGA staff)
	<b>Users</b> <b>362</b> users with Sandpit access
	<b>Records</b> <b>77</b> UDI records created (using portal and bulk upload)
	<b>Calls</b> <b>220</b>
	<b>Emails</b> <b>398</b>
	<b>Sandpit Updates</b> <b>4 updates to fix errors and introduce enhancements</b> <b>Next update is being finalised and includes:</b> <ul style="list-style-type: none"><li>• Fixes to bugs identified by Sandpit users and testing</li><li>• Enhancements for mobile users</li><li>• Enhancements to process of adding packing information</li><li>• Revisions and corrections to rules for Secondary, Previous and Direct Marking DI's</li><li>• Revisions to bulk upload template</li></ul>

# Regulatory framework



Consultation 3 closed on 11 October 2022

We are in the process of reviewing the responses and the feedback will be provided to the Government for a decision and implementation of the regulatory framework



## Collaboration and engagement



Technical Working Group is meeting regularly  
Monthly webinars continue  
'Sandpit' remains open

# Agenda

Project Update

**Special Invited Guest Presentation - Brett Newstead from Zebra**

Questions and Answers





# Capturing the power of Unique Device Identification, UDI

With fewer workarounds,  
there's more time to care

Brett Newstead, Zebra Technologies  
18 October 2022





# Agenda



- Introduce Zebra Technologies.
- Unique Device Identification.
- Key Healthcare technologies.
- UK Scan4Safety.
- Australian case studies.
- Why UDI is more important than ever.
- Conclusion.





*Brett Newstead is Director of Sales with Zebra Technologies. In this role, he advises healthcare, retail, transport, logistics and manufacturing providers on how secure purpose-built mobile and tracking technologies empower front line workers and provides operational visibility for improved safety and operations. He has a Bachelor's Degree in Mechanical Engineering and Computing from Monash University. Brett is based in Melbourne at Zebra's Australian headquarters.*



*Wayne Miller is the Director of the EMEA Healthcare Practice for Zebra Technologies. Working with both partners and end users, Wayne assures that Zebra delivers the latest solutions that assist hospitals and healthcare organizations deliver ever-greater efficiencies and improve patient care and outcomes. Wayne was educated at both the University of Central Lancashire and at Preston College. He based near Liverpool.*



*Johnny Ong is the APAC Healthcare Practice Leader for Zebra Technologies. In this role, he advocates for the role technology plays in improving the quality, safety, and efficiency of patient care and for the value of unifying global best practices to improve healthcare across the Asia Pacific region. He is a Registered Nurse with a Bachelor's in Health Science – Nursing from the University of Sydney. He is also a Graduate from Harvard Business School in General Management. Johnny is based in Singapore.*

# Zebra Technologies

A global leader in purpose-built front-line worker and asset visibility solutions



**\$5.6B**  
global sales



**100+**  
offices  
across 45 countries



**4,900+**  
Patents  
US and INTL patents issued  
and pending



**9,800+**  
employees  
worldwide



**10,000+**  
channel partners  
in over 100 countries



**\$447M+**  
R&D\*  
\* 10% of sales



# About Unique Device Identification (UDI)<sup>1</sup>

- The unique device identifier (UDI) is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard, and applied to a specific model of medical device.
- It is comprised of both device information and production information, and is applied to the device label and all levels of packaging for that device in both machine readable (such as a barcode) and human readable forms. It allows the unambiguous identification of a specific model of medical device on the market.
- It is used as the ‘access key’ to information stored in a UDI database and is the data that allows the linking of device information across other systems such as registries, and in patients’ My Health Record.
- When the UDI system is fully implemented, the label of most devices will include a UDI in both a human and machine-readable form (such as a barcode). Globally harmonised, core data about those devices will be publically available through the Australian UDI Database (AusUDID).

