volpara®analytics™
Screening performance metrics™

> Critical Insight for Breast Imaging Quality and Workflow

VolparaAnalytics provides key mammography metrics to support breast imaging centers in delivering high quality breast screening services to women. VolparaAnalytics collates data from digital mammography and tomosynthesis systems to enable cross-comparison of patient populations, mammography units, and operator performance. Utilizing the unique quantitative information and context provided by Volpara's volumetric breast assessments, centers can improve quality assurance and resource planning.

VolparaAnalytics is in use supporting quality assurance at sites around the globe. Following are case studies using real data from actual sites using VolparaAnalytics to help maintain accuracy and consistent quality in breast imaging.

> Quality Control and Density Population

Mammography quality control statistics such as recall rates, sensitivity, and specificity depend on the patient population of each given breast imaging center. Resource planning for efficient and productive adjunctive imaging requires knowledge of the number and percent of patients with dense breasts and which centers they are attending.

	Unit 1	Unit 2	Unit 3
Number of Studies	330	288	198
Median Volumetric Breast Density (%)	5.5	5.4	6.6
VDG 1 (%)	33.9	33.0	14.6
VDG 2 (%)	34.8	39.6	44.4
VDG 3 (%)	24.5	22.2	30.3
VDG 4 (%)	6.7	5.2	10.6

Figure 1 – Population Density and Resource Management

VolparaAnalytics helps mammography providers allocate staff and resources between sites. In this example, shown in Figure 1, a breast imaging center in Florida wanted to implement a breast ultrasound program for patients with dense tissue. While the site with mammography Unit 3 would appear to need decreased access to ultrasound based on exam volume, VolparaAnalytics demonstrated that this site would actually need slightly more ultrasound than the site with Unit 2 because its patient population is much denser with 40.9% (81 studies) classified as highly dense (VDG 3 and 4) compared to approximately 27% (79 studies) for unit 2.

> Technologist Performance: Breast Compression

Accurate compression is required to provide the optimal balance of image quality, low x-ray dose, and patient comfort. With insufficient compression, patient movement can blur images,

dose exposure is increased and separation of overlapping tissue is poor. On the other hand, excessive compression can increase patient discomfort and pain and can also result in severe paddle tilt, which can degrade image quality.

> Applied Pressure and Mammographic Quality

A key metric available with VolparaAnalytics is the determination and tracking of patient-specific compression *pressure*. All mammography systems display the force used to compress each breast. However, the force necessary for accurate compression varies dramatically depending on breast size (see Figure 2). More force is required to compress a large breast, less force is required for a small breast, but the necessary amount of pressure is similar.

The Volpara algorithm calculates the area of breast in contact with the top compression paddle and then derives compression *pressure* values (in kilo-Pascals (kPa) or pounds per square inch (PSI)) by dividing the compression force by contact area. By tracking median compression pressure used by each system and operator, users of VolparaAnalytics have discovered mammography units in need of calibration or repair and technologists who might benefit from additional training.

In the following case from the Breast Center of Acadiana in Louisiana, VolparaAnalytics identified that a part-time technologist was under compressing the breast during exams despite servicing a population of women with average breast volume for this site (see Figure 3). Operator 11

	Op 8	Op 9	Op 10	Op 11
Number of Studies	44	37	30	18
Median Breast Volume (cm^3)	600	550	750	632
Median Volumetric Breast Density (%)	6.8	7.3	6.1	7.8
Median Compression Force (N)	108	73	70	58
Median Applied Pressure (kPa)	12.6	8.9	10.3	6.4

Figure 3 – Insufficient Compression Can Be Identified and Corrected

was re-trained and is now performing to standard. In another example of how VolparaAnalytics can provide objective data to evaluate technologist performance, Breast Center of Acadiana had received patient complaints about one technologist. Upon review, the data showed that Operator 3 was delivering a median compression force double that of the other technologists and that the median pressure applied was up to 40% higher than other technologists despite comparable breast volume among the patients (see Figure 4). This analysis gave the Breast Center of Acadiana objective, impartial data with which to manage their staff and the technologist in question.

