

A MedTech SaaS company improving the early detection of breast cancer globally

Presentation of the Annual Report, FY2018

volpara[®]solutions[™]

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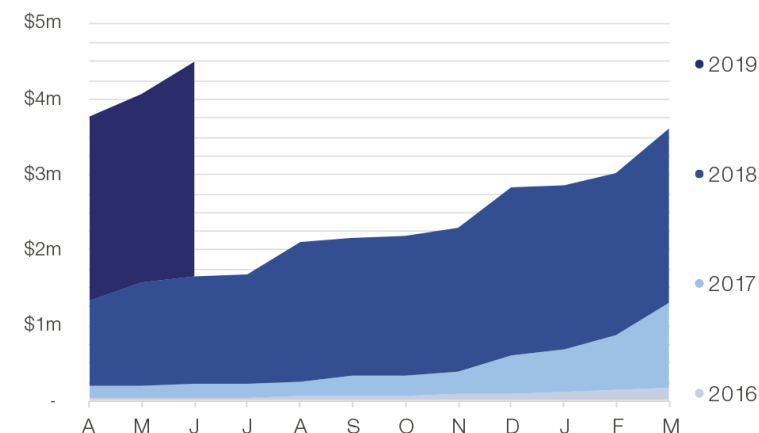
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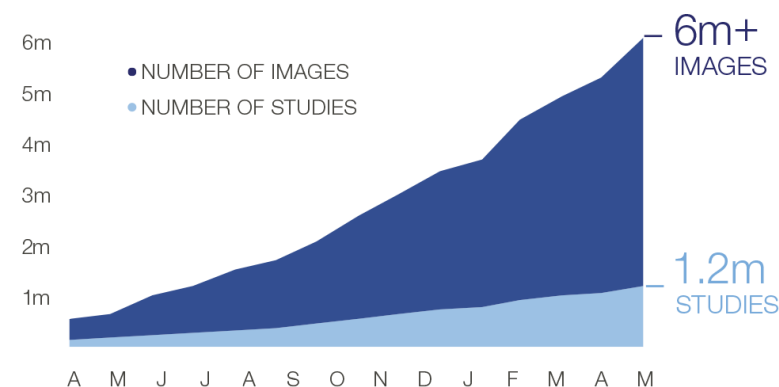
Chairman's Report – FY2018, a successful year

- FY2018 was very successful, the engineering team is delivering world-class products to a global audience, and we have an outstanding sales force in place predominantly in the US focusing on our largest market, which makes up ~90% of our sales.
- The key was VolparaEnterprise, our cloud-based breast imaging analytics software, for which FY2018 was the first year of real sales effort as we completed the move from capital to SaaS, and started to look at long-term contracts and increasing ARPU (price per woman).
- We also have a phenomenal data set now on which to develop new products using AI to continue to help reduce the overall impact of breast cancer, both in terms of mortality and cost.

GROWTH IN ARR



IMAGES AND STUDIES



Thank you Lyn, hello Monica & Paul



Dr Monica Saini

Chief Medical Officer

- Joined us Nov 2017
- Former Chief Breast Imaging in US radiology practice
- Former Medical Director, GE Breast Ultrasound Globally
- Lead radiologist at Hutt Valley, DHB, New Zealand
- Medical Advisor of Breast Cancer New Zealand Foundation



Paul Reid

Non-Executive Director

- Joined the Board in 2018, based Wellington.
- Former CEO of MetService, Figured, and Executive at AirNZ, Carter Holt Harvey.
- Chairman of Figured, Pukeko Pictures, Netlogix and Director for NZ listed Comvita.

We are well placed for FY2019 and beyond, thanks to the successful capital raise which was very well supported, and we'd like to thank new and existing investors who participated as well as Morgan's and Bell Potter for their help in that raise.

And thank you to the entire Volpara team for their contributions during FY2018.



CEO's Report – Breast cancer rates continue to rise

JAMA Oncology | Original Investigation

Global, Regional, and National Cancer Incidence, Mortality, Years of Life Lost, Years Lived With Disability, and Disability-Adjusted Life-Years for 29 Cancer Groups, 1990 to 2016

A Systematic Analysis for the Global Burden of Disease Study

Global Burden of Disease Cancer Collaboration

JAMA Oncol. doi:10.1001/jamaoncol.2018.2706

Published online June 2, 2018.



- Every year 1.5 million women are diagnosed with breast cancer globally.
- 535,000 women globally die annually of breast cancer, making it the leading cause of cancer death in women.
- Rates of breast cancer continue to rise across Asia and Africa at alarming rates.....and the National Cancer Institute forecasts number of breast cancers diagnosed in the US to increase by 50% by 2030.

Major new studies give hope, but early detection is still key

Precision Medicine and Radiogenomics in Breast Cancer: New Approaches toward Diagnosis and Treatment¹

Katja Pinker, MD, PhD²
Joanne Chin, BS, MFA
Amy N. Melsaether, MD
Elizabeth A. Morris, MD
Linda Moy, MD

radiology.rsna.org • **Radiology**: Volume 287: Number 3—June 2018

Many breast cancer patients can skip chemo, landmark study finds

MARILYNN MARCHIONE
Last updated 02:03, June 4 2018



lev.dolgachov/123RF

A landmark study has found chemo does not have much use for many women with breast cancer.

Most women with the most common form of early-stage breast cancer can safely skip chemotherapy without hurting their chances of beating the disease, a landmark US study finds.

The study is the largest ever done of breast cancer treatment, and uses genetic testing to gauge each patient's risk.

The results are expected to spare up to 70,000 patients a year in the United States and many more elsewhere the ordeal and expense of these drugs.



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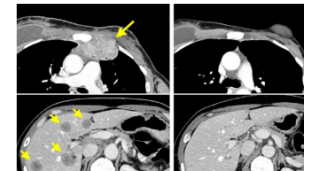
NEWS RELEASES

Monday, June 4, 2018

New approach to immunotherapy leads to complete response in breast cancer patient unresponsive to other treatments



A novel approach to immunotherapy developed by researchers at the National Cancer Institute (NCI) has led to the complete regression of breast cancer in a patient who was unresponsive to all other treatments. This patient received the treatment in a clinical trial led by Steven A. Rosenberg, M.D., Ph.D., chief of the Surgery Branch at NCI's Center for Cancer Research (CCR), and the findings were published June 4, 2018 in *Nature Medicine*. NCI is part of the National Institutes of Health.

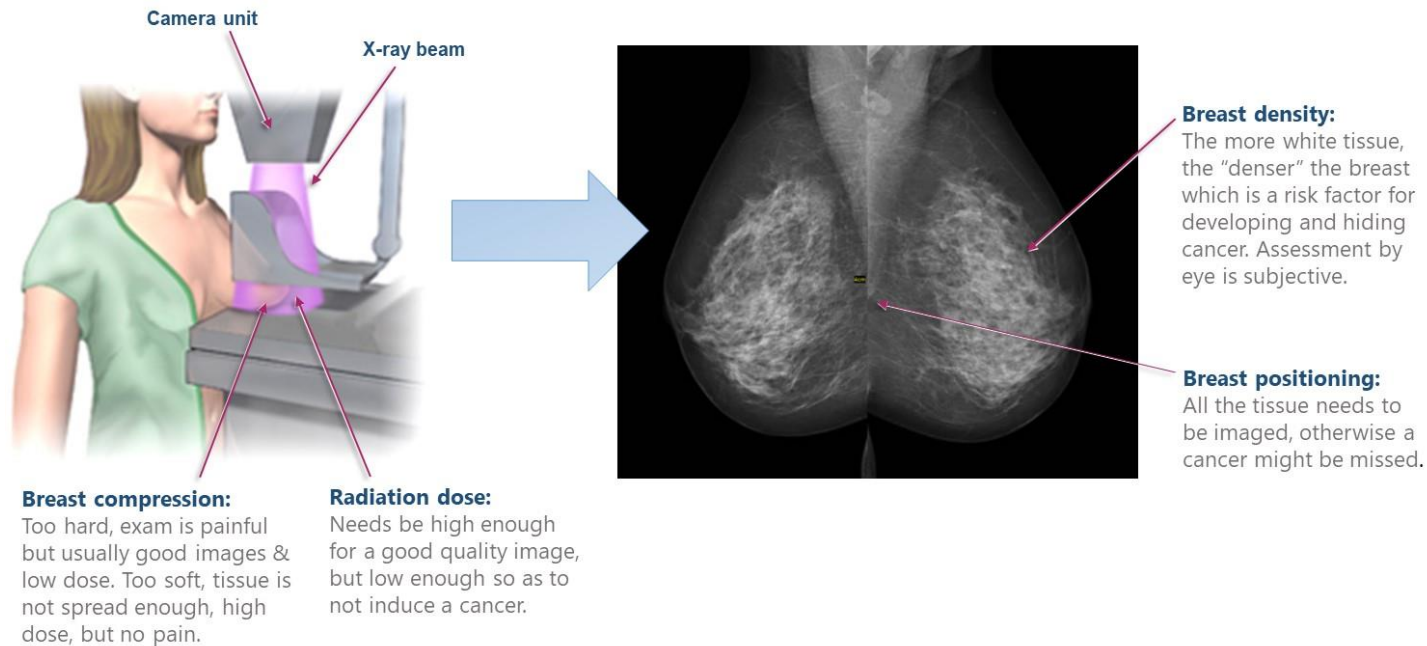


Early detection leads to reduced mortality, less invasive cancer treatment, and reduced cost.