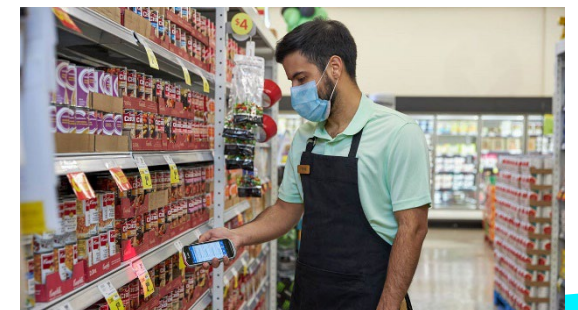
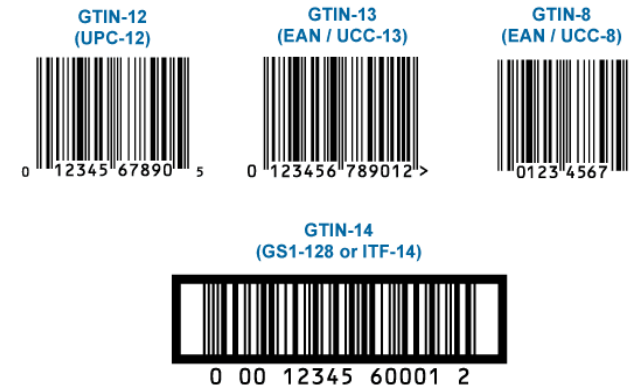
More on “Unlocking the Benefits of UDI” at <https://www.youtube.com/watch?v=levy8quH6OI>.

<sup>1</sup> = Therapeutic Goods Administration.(30 June 2021) *Unique Device Identification system: Strengthening patient safety*. Retrieved from <https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system/unique-device-identification-system-strengthening-patient-safety>.

# UDI Solutions Are Extensively Used Across Multiple Industries Today



- Uniquely Identify Manufactured products using a GTIN, Global Trade Item Number
- Providing supply chain visibility
  - Global / local movement of bulk/palletized or individual products.
  - Warehouse operations receiving, putting away, picking and dispatching.
  - eCommerce parcels ordered online and delivered to the doorstep.
  - Inventory delivered to retail store shelves and scanned at check out



# Key Healthcare Technologies



Positive Patient Identification



Clinical Mobility



Tracking and Locating

## Patient Identification Solutions




Specialty Printers	Wristbands	Labels	Scanning	Mobile Computers
ZD510-HC ZD620-HC ZD420-HC	Z-Band & Laserband	Barcode RFID IQColor	DS4600-HC DS8100-HC CS60-HC DS9900 HD	DS4600-HC TC26-HC TC52-HC



# Key Healthcare Technologies

 Positive Patient Identification

 Clinical Mobility

 Tracking & Locationing

## Clinical Mobility Solutions



Tablets	Mobile Computers	Mobile Printers	Scanners	Solutions
ET45-HC	TC52-HC TC26-HC	ZQ620-HC ZQ 610-HC	DS8100-HC DS4600-HC CS60-HC	MotionWorks Healthcare Workforce Connect

## Clinical Mobility Solutions



# Key Healthcare Technologies



Positive Patient Identification



Clinical Mobility



Tracking and Locating

## Tracking and Locating Solutions



### RFID Supplies

Printable RFID  
Labels Patient ID  
Wristbands

### Motion Works Healthcare and Real-Time Intelligence

TC52-HC	RTLS Sensor Tags
FX7500	Fixed RFID Antenna
RFD8500	ZD500R
RFID Sled	RFID Printer

## Tracking Solutions





# UK NHS Scan4Safety Program

## A Proven Approach To Harnessing the Power of Unique Identifiers and Digitisation



- Investigate how consistent use of point-of-care scanning might improve efficiency and safety within the NHS
- Scanning People, Products, Places and Process to test the benefits of digitisation via the use of globally unique identifiers from GS1
- Six UK National Health Service (NHS) Trusts served as demonstrator sites
- Conducted over 2 years



# UK NHS Scan4Safety

Improve efficiency, auditing and safety

- **Patient safety:** Enhancing patient safety through complete traceability, speedy and accurate recall, reduction of drug error and “Never Events”, and improving routine observations and patient identification.
- **Trace patients and their treatments.** Supporting clinical decisions and ensuring the right patient receives the right treatment, the right drug or the right blood, at the right time.
- **Monitor the effectiveness of their equipment.** Global Location Numbers (GLNs) allow traceability of patients, equipment, care teams, and accurate communication.
- **Manage medical supplies.** Restocking supplies and medications based on usage and not presumptions. The right product, in date and in stock.

GS1 UK’s analysis of Scan4Safety’s results are instructive on the program’s benefits and can be found at [https://healthcare.gs1uk.org/scan4safety/gs1\\_uk\\_a\\_scan\\_of\\_the\\_benefits\\_report.pdf](https://healthcare.gs1uk.org/scan4safety/gs1_uk_a_scan_of_the_benefits_report.pdf).



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### Breast implants and other medical items get safety barcodes

© 29 December 2016



Barcodes are being printed on breast implants and other medical items for patient safety reasons.

