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Investigation of New Level Technologies in Single Use, Disposable Systems

by David Ladoski and Dan Klees

This article presents guided wave radar level measurement as an acceptable, less expensive alternate to load cell systems.

Different technologies have been utilized to measure level, volume, and/or mass in single use, disposable bags in the biotech industries. The most common include:

1. Load Cells (weight)
2. Floor Scales (weight)
3. Pressure Transmitters (liquid head or weight)
4. Graduated Marks (manual measurement of level)
5. Guided Wave Radar (level)

Each of the above technologies has its benefits as well as its limitations. The purpose of this article is to only discuss experience with guided wave radar transmitters – not to discuss the first four listed technologies.

There are currently several hundred guided wave radar level installations on single use, disposable bags in cGMP facilities.

Technology

Guided Wave Radar (GWR) is a well known technology that has been available for process measurement for more than 20 years. Basically, a microwave pulse is sent down a wave guide (also referred to as an antenna or probe). Energy is then reflected back from a surface where there is a change in dielectric. The amount of energy reflected is proportional to the difference in dielectric between air and the process medium. Typically, the wave travels first through air (dielectric of 1) and then is reflected off of a surface of a liquid (WFI has a dielectric of approximately 12).

In the case of biotech-type liquids, which are typically high dielectric, almost all of the energy on the wave guide probe is reflected back up the probe, resulting in a very strong signal and maximum accuracy of measurement.

By knowing the time of flight required for the speed-of-light microwave pulse to travel down the wave guide, reflect off of the surface of the liquid and then travel back, one can determine the distance to the surface of the liquid. Level in the vessel (or bag in this case) can then be mathematically calculated.

Simplified diagrams of guided wave technology are shown in Figure 1 and Figure 2.

Potential Single Use Bag GWR Difficulties

In single use, disposable bag level technology, the GWR

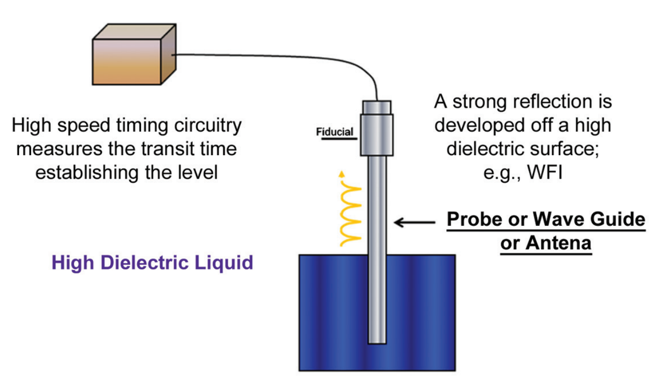

Figure 1. Guided wave technology.

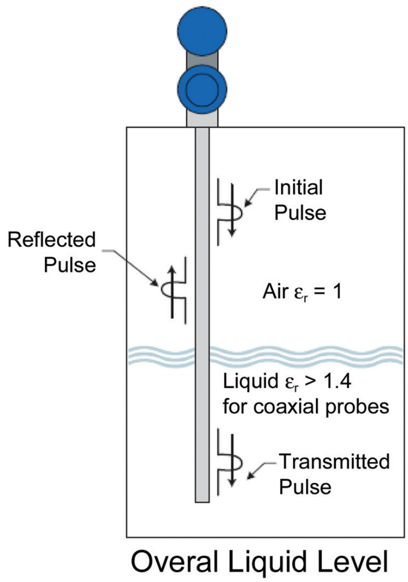

Figure 2. Guided wave reflected pulse.

probe is not in contact with the liquid – but rather, is in direct contact with the outside of the bag. This non-contact application can result in difficulties that are not normally experienced with typical GWR probes that are in direct contact with the process:

1. The microwave pulse is concentrated around the outside of the probe. Since the probe is separated from the process liquid by the thickness of the bag, only the portion of the reflected microwave pulse is actually available for processing as the level signal. This reflected signal strength is typically less than 50% of the amplitude that would be processed if the wave guide was in direct contact with the liquid.

2. The bag may not lay flat against a probe when filling or emptying – causing a deformity in the bag wall. This deformation of the bag can be caused by obstructions within the tote or bin, the GWR probe itself, the shape of the bag as related to the tote/bin shape, and even the seam of the bag. As a result, the signal propagation (speed) of the microwave pulse will vary as it traveling through both the air due to bag deformity and through the plastic of the bag itself. Signal propagation will vary as the inverse of the square of the material dielectric constant. Since the speed of the microwave pulse will be reduced when in contact with the bag as compared to when it is in contact with air, the time that it takes the microwave pulse to travel down the probe, reflect off of the surface of the liquid in the bag, and travel back up the probe will be variable depending on the position of the bag with reference to the probe. The results will not always be the same, system to system or bag to bag.

3. A disposable single use bag tends to "curve away" from the probe near the top of the fill level. Then, as the bag fills or empties, less of the bag sidewall containing liquid becomes in direct contact with the probe. This causes two issues. The first issue is that level is not proportional to volume. The second issue is that since the actual liquid level is not in direct contact with the side wall of the bag and probe, the GWR transmitter measures a different level due to the change in speed of the microwave pulse. This difficulty is avoided if the bag is preformed to the exact shape of the bin/tote/container and the bag is pre-inflated.

4. Measuring low liquid level is also challenging for the GWR since the GWR needs to fit the bottom shape of the tank. The transition between the sidewall and the bottom results in a near 90 degree bend of the GWR antennae. Tighter bends seem to reduce the GWR signal resulting in a poor level signal. A five inch or greater radius for ¼" cable seems to deliver best performance.

5. Bag seams also create a challenge especially at the bottom to sidewall transition. The bag seam is generally more rigid and does not lay completely flat to the GWR cable, which in turn leaves an air gap. This air gap generally occurs in the middle of the GWR bend radius and reduces signal.

Stainless Steel Bins with Rigid Probes

GWR transmitters will measure only to the bottom of the probe. The probe was initially a rigid 0.5" (12 mm) rod supported off the side wall of the bin by PTFE insulators. These PTFE stand-offs have typically run the continuous length of the probe and have positioned the probe about 1" (25 mm) off the bin wall. This stand-off allowed the bag to "wrap around" the probe, giving a substantial liquid surface area for the microwave pulse to reflect off of the liquid in the bag. See Figure 3, Figure 4, and Figures 5a and 5b.

Since most of the licensed facilities wanted to measure level as close to the bottom of the bag as possible, the 12 mm diameter rigid probe was positioned down the sidewall of the bin and then bent across the bottom of the bin toward the lowest point of the bag as shown in Figure 4 and Figures 5a and 5b.

With the installation of the rigid bent probe, it was observed that the typical level measurement repeatability from bag to bag was better than **5%** after "strapping" the first bag and tote/bin.

Strapping Explanation: "strapping" is the configuration of a GWR level transmitter and probe to a vessel with respect to a standard. Typically, an empty bag is inserted into a tote/bin. A specific volume of