Screening using x-rays remains the best method of early detection.

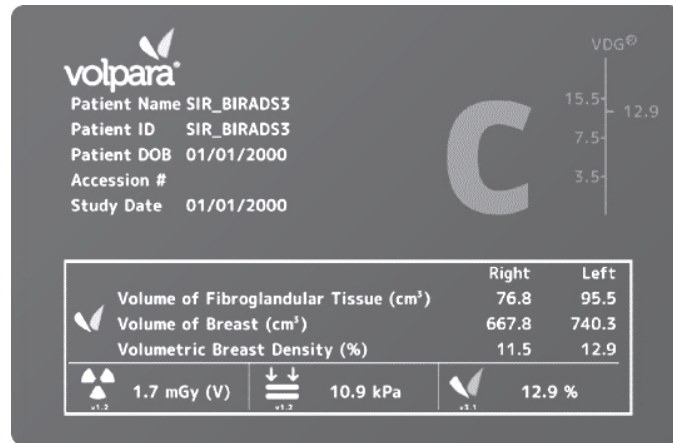
The VHT mission has expanded beyond screening

To reduce the mortality and cost of breast cancer through software that allows control of high-quality screening, diagnosis & treatment.



Volpara is unique in measuring and reporting on all these metrics for all major x-ray vendors.

VolparaDensity correlates to risk of missing cancer



Automated Volumetric Analysis of Mammographic Density in a Screening Setting: Worse Outcomes for Women with Dense Breasts

Nataliia Moshina, MD, PhD • Sofie Sebuodegård, MSc • Christoph I. Lee, MS, MD • Lars A. Akslen, MD, PhD • Kaitlyn M. Tsuruda, MSc • Joann G. Elmore, MD, MPH • Solveig Hofvind, PhD

From the Cancer Registry of Norway, Oslo, Norway (N.M., S.S., K.M.T., S.H.); Departments of Radiology (C.I.L.) and Medicine (J.G.E.), University of Washington School of Medicine, Seattle, Wash; Department of Clinical Medicine, Section for Pathology, Centre for Cancer Biomarkers (CCBIO), Bergen, Norway (L.A.A.); Department of Pathology, Haukeland University Hospital, Bergen, Norway (L.A.A.); and Oslo Metropolitan University, Faculty of Health Science, Oslo, Norway (S.H.). Received December 20, 2017; revision requested February 2, 2018; final revision received March 26; accepted April 12. Address correspondence to S.H. (e-mail: Solveig.Hofvind@kreftregisteret.no).

Conflicts of interest are listed at the end of this article.

See also the editorial by Philpotts in this issue.

Radiology 2018; ■:1–10 • <https://doi.org/10.1148/radiol.2018172972> • Content code: BR

Puliti et al. Breast Cancer Research (2018) 20:95
<https://doi.org/10.1186/s13058-018-1025-8>

Breast Cancer Research

RESEARCH ARTICLE

Open Access



Volumetric breast density and risk of advanced cancers after a negative screening episode: a cohort study

Donella Puliti^{1*}, Marco Zappa¹, Paolo Giorgi Rossi², Elena Pierpaoli³, Gianfranco Manneschi¹, Daniela Ambrogetti³, Leonardo Ventura¹, Paola Mantellini³ and the DENSITY Working Group

Annals of Internal Medicine

ORIGINAL RESEARCH

Automated and Clinical Breast Imaging Reporting and Data System Density Measures Predict Risk of Screen-Detected and Interval Cancers

Karla Kerlikowske, MD; Christopher G. Scott, MS; Amir P. Mahmoudzadeh, MScEng; Lin Ma, MS; Stacey Winham, PhD; Matthew R. Jensen, BS; Fang Fang Wu, BS; Sergei Malkov, PhD; V. Shane Pankratz, PhD; Steven R. Cummings, MD; John A. Shepherd, PhD; Kathleen R. Brandt, MD; Diana L. Miglioretti, PhD; and Celine M. Vachon, PhD

VolparaDensity and risk of developing breast cancer

European Journal of Cancer 88 (2018) 48–56



Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.ejancer.com



Original Research

Mammographic density and breast cancer risk in breast screening assessment cases and women with a family history of breast cancer

Stephen W. Duffy ^{a,*}, Oliver W.E. Morrish ^b, Prue C. Allgood ^a, Richard Black ^b, Maureen G.C. Gillan ^c, Paula Willsher ^d, Julie Cooke ^e, Karen A. Duncan ^f, Michael J. Michell ^g, Hilary M. Dobson ^h, Roberta Maroni ^a, Yit Y. Lim ⁱ, Hema N. Purushothaman ^j, Tamara Suaris ^k, Susan M. Astley ^l, Kenneth C. Young ^m, Lorraine Tucker ^d, Fiona J. Gilbert ^d



Astley et al. Breast Cancer Research (2018) 20:10
DOI 10.1186/s13058-018-0932-z

Breast Cancer Research

RESEARCH ARTICLE

Open Access



A comparison of five methods of measuring mammographic density: a case-control study

Susan M. Astley^{1,2†}, Elaine F. Harkness^{1,2†}, Jamie C. Sergeant^{3,4}, Jane Warwick⁵, Paula Stavrinou², Ruth Warren⁶, Mary Wilson², Ursula Beetles², Soujanya Gadde², Yit Lim², Anil Jain^{2,7}, Sara Bundred², Nicola Barr², Valerie Reece², Adam R. Brentnall⁸, Jack Cuzick⁸, Tony Howell^{2,9} and D. Gareth Evans^{2,9,10}

These papers led to the PROCAS II project which are around implementation of density and risk into the UK's NHS BSP.

The trial goes live shortly – exciting not only for the commercial possibilities, but also this is our first IoT implementation – should dramatically reduce costs in future for support, critical as we continue to grow globally.

Breast Density – US State & Federal Laws – 88% women now covered



DenseBreast-info, Inc.

Yesterday at 4:50 AM · 🌐

35th state: Illinois Gov. Rauner has signed that state's density inform bill into law; effective 1/1/19. Now 88% of American women live in states that require some level of density inform. Look for map update tonight.
<http://www.ilga.gov/legislation/BillStatus.asp...>



Nancy Cappello, PhD

@DrNancyCappello



Illinois @GovernorRauner approves 36th state #BreastDensity law/Illinois is PINK on @AreYouDenseAdvo map/time for a national standard @SGottliebFDA @US_FDA/10 years ago no laws until #Connecticut disrupted the status quo in 2009! Learn More AreYouDenseAdvocacy.org @ahraonline