Median Values	Op 1	Op 2	Op 3
Breast Volume (cm^3)	919	818	829
Breast Thickness (mm)	71	69	59
Compression Force (N)	62	61	129
Applied Pressure (kPa)	7.9	8.5	13.5

Figure 4 – Excessive Compression Force results in patient complaints

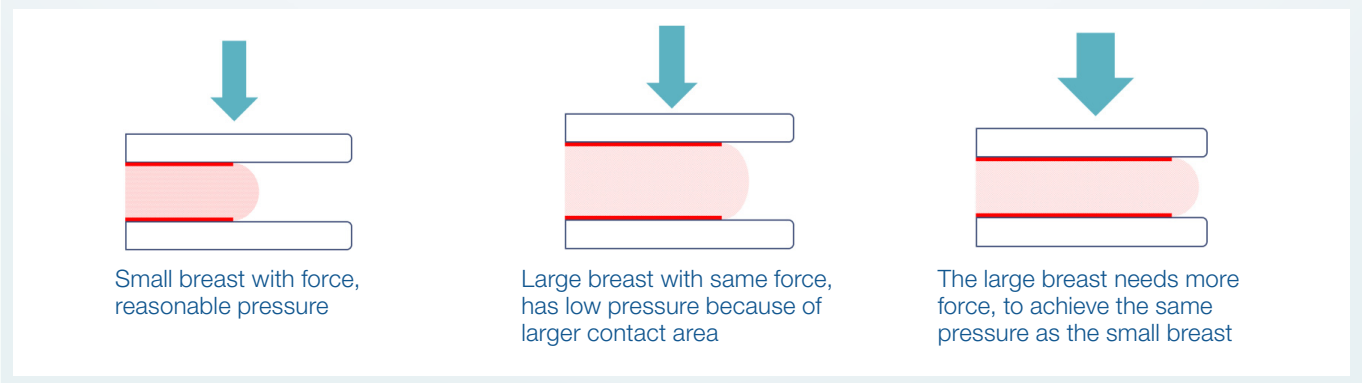

Figure 2 – Compression Force and Contact Area

> Force Can Be Deceptive

Current mammographic compression guidelines are based on applying a standardized force to each breast. Because breast size is not taken into consideration, this approach leads to large variations in applied pressure. Research demonstrates that pressure-controlled compression protocols may improve standardization and reduce discomfort with limited effects on image quality and dose.

> Tracking only force can show issues where there aren't any:

In the example from Weinstein Imaging in Pittsburgh, PA., shown in Figure 5, the average compression force on Unit 1 is 60 N compared to an average compression force of 80 N on the other systems, which could suggest a problem with under compression. However, when reviewed with additional volumetric context, Unit 1 is a GE mammography system with a small detector and used to image only small breasts. VolparaAnalytics shows that although the median compression force is 25% lower on Unit 1, the median applied pressure of 6.8 kPa for the system is only 13% lower than the average pressure of 7.8 kPa.

> And hide situations where there are issues:

In this case, average compression force on Unit 2 is 80 N and average compression force on Unit 3 is 85 N, which by itself, suggests both are providing proper compression. However, Unit 2 is seeing breasts averaging 800 cm^3 and Unit 3 is seeing breasts averaging 1188 cm^3. As a result, the applied pressure on Unit 3 is 6.5 kPa is the lowest of all units at the site (7.8 average), while Unit 2 is using a median of 8.2 kPa. In this case, analyzing force without volumetric context was hiding under compression on Unit 3.