The Department of Health initiative is to avoid future scandals like the PIP breast implant scare of 2010.

# UK NHS Scan4Safety

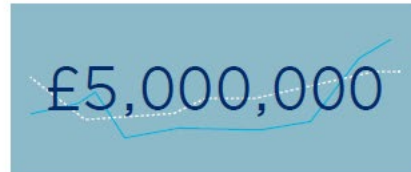
## Key Outcomes



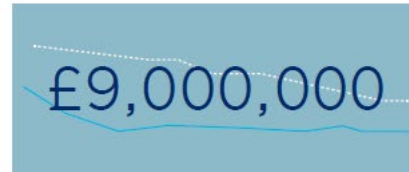
Among the headline findings:



140,000 hours of clinical time have been released to care



Recurrent inventory savings worth nearly £5m across the six trusts



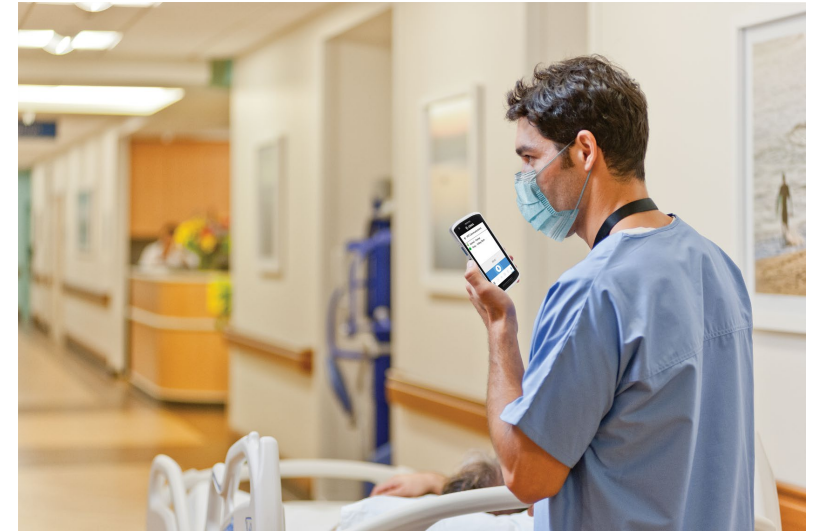
Non-recurrent inventory reductions have amounted to £9m



At Leeds Teaching Hospitals NHS Trust, the average time taken for product recalls has fallen from 8.33 days to less than 35 minutes following the introduction of Scan4Safety. The organisation estimates it will save £84,411.07 each year on such recalls