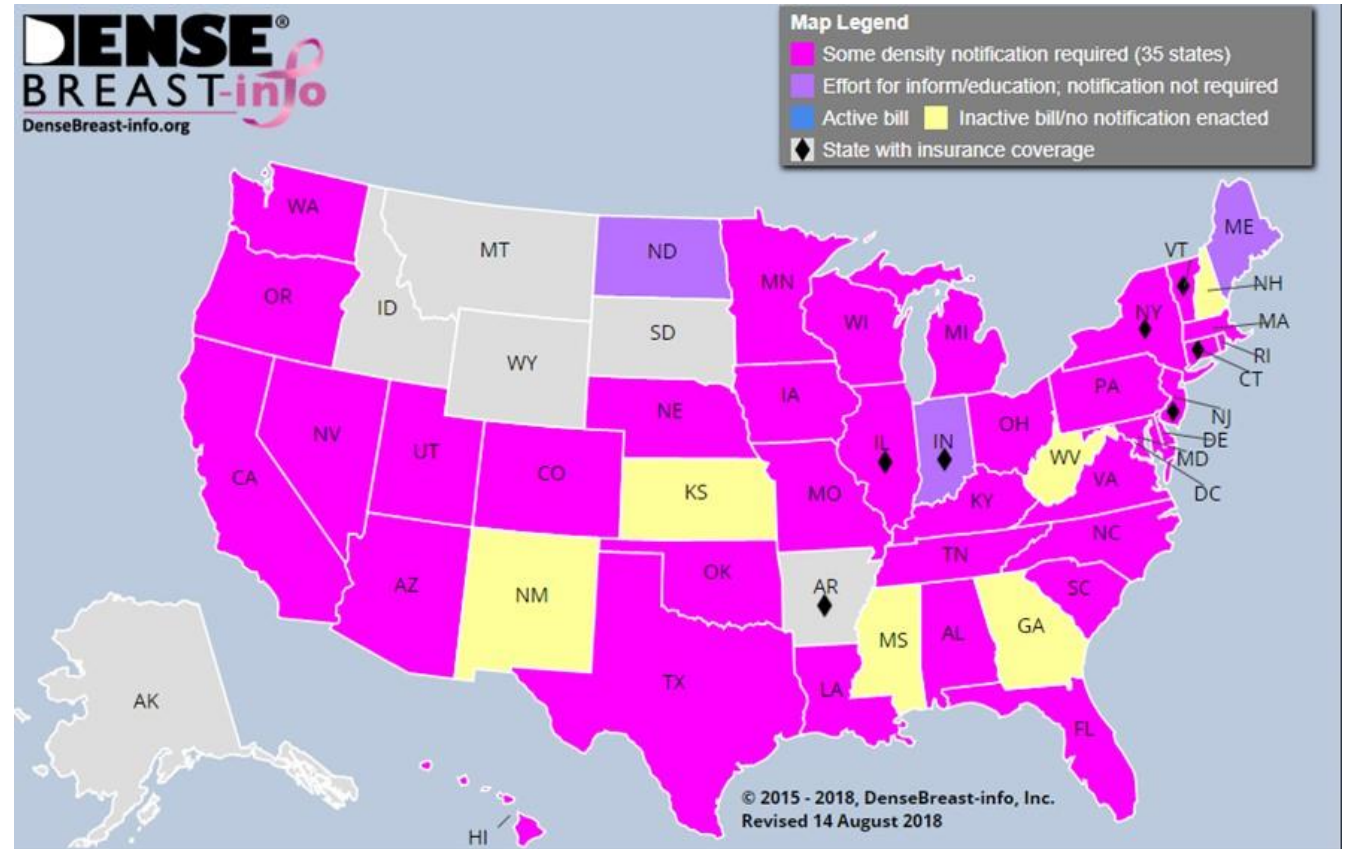
7:23 AM - Aug 14, 2018



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See Nancy Cappello, PhD's other Tweets



Breast Density – Australia

Facebook Twitter Email

Ethical and Legal Considerations in Breast Density Workshop

Thursday 23rd August 10 am – 4 pm 2018
Basil Hetzel Institute
37A Woodville Rd, Woodville, South Australia

In this workshop, experts in breast density, breast cancer screening, health ethics and the law, together with patients and clinicians, will identify and explore ethical and legal issues associated with breast density notification.

Attendance is free, however you need to register for catering purposes by Friday 17th August.
To download the registration form, please click [here](#).
To view the program and list of presenters, please click [here](#).

Ethical and Legal Considerations in Breast Density

Adelaide Workshop 2018

Please direct queries to A/Prof Wendy Ingman
Email: wendy.ingman@adelaide.edu.au
Phone: (08) 8222 6141

Why Study Mammographic Density? Conference

October 10-11, 2018
Victorian Comprehensive Cancer Centre
Melbourne, Australia

Please join us this **October 10th-11th in Melbourne, Australia** at the new Victorian Comprehensive Cancer Centre to discuss recent developments in mammographic density research and how to translate what we know into clinical practice.

Please visit the conference [website](#).

Register [here](#) and submit your Abstract [here](#)!

Deadline for Abstract submission: August 15th, 2018

Email [here](#)
Follow us on Facebook [here](#)

INFORMD
INformation FORum on Mammographic Density

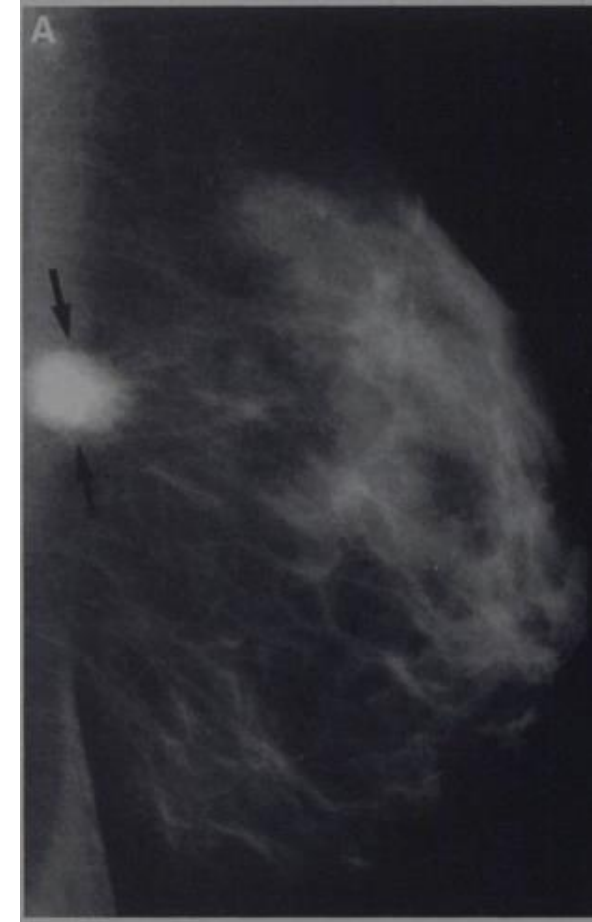
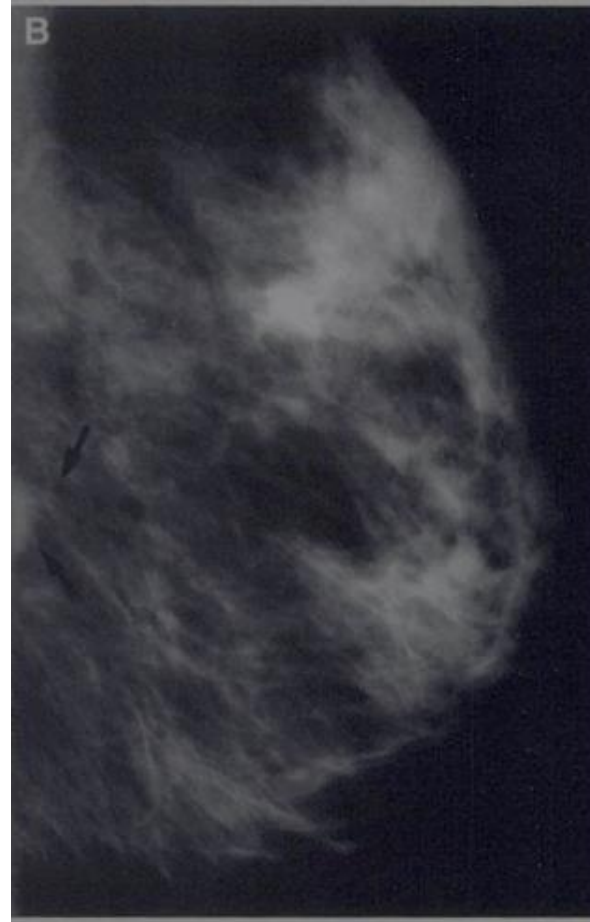
Today (22nd August) in Adelaide.