Median Values			GE		Hologic		Hologic	
	All	Total Images	Unit 1	Number of Images	Unit 2	Number of Images	Unit 3	Number of Images
Volumetric Breast Density (%)	5.9	19200	7.9	630	5.9	7119	5.7	925
Breast Volume (cm^3)	866.6	19200	525.7	630	800.3	7119	1188.3	925
Fibroglandular Volume (cm^3)	51.3	19200	41.9	630	47.6	7119	65.3	925
Breast Thickness (mm)	62.0	19200	50.0	630	62.0	7119	68.0	925
Compression Force (N)	80.5	18920	60.0	536	80.1	7101	84.6	782
Applied Pressure (kPa)	7.8	18920	6.8	536	8.2	7101	6.5	782

Figure 5 – Force Without Context Can Hide Image Quality Issues

> System Performance - Inconsistent Compression

At Elizabeth Wende Breast Care in Rochester, NY, VolparaAnalytics determined that one of 12 mammography units at the center was delivering significantly lower compression force and pressure despite consistent breast volumes among patients (see Figure 6). In many cases, technologist performance might be the anticipated cause of the variations in exam quality; however, it turned out that the mammography unit's automatic compression settings were not set properly. Once the staff physicist re-set the compression settings, exam compression performance returned to normal and confirmed there was no technologist error.

This case also demonstrates how VolparaAnalytics can help identify other potential quality control

Median Values	Unit 2	Unit 3	Unit 4	Unit 5
Breast Thickness (mm)	61	59	59	59
Breast Volume (cm^3)	804	808	835	811
Force (N)	86	105	109	103
Pressure (kPa)	8.0	9.9	9.9	9.6

Figure 6 – Improper System Compression Settings Impact Image Quality

issues. For example, in addition to flagging improper compression settings, VolparaAnalytics also identified that exams performed on Unit 2 during this timeframe had an average breast thickness 2 mm greater that the other units despite smaller breast volumes. This could suggest lower image quality and increased patient dose.

VolparaAnalytics enables practices to monitor for improper compression and take corrective action quickly in order to operate in an optimal range that improves patient experience, attendance rates, and image quality.

Patient-Specific Mammographic Dose

Radiation dose in mammography is low, but the breast is radio-sensitive and when millions of healthy women are screened annually for up to forty years or more, it is important to ensure that the dose remains as low as reasonably possible while preserving diagnostic image quality.

> Variations in Manufacturer Dose

Median Values	Unit 1	Unit 2
Breast Volume (cm^3)	775	785
Volumetric Breast Density (%)	6.8	6.3
Manufacturer MGD per Image (mGy)	1.46	1.58
VolparaDose per Image (mGy)	1.49	1.82

Figure 7 – VolparaAnalytics Provides Patient Specific Mammographic Dose

Radiation dose estimations provided by mammography manufacturers use calculations based on assumptions of a homogeneous mixture of fat and fibroglandular tissue in standard, non-personalized proportions. This results in dose being routinely under- or over-estimated, and patient dose estimations which are not comparable.

"At Weinstein Imaging, we want to ensure our patients are safe, comfortable and informed during screening. Part of that includes monitoring and recording patient dose, VolparaDose enables true comparison of dose across machines so that we can spot issues early and truly keep women safe, comfortable and informed," said Dr Marcela Böhm-Vélez, practicing radiologist and president of Weinstein Imaging.

In this case from Weinstein Imaging (see Figure 7), VolparaAnalytics data shows that despite being used on patient populations with comparable

breast volume and volumetric breast density, the dose reported by two manufacturers show only an 8.2% difference while the patient-specific doses measured by VolparaDose show a difference of more than 22%.

VolparaDose uses the patient's breast density to generate patient-specific radiation dose estimations in a standard manner, which may give a better indication of the actual dose delivered to the patient. Research presented at AAPM 2014 shows that with VolparaDose it is possible to improve the accuracy and personalization of radiation dose estimation, which may, in turn, allow for better optimization of dose in breast screening, both in mammography and tomosynthesis. Typically, the manufacturer's displayed dose underestimates dose in fatty breasts by approximately 25%, and matches more closely with VolparaDose for dense breasts.