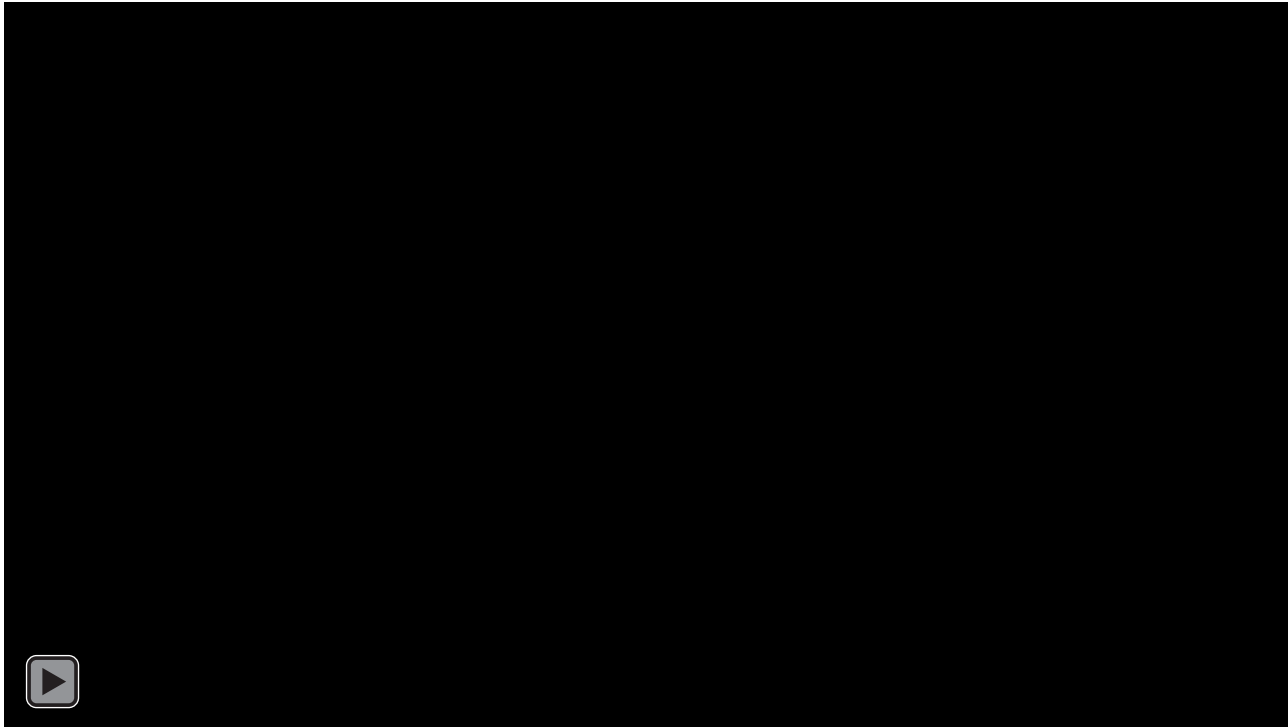


By introducing scanning in pharmacy, Royal Cornwall Hospitals NHS Trust reduced prevented-error rates by 76 per cent, including elimination of all errors caused by wrong patient, wrong drug, wrong dose and wrong form



# UK NHS Scan4Safety - Key Insights & Outcomes

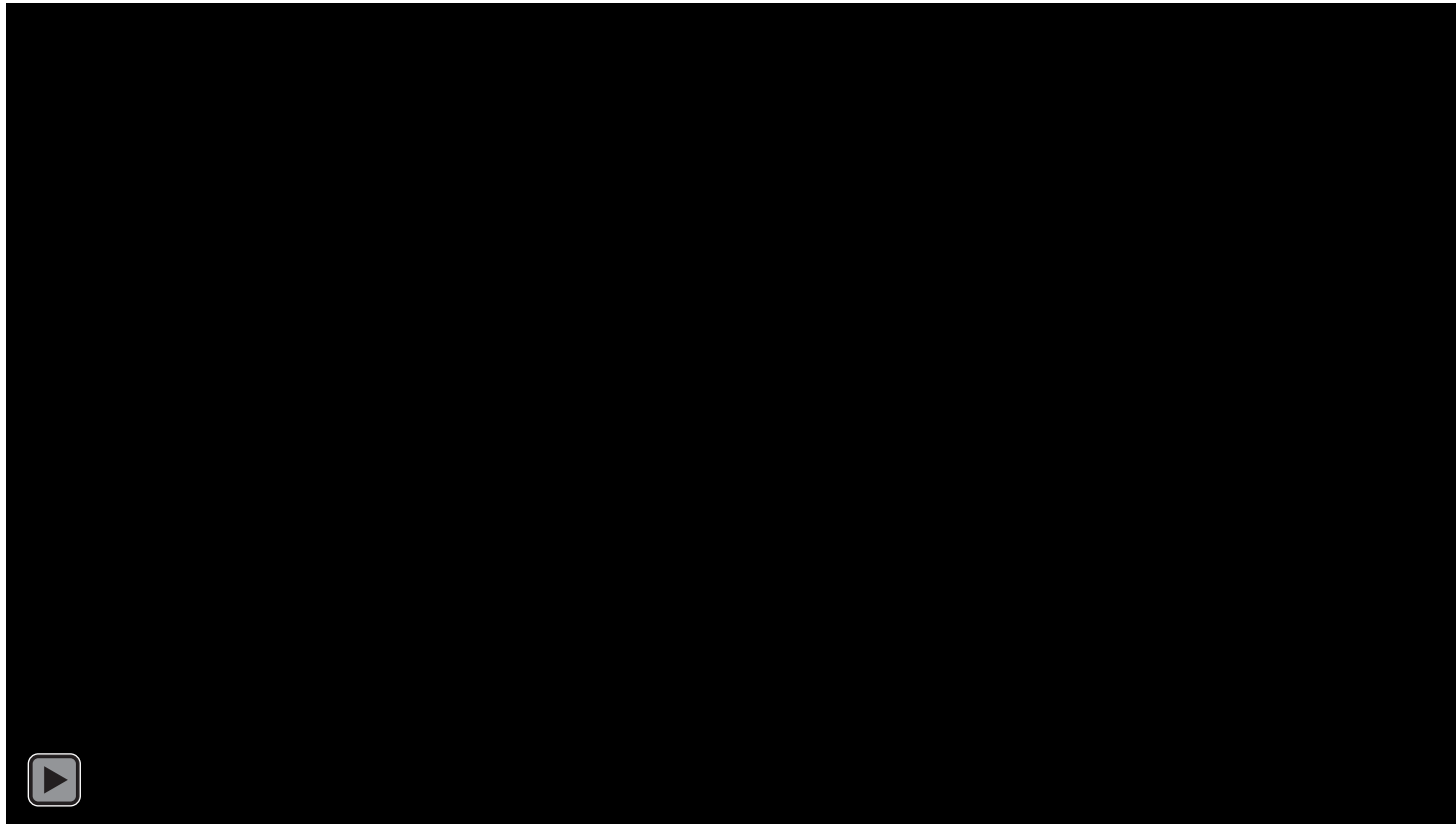
Wayne Miller, European Healthcare practice lead