Quality is also critical, FDA EQUIP continues to drive sales



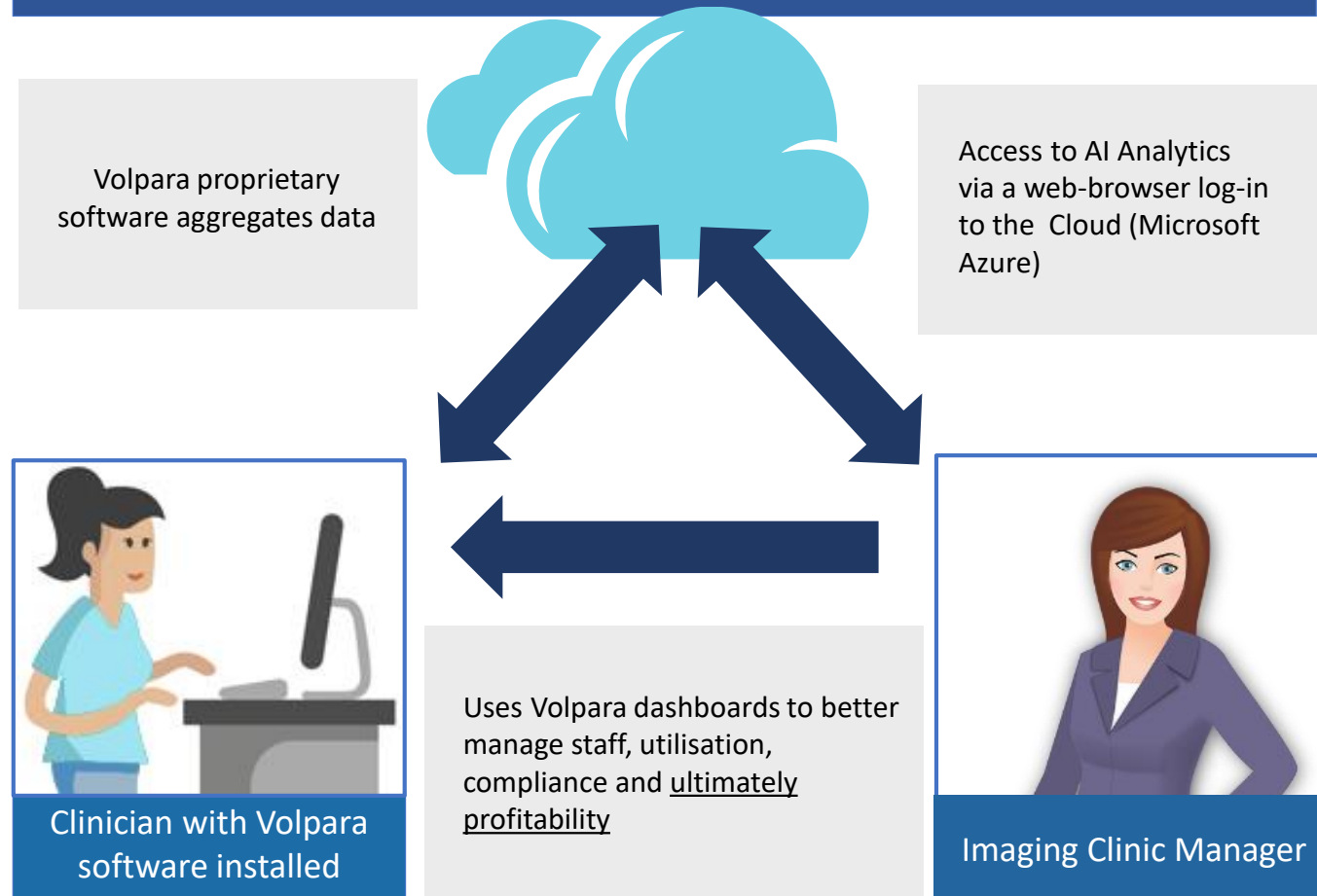
EQUIP: Enhancing Quality Using the Inspection Program

" MQSA's emphasis on the significance of clinical image quality, which is one of the most important determinants of the accuracy of mammography. "

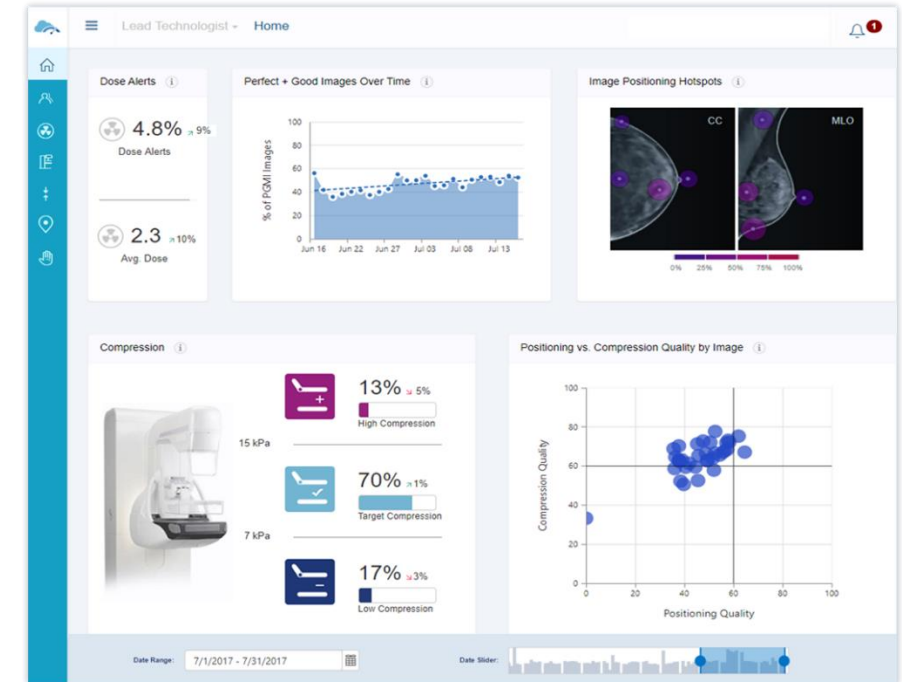


VolparaEnterprise – Cloud-based Breast Imaging Analytics

Volpara Cloud powered by Artificial Intelligence



VolparaEnterprise Dashboard



End March 2018, over 1M women's images flowing to our Cloud.

VolparaEnterprise 2.2.1 launched

VolparaEnterprise™

Home

Technologist

Dose

Maps

Positioning

Compression


Machine

Compliance

Technologist Performance Review

Accreditation

Lead Technologist ▾ Compliance > Technologist Performance Review

Volpara Clinic 

Positioning Summary ⓘ

Technologist: Unselected

Perfect
16.6%

Good
21.5%

Moderate
59.9%

Inadequate
2.0%

Positioning Summary ⓘ

Positioning Metrics	ImageView	% of Images	Top 10%	Rating
IMF Missing	MLO	35.0%	13.9%	☆☆☆☆
MLO Cutoff	MLO	2.0%	0.7%	☆☆☆☆
Pec Skinfolds	MLO	7.4%	4.1%	☆☆☆☆
Pec to PNL Not Met	MLO	33.8%	22.3%	☆☆☆☆
CC PNL Not Met	CC	25.7%	13.8%	☆☆☆☆
Inadequate Pec	MLO	47.4%	33.1%	☆☆☆☆
CC Cutoff	CC	1.2%	0.4%	☆☆☆☆
Concave Pec Shape	MLO	21.2%	16.1%	☆☆☆☆
MLO Nipple Not in Profile	MLO	14.8%	11.2%	☆☆☆☆
Nipple Excessive Exag	CC	21.2%	16.5%	☆☆☆☆
CC Nipple Not in Profile	CC	14.3%	13.6%	☆☆☆☆

Compression Summary ⓘ

High
10.6%

Target
58.5%

Low
30.9%

Positioning Summary ⓘ

Compression Classification	CC	MLO
High Compression	18.7%	2.4%
Low Compression	19.5%	42.6%
Target Compression	61.8%	55.0%

Image Review ⓘ

Study Date	Study ID	Image ...	Image Side	Image View	Mammo...	Position...	Patient ID
17 August 2...	13612	55456	Left	MLO	WC Cent...	Moderate	c7loizbb...
17 August 2...	13612	55459	Right	MLO	WC Cent...	Moderate	c7loizbb...
17 August 2...	14133	57031	Right	CC	WC Cent...	Good	j2lyfwn3...
17 August 2...	14133	57033	Left	CC	WC Cent...	Good	j2lyfwn3...
17 August 2...	14136	57040	Right	CC	WC Cent...	Moderate	6dr7af4...
17 August 2...	14136	57041	Left	CC	WC Cent...	Moderate	6dr7af4...
17 August 2...	14139	57054	Right	CC	WC Cent...	Good	dhg524...
17 August 2...	14139	57055	Left	MLO	WC Cent...	Moderate	dhg524...
17 August 2...	14265	57530	Right	MLO	WC Cent...	Moderate	hab6ifvs...
17 August 2...	14265	57532	Right	MLO	WC Cent...	Moderate	hab6ifvs...
17 August 2...	14281	57589	Left	CC	WC Cent...	Moderate	n3q33u...
17 August 2...	14281	57591	Right	MLO	WC Cent...	Good	n3q33u...
17 August 2...	14281	57592	Right	CC	WC Cent...	Moderate	n3q33u...
17 August 2...	14343	57864	Left	MLO	WC Cent...	Moderate	xp4urxd...
17 August 2...	14343	57865	Right	MLO	WC Cent...	Moderate	xp4urxd...
17 August 2...	14343	57867	Right	CC	WC Cent...	Moderate	xp4urxd...
17 August 2...	14408	58143	Left	CC	WC Cent...	Moderate	iyuvav2h...
17 August 2...	14408	58144	Left	MLO	WC Cent...	Moderate	iyuvav2h...
17 August 2...	14408	58145	Right	MLO	WC Cent...	Moderate	iyuvav2h...
17 August 2...	14410	58152	Right	CC	WC Cent...	Moderate	3717m5l...