Poor Compression Can Lead to Higher Patient-Specific Dose *In the study "Practitioner compression force variation in mammography: A 6-year study" recently published in the British Journal of Radiology, Mercer et al established that there is a wide variation in compression force and breast thicknesses for the same patient when they are imaged by different technologists. Clinical implications of this range from variations in dose exposure to potential variations in image quality and lesion visibility.*

VolparaAnalytics was used as part of a training session at Capital Imaging in New York to help evaluate variations in compression among six technologists, who on average, were seeing patient populations with similar breast volumes and volumetric breast density (see Figure 8). While compression force varied slightly across all technologists, VolparaAnalytics identified that Operator 3 was consistently applying under 50 N of compression force with an applied pressure of approximately 5 kPa, which could impact image quality and result in a higher mean glandular dose being received by patients.

"This is a conscientious technologist who wants to give her patients a positive exam experience with no pain and as little radiation as possible," said Michael J. Masone R.T. (R)(M)(MR)(S), R.D.M.S., Director, Capital Imaging Associates. "When we showed her the VolparaAnalytics data, she understood that as a result of under-compression, her patients were, in fact, getting more dose than other patients." The technologist was re-trained and is now in line with appropriate compression.

Median Values	Op 1	Op 2	Op 3	Op 4	Op 5	Op 6
Breast Volume (cm^3)	845.4	862	813.8	824.9	870.4	870.3
Volumetric Breast Density (cm^3)	6.3	5.8	7.0	6.5	6.1	6.6
Breast Thickness (mm)	57.5	56.8	61.5	57.8	58.9	54.0
Compression Force (N)	90.7	69.4	47.1	76.3	61.1	69.4
VolparaDose (mGy)	1.0	0.9	1.2	0.9	0.9	0.8

Figure 8 – Insufficient Compression Can Lead to Higher Patient Dose

Tilt Paddle and Compression Force

Compression in mammography is essential for reducing radiation dose, preventing motion artifacts, and for obtaining a homogeneous tissue thickness for optimized image quality. Unfortunately, compression can also result in pain and discomfort for women.

In addition to compression force, VolparaAnalytics has the ability to monitor tilt angle, or the slant of flexible compression paddles, which were developed with the goal of improving comfort in mammography. Data shows that as compression force increases the tilt angle also increases (see Figure 9). A paddle tilt of four degrees leads to 12 mm less tissue being visible around the nipple area, which could result in significant image quality issues.

Research shows that while patients received slightly lower dose with tilting paddles, the fibroglandular tissue near the chest wall tended to be forced out of the image acquisition area by the flexible paddle, resulting in reduced contrast near the chest wall. VolparaAnalytics may be used to monitor paddle tilt to help ensure uniform image quality.

Median Values	Unit 1	Number of Images	Unit 2	Number of Images	Unit 3	Number of Images
Breast Volume (cm^3)	778.3	4446	807.4	7820	794.6	10658
Breast Thickness (mm)	60.0	4446	62.0	7820	57.0	10658
Compression Force (N)	84.6	4366	84.6	7705	115.6	10637
Applied Pressure (kPa)	8.5	4366	8.7	7705	10.9	10637
VolparaDose per Image (mGy)	1.4	4446	1.5	7810	1.8	10646
Paddle Tilt Angle (degrees)	2.2	4446	1.9	7820	3.4	10658

Figure 9 – VolparaAnalytics Measures Tilt Angle, or Slant, to Help Maintain Image Quality

"Tilting paddles are popular in some regions as a potential method of reducing pain and discomfort; however, image quality can be impacted at higher forces. The performance of tilt paddles needs to be evaluated further by monitoring the impact of compression force on paddle slant and image quality. The ability for VolparaAnalytics to monitor tilt angle, force, pressure, mean glandular dose and other breast imaging metrics, will help us to objectively study this issue," said Prof. dr G.J. den Heeten, LRCB (the Reference Center for Breast Cancer Screening in the Netherlands).