[https://healthcare.gs1uk.org/scan4safety/gs1\\_uk\\_a\\_scan\\_of\\_the\\_benefits\\_report.pdf](https://healthcare.gs1uk.org/scan4safety/gs1_uk_a_scan_of_the_benefits_report.pdf)


# Australian Case Study – Scanning blood bags

Johnny Ong, AsiaPac Healthcare Practice Lead



**SUCCESS STORY**  
THE ROYAL CHILDREN'S HOSPITAL, MELBOURNE

**ZEBRA** CAPTURE YOUR EDGE



**SUMMARY**

**Customer**  
The Royal Children's Hospital, Melbourne

**Industry**  
Healthcare

**Challenge**  
Update scanning technology and increase the efficiency of the barcode-based blood scanning process

**Solution**  
Zebra DSB100 Handheld Imager, with custom I23SCAN software

**Results**

- Significantly increased staff satisfaction and reduction in stress
- Increasing scanning speed by approximately 50%
- Increased patient safety

## The Royal Children's Hospital Improves Patient Safety With Accurate Scanning Of Blood Products

The Royal Children's Hospital Melbourne (RCH) has provided specialised paediatric care for over 150 years. As one of Australia's largest children's hospitals, the RCH has a staff base of more than 4,000 employees who provide a full range of clinical services and care to patients. The hospital is the designated major trauma centre for children and adolescents in Victoria and a national centre for cardiac and liver transplantation. In 2019-20, more than 46,800 children were admitted into RCH wards, and over 15,000 surgeries were performed.

The RCH brings together six levels of clinical, research and education facilities over 200,000 square metres within the 4.1-hectare site in Parkville, Melbourne.

### Challenge

The hospital's primary focus is delivering the highest quality care to all its patients and to provide Great Care, Everywhere. When the RCH became aware of opportunities to enhance their blood scanning processes, they approached Zebra Technologies to create a custom solution.

The hospital's blood bags are labelled with an average of 10 different barcodes, each used for a different purpose and serving a specific function. Having multiple barcodes is critical to ensure that the right blood is delivered to the right patient, at the right time.

The barcodes scanned by clinicians are registered into the hospital's Electronic Medical Records (EMR) system. This process ensures the blood bag matches the sample collected from the patient receiving the transfusion and provides a clear audit trail in the event of an error. However, these barcodes must be scanned in a particular sequence, to ensure the data is registered correctly into the EMR.



Video: <https://www.zebra.com/ap/en/resource-library/success-stories/rch.html>

Case study: [https://www.zebra.com/content/dam/zebra\\_new\\_ia/en-us/solutions-verticals/vertical-solutions/healthcare/success-stories/healthcare-success-story-rch-en-au.pdf](https://www.zebra.com/content/dam/zebra_new_ia/en-us/solutions-verticals/vertical-solutions/healthcare/success-stories/healthcare-success-story-rch-en-au.pdf)

# Australian Case Studies – Prospitalia h-trak



h-trak decodes industry standard barcodes to accurately identify products used in hospitals, particularly departments where surgical and interventional procedures are performed.

When combined with other data captured in the system, h-trak provides a rich source of procedure information, including the procedure costs.