Last Updated: Aug 19 2018 12:02PM

Filters

Breast Implants

Clinic

Study Purpose

Image View

Study Positioning Score


Technologist


Compression Pressure Classification

Export table data

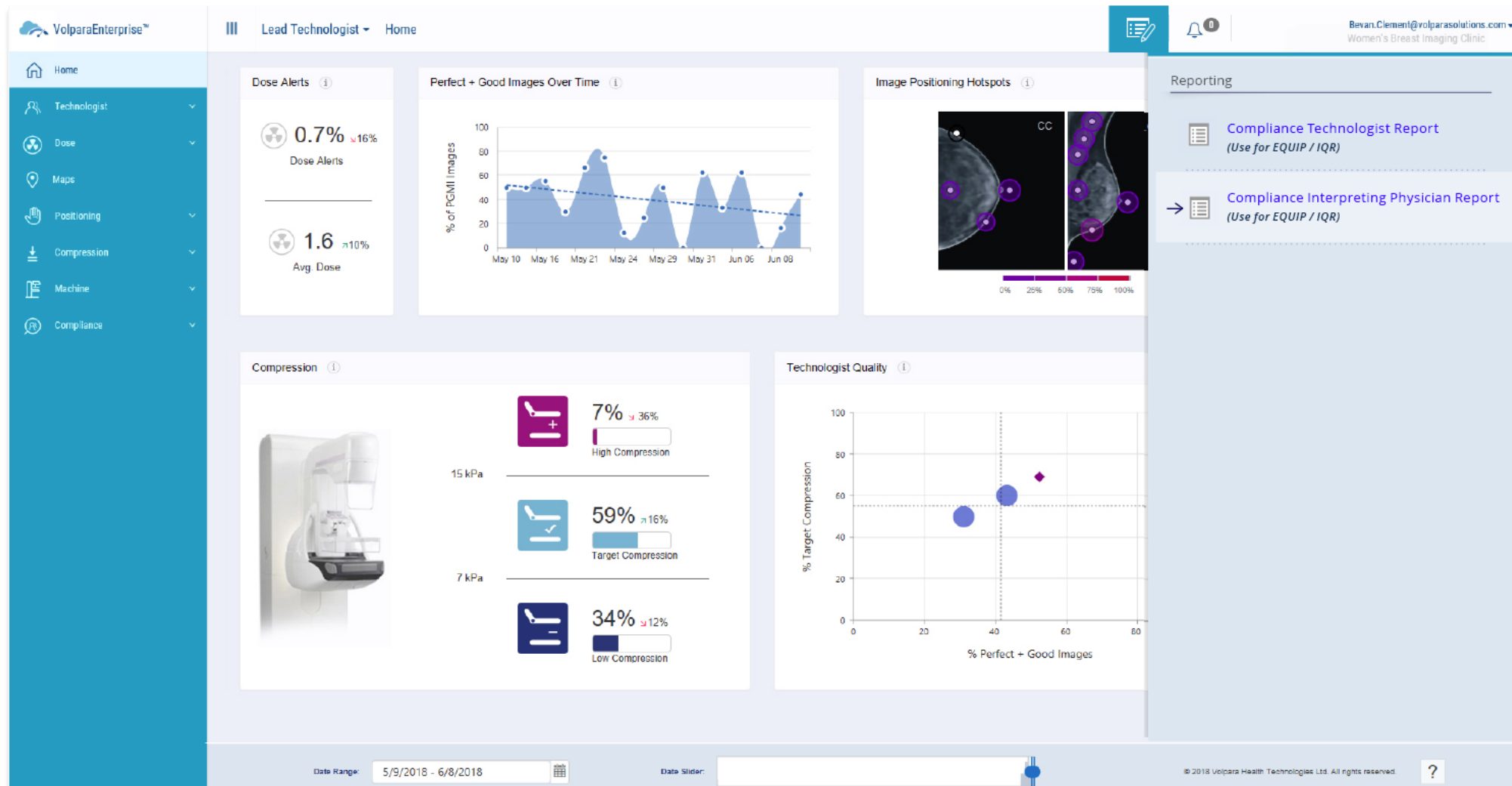
Export

Date Range: 7/20/2018 - 8/19/2018

Date Slider: 

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VolparaEnterprise 2.2.2 due for release Sept 2018



VolparaEnterprise case studies – Mayfair, Canada

Facts and Figures

- 10 breast imaging locations in Calgary, Alberta, Canada
- 54,000 mammograms annually
- 44 technologists
- 10 FFDM systems offering screening and diagnostic imaging
- Centralized quality control
- VolparaEnterprise software in use since February 2017

Mayfair Diagnostics Locations



"There is something comforting about having the quality assessed on every mammogram I take," Katie adds. "It gives me constant and very specific reminders about what I can do to improve, and provides me with a rewarding feeling when I'm doing a good job. I can't imagine doing mammography without VolparaEnterprise."



Jan.-June 2017 compared to July-Dec. 2017

Inadequate Images



Jan.-June 2017 compared to July-Dec. 2017

Target Compression



Jan.-June 2017 compared to July-Dec. 2017

Technical Recalls



Jan.-June 2017 compared to July-Dec. 2017

VolparaEnterprise case studies – Invision Diagnostics



"As a radiologist, my ability to detect breast cancer is limited by the quality of the mammogram images that are presented. VolparaEnterprise gives us the ability to monitor the technical quality of every mammogram performed in our mobile coaches. This provides our patients and their physicians with the confidence that they will consistently receive a high-quality mammogram," said Kenneth Fox, MD, Chief Medical Officer, Invision Diagnostics. "Additionally, with objective breast density assessment, we can more accurately identify high-risk patients that may require adjuvant screening."

VolparaEnterprise case studies – image quality is improving

Month on Month Comparison

Technologist	# of Images - Prev	# of Images - Current	Quality Score - Prev	Quality Score - Current	% Change	Positioning Quality - Prev	Positioning Quality - Current	% Change	Compression Quality - Prev	Compression Quality - Current
1	1167	969	1.90	2.20	16%	36%	48%	35%	64%	64%
2	182	170	1.60	2.00	25%	31%	43%	36%	55%	60%
3	1523	1748	2.00	2.10	5%	43%	46%	7%	58%	64%
4	155	50	1.30	1.70	31%	21%	40%	92%	49%	47%
5	686	857	2.00	2.20	10%	43%	47%	8%	61%	66%
6	1176	1072	1.60	2.00	25%	26%	44%	70%	63%	60%
7	789	1000	1.30	2.20	69%	23%	48%	113%	49%	63%
8	1477	1700	1.80	1.90	6%	39%	41%	6%	55%	59%
9	733	726	1.50	2.20	47%	24%	49%	103%	55%	64%
10	931	937	1.30	2.10	62%	24%	46%	95%	48%	64%
11	760	995	1.20	2.30	92%	15%	51%	231%	55%	70%
12	910	987	1.70	2.20	29%	27%	49%	81%	64%	65%
13	575	329	1.60	1.70	6%	29%	45%	54%	54%	39%
14	1592	1845	1.70	1.80	6%	40%	42%	4%	47%	50%
15	182	189	1.70	1.80	6%	40%	41%	3%	46%	54%
16	1393	1733	1.70	1.90	12%	31%	43%	38%	61%	53%
Total	14231	15307	1.62	2.02	28%	31%	45%	61%	55%	59%

New Zealand continues to adopt



St Marks (Auckland)

Auckland Breast Centre

Mercy Radiology (Auckland)

**Broadway Radiology
Palmerston North**

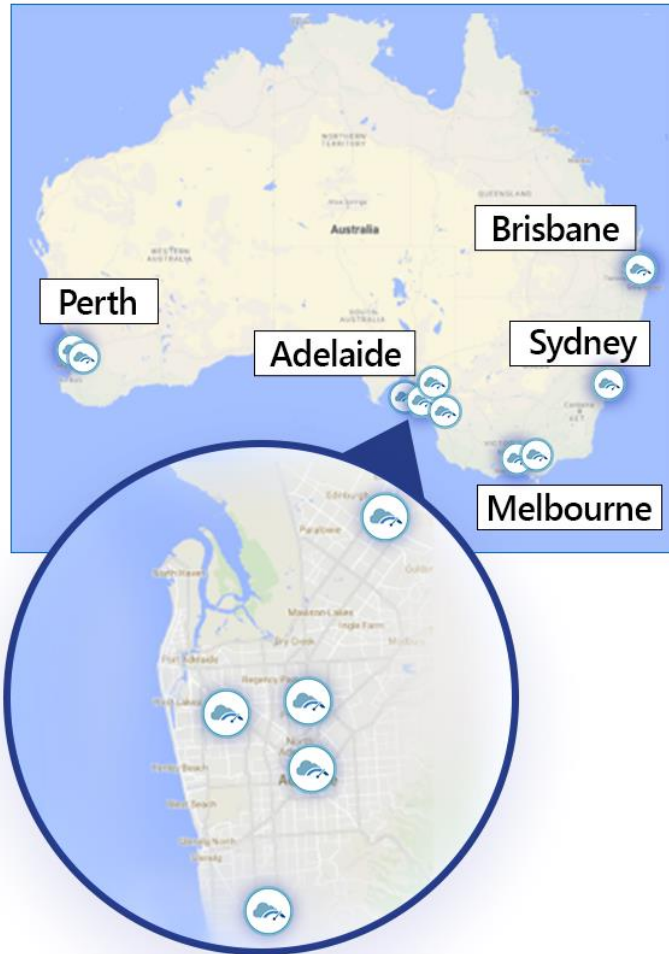
Private screening gives patients a density score, and use risk models such as Tyrer-Cuzick 8 to triage patients.

Mercy & Broadway are also Enterprise customers.

One NZ public screening site is trialing VolparaEnterprise:

- 3 Public Screening Sites, 1 Hospital, 1 mobile truck
- Their focus is on PGMI and Radiographer training, i.e. quality

Australia adoption in each major center



Adelaide

Jones and Partners, Lyall McKeon and Flinders, Queen Elizabeth Hospitals

Brisbane

Wesley Clinic

Sydney

Alfred\Mater Imaging- latest Enterprise Sale in Australia

Melbourne

Imaging Associates- PGMI and TC8 Risk experts
MIA Monash – part of iMed.

Perth

WBI, renewing Enterprise contract for 3rd year
Royal Perth Hospital using Volpara for Dose and CESM



Every hour the technologist spends using our software they qualify for continuing professional development credits.

Big screening programs – interest is rising

Region	Status
UK	PROCAS II trial underway around Manchester UK, goes live imminently, this is a 2 year IT implementation trial.
Australia	We have one successful state-wide trial complete, working through budget process now, and another about to start.
New Zealand	Trial of Enterprise underway with one region.
Norway	Publishing many papers and working closely with us across a range of matters, but principally breast density.
Netherlands	The DENSE trial is in to its 9 th year, results on doing breast MRI on women with extremely dense breasts are close.

Intellectual property position

VHT protects its on-going innovation with the most effective combinations of IP rights, to anticipate new product development globally

VHT intellectual property currently includes:

35 granted patents

34 national patent applications in final stage of process

2 international patent proceeding in 80 countries

2 new international patent applications

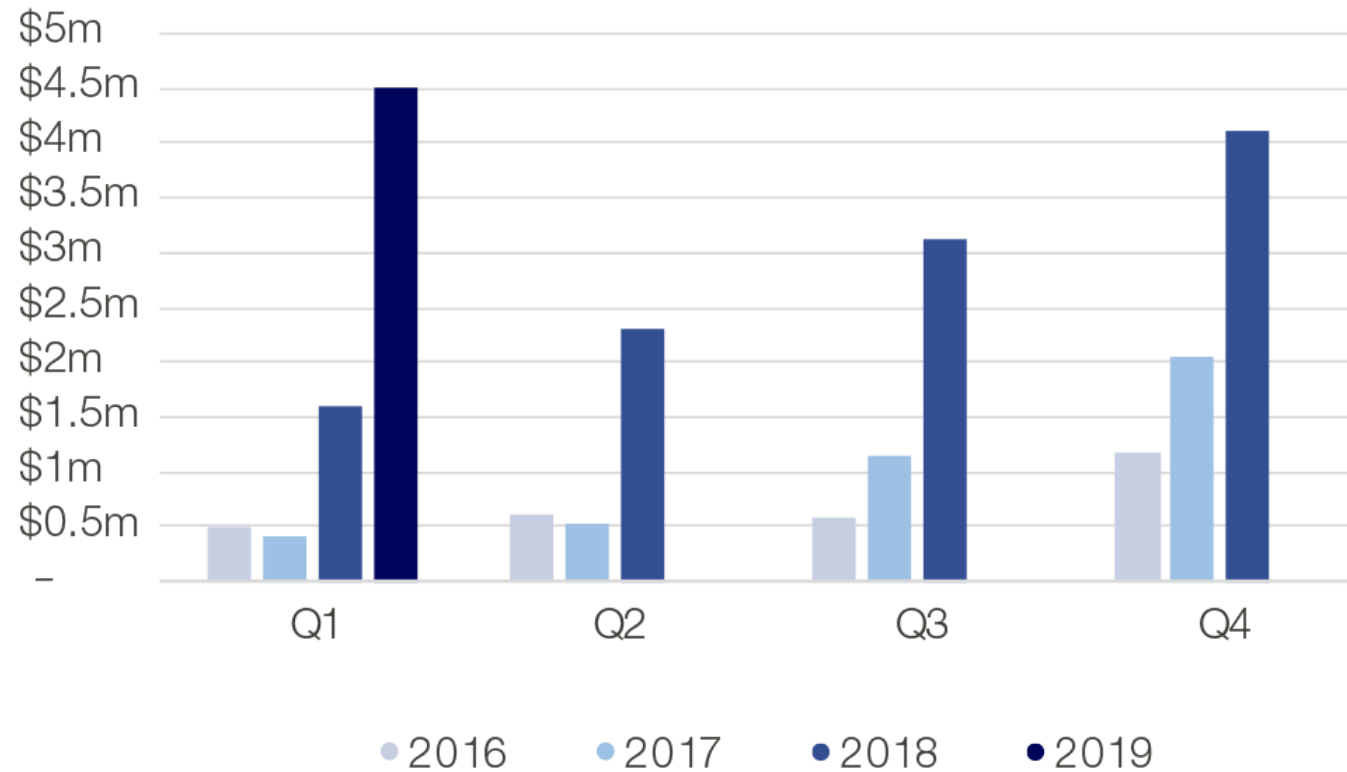
registered trademarks in 39 countries

copyright works (software, graphics and text) and

Trade Secrets (which protect the key part of the code)

Thank you to all our inventors, including Director Mike Brady and Scientific Advisors Nico Karssemeijer and Martin Yaffe

Achievements in FY2018 – Total Contract Value (TCV) growth



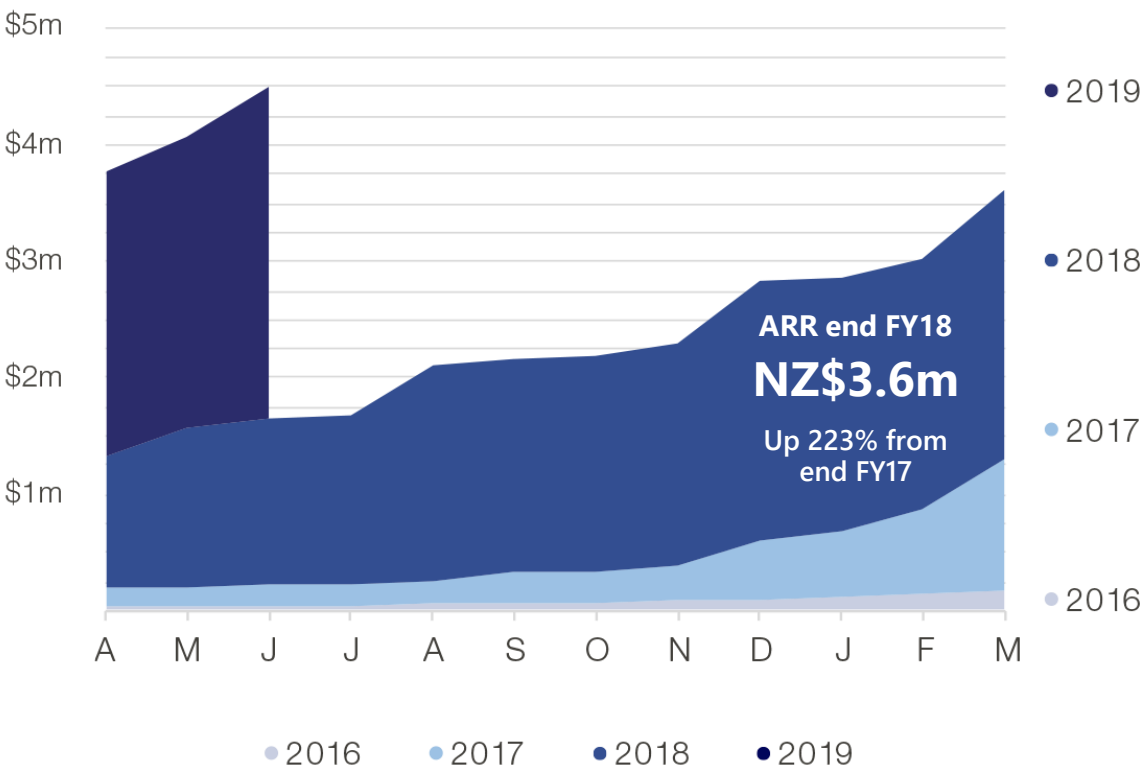
Total Contract Value
(SaaS, Service & Capital)
signed in FY18