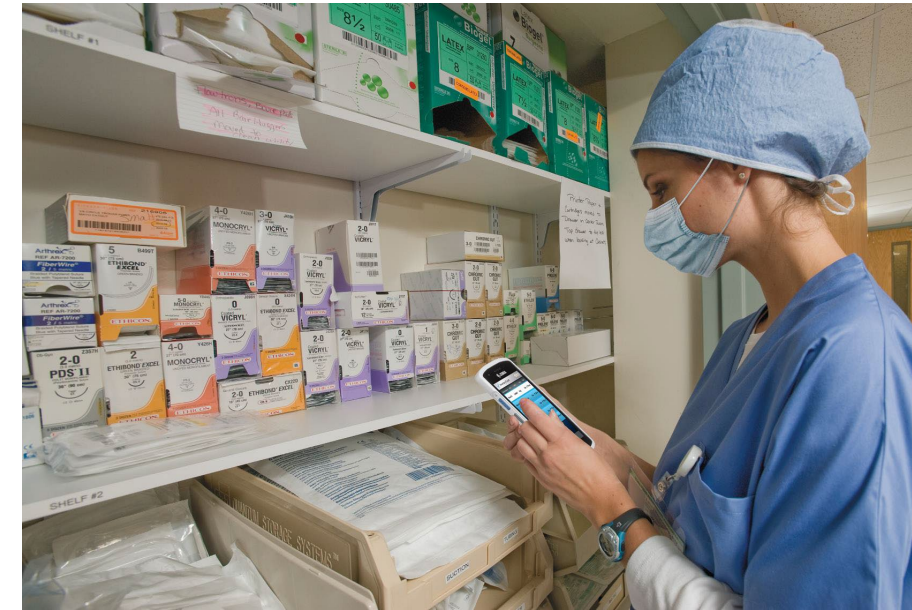
“Prostheses and patient billing – 8 hours reduction in processing time – savings of \$1.2 million per annum”



“Revenue for prostheses billing pre h-trak ~ \$3.8 million – post h-trak ~ \$5 million = 30% improvement and counting”



“Improved revenue for prostheses billing by \$6 million per annum (\$3m -> \$9m)”



# Finally, UDI is more important than ever as protecting the well-being of nurses and frontline healthcare workers is essential

**Nurses create 27 workarounds each shift<sup>1</sup>**

**Nurses spend 21 minutes per shift hunting down equipment<sup>2</sup>**

**80% of physicians are at capacity or overextended<sup>3</sup>**

**For every hour clinicians spend with patients, they spend nearly two hours documenting<sup>4</sup>**



<sup>1</sup> Source: [Nurse Innovation: Saving the Future of Healthcare](#) | Rebecca Love | TEDxBeaconStreet, 2018

<sup>2</sup> Source: GE Healthcare, 2012

<sup>3</sup> Source: The Physicians Foundation, 2018 survey of America's physicians: Practice patterns & perspectives, September 2018

<sup>4</sup> American Medical Association: Annals of Internal Medicine, 2016

# Building Digital Health for Australia's Future



- UDI is based on global labelling standards
  - recognized and accredited product ID standards.
- Positive digital identity is the foundation for:
  - Patient safety
  - Fewer workarounds
  - Reducing frontline nursing fatigue
  - Improved care
  - Lower costs
- Purpose-built, healthcare-grade technologies provide the optimal method for capturing these benefits.



More on “Unlocking the Benefits of UDI” at  
<https://www.youtube.com/watch?v=levy8quH6OI>.



# Thank you

## Contact Information ...

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# Agenda

Project Update

Special Invited Guest Presentation - Brett Newstead from Zebra

**Questions and Answers**



# Website and link references

UDI hub	<a href="https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system">https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system</a>
Third UDI consultation paper	<a href="#">Consultation: Detailed considerations for implementing the proposed Australian medical device UDI regulatory framework   Therapeutic Goods Administration (TGA)</a>  *Closed on 11 <sup>th</sup> October
Second UDI consultation paper	<a href="https://www.tga.gov.au/consultation/consultation-exploring-options-introduction-australian-unique-device-identification-udi-system">https://www.tga.gov.au/consultation/consultation-exploring-options-introduction-australian-unique-device-identification-udi-system</a>
First UDI consultation paper	<a href="https://www.tga.gov.au/consultation/consultation-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia">https://www.tga.gov.au/consultation/consultation-proposal-introduce-unique-device-identification-udi-system-medical-devices-australia</a>
Previous webinars	<a href="#">Unique Device Identification system: Communications and stakeholder engagement   Therapeutic Goods Administration (TGA)</a>

# Questions and Answers



**Michelle van Wijk**  
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# More information



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TGA YouTube <https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw>



TGA topics blog <https://www.tga.gov.au/blogs/tga-topics>



TGA LinkedIn <https://www.linkedin.com/company/therapeutic-goods-administration/>



TGA Instagram <https://www.instagram.com/tgagovau/?hl=en>



**Australian Government**

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**Department of Health and Aged Care**  
Therapeutic Goods Administration