NZ\$11.2m

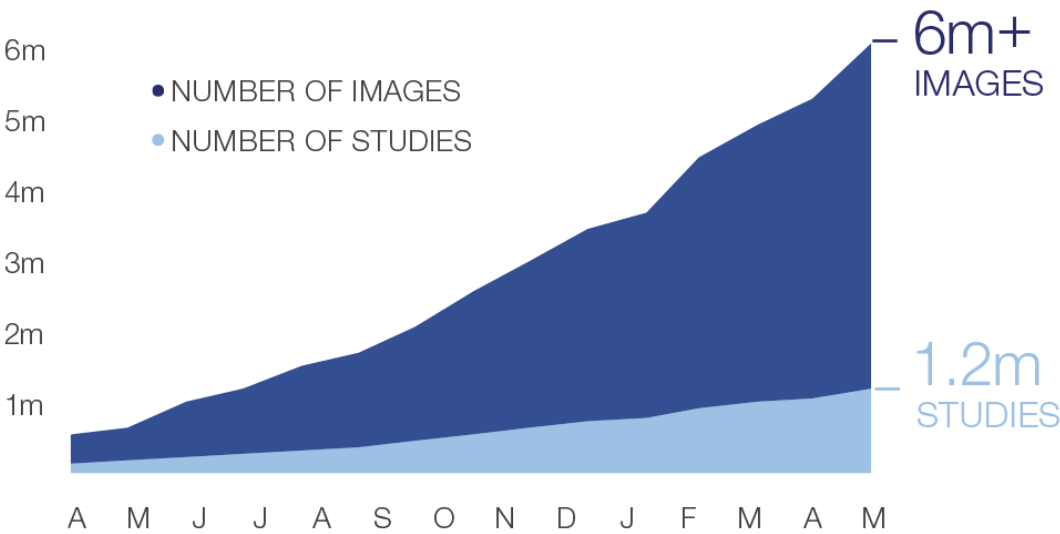
Up 173% from
end FY17

Achievements in FY2018 – Annual Recurring Revenue (ARR) growth

GROWTH IN ARR



IMAGES AND STUDIES



Approximately **3.7%** of the US women being screened were going through Volpara at end June 2018.

Changing product mix

CHANGING PRODUCT MIX

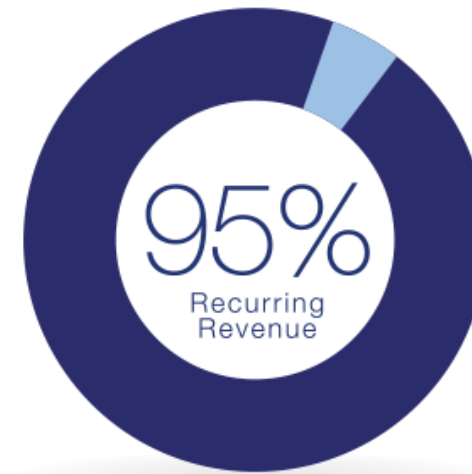
- Capital Sales
- Recurring Revenue



FY16



FY17



FY18

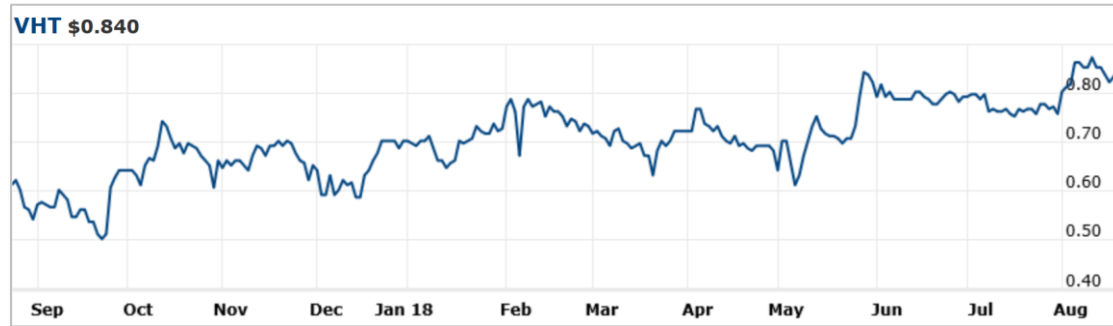
We've moved recurring revenues from 8% in **FY16** to over 95% in **Q1 FY19**, almost all from SaaS contracts. These contracts are building a growing pipeline of future revenue, but with many of the customers paying annually up front.

Key FY17 vs FY18 numbers

	FY18 NZ\$ '000's	FY17 NZ\$ '000's	\$ Variance NZ\$ '000's	% Variance
SaaS revenue	1,902	93	1,809	+1,945%
Capital revenue	575	1,527	(952)	-62%
Service maintenance agreement revenue	304	219	85	+39%
Other revenue	31	-	31	+100%
Total revenue	2,812	1,839	973	+53%
Total income, incl. grants	3,535	2,047	1,488	+73%
Gross margin percentage (%)	70	63	7	+11%
Net loss after taxes (NZ\$ '000's)	(8,818)	(9,571)	753	-8%
Cash receipts from customers (NZ\$ '000's)	3,068	2,270	798	+35%
Total no. of VolparaEnterprise contracts signed	57	14	43	+307%

Corporate overview

VHT's recent share price momentum reflects confirmation of achievement of FY2018 sales targets, a strong start to Q1FY19 and the successful, oversubscribed, placement and share purchase plan in May 2018.



Share Register Breakdown



- Brought on a number on institutions in the May '18 placement
- The Founders and Directors have agreed to escrow their mandatory IPO escrowed shares (51.48m) for a further 12 months (until 27 April 2019).

Thank you WE Buchan.

Share & financial information

Share price (22 August 2018)	A\$0.84
52 week low / high	A\$0.50-A\$0.89
Current shares on issue:	
- Listed ASX	127.67m
- Subject to voluntary escrow ¹	51.48m
Total Shares	179.16m
Market Capitalisation	A\$150.4m
Cash (30 June 2018)	NZ\$22.785m / A\$20.96m
Debt (30 June 2018)	No debt
Enterprise value	A\$129.4m

1. Voluntary escrow of founders / directors shares until 27 April 2019
2. Assumes AUD / NZD exchange rate of A\$0.92/NZ\$1.00

Capital raise objectives and status

We raised \$20M in April 2018 to:

Build out our US market share:

- We now have 15 direct sales people on the ground in the US with support staff
- We now have a dedicated person for the OEM's
- Challenges include IT security (ISO27001), regulatory changes globally
- Targeting NZ\$9M ARR, which is 9% of US market at \$2 ARPU.

Bring more products through and increase ARPU (price per woman)

- Resources flowing into Wellington to allow multiple product delivery at once
- Expanded service delivery team ensuring up-time
- Real-time quality control into alpha testing and regulatory
- Expanding knowledge of surgery
- Expanding our machine learning capabilities

Do more in Asia

- US team expansion has freed up APAC team.
- Major trial underway across Singapore with big private health chain
- Targeting big OEM for Japan

RSNA 2018
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RADIOLOGY TODAY
NOVEMBER 25-30



Appendix

volparasolutions.com | NZ 2206998 | ARBN 609 946 867



Global regulatory status

VolparaDensity is considered in most jurisdictions to be a medical “device” since it measures and estimates specific information about the patient.

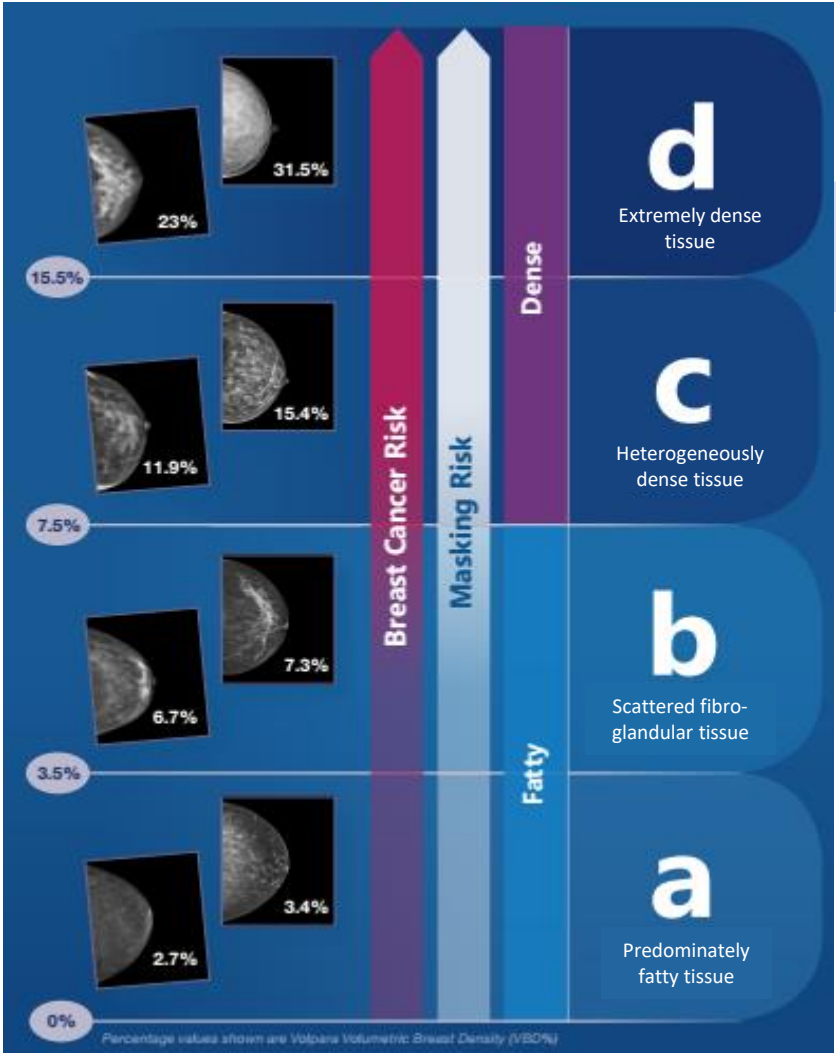
Regulatory bodies in each market dictate that medical devices must be manufactured to the highest standards and cleared before they can be marketed in that country. This presents significant barriers to entry for new market participants.

In the US, Volpara has achieved three FDA 510(k) clearances so far covering *VolparaDensity*:

K102556 (2010), K152028 (2015), and K153427 (2016).

We are also cleared in Europe (Class 1m), Australia, NZ, Canada, South Korea, Thailand, Japan & Taiwan, and other countries that do not regulate software medical devices.

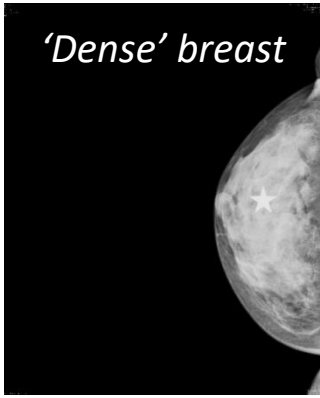
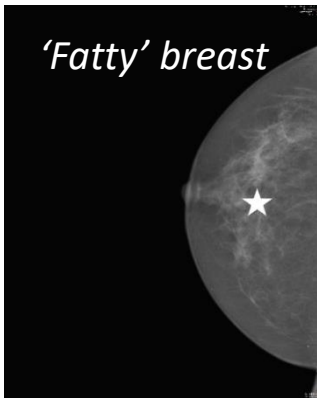
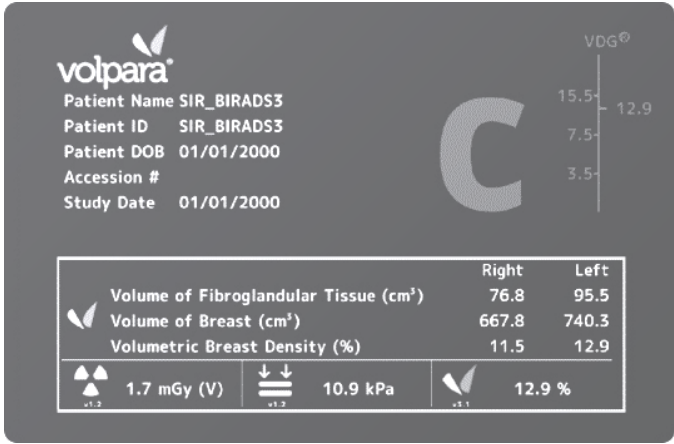
VolparaDensity



FDA cleared 510(k)

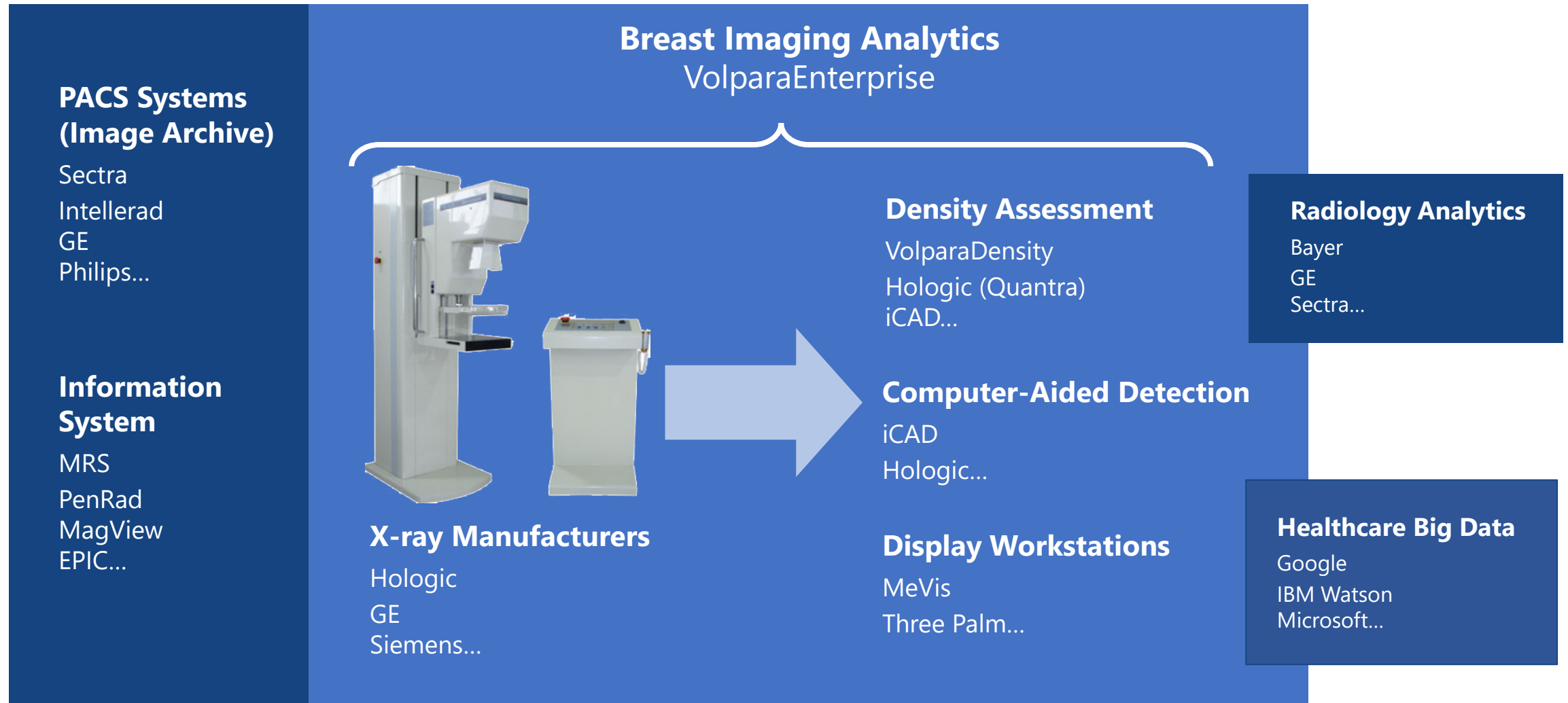
Volpara Density

Automated, objective, density, dose and compression scoring for each patient.



The white star mimics a cancer – easy to see in a fatty breast, much harder on a dense breast.

Companies* in our space in the US



*Main companies with FDA clearance, there are many smaller ones in the space.

Competitive Analysis* – Density, Dose and Pressure

To the best of our knowledge, based on marketing materials, FDA information, trade shows and other public sources:

Criteria	Volpara Density	iCAD iReveal	Hologic Quantra
FDA cleared to assess breast density for some x-ray systems	Y	Y	Y
Independent, vendor neutral – FDA cleared to work with all leading system manufacturers for 2D mammography & 3D tomosynthesis	Y	Y	N
Automatically generates a quantitative volumetric measurement of density	Y	N	Y
Measures compressed thickness of dense tissue to show “focal density” masking risk	Y	N	Y
Clinical Density Map with 1 cm focal density indicator	Y	N	N
Reduces challenge of determining density in synthetic 2D images: C-View, V-Preview	Y	Y	Y
Backed by global validation and more than 250 publications	Y	N	N
Correlated to breast cancer risk and mammography sensitivity in multiple studies	Y	N	N
Patient-specific dose and applied pressure measurements	Y	N	N
Included directly into Tyrer-Cuzick breast cancer risk tool?	Y	N	N

*Philips, Siemens, Densitas, MammoRisk limited user-base



Competitive Analysis* – Analytics and Management Tools

To the best of our knowledge, based on marketing materials, FDA information, trade shows and other public sources:

Criteria	Volpara Enterprise	Philips Intellispace	GE Health Cloud (Dose Watch)	Siemens Teamplay	Sectra Cloud (Dose Track)
Designed primarily for breast rather than general radiology	Y	N	N	N	N
Vendor-neutral density, dose, compression	Y	N	N	N	N
Image viewing in the cloud	Y	Y	Y	Y	Y
Technologist workflow analytics	Y	?	?	?	?
Application of cloud-based learning: • Clinical application for breast density, personalized dose based on breast density and breast compression pressure	Y	N	N	N	N
Automated analysis of patient positioning in mammography	Y	N	N	N	N
Clinical applications support 2D and 3D mammography	Y	N	N	N	N
Embedded technologist training	Y	N	N	N	N

*there are other smaller players operating in this space, including some of the mammography reporting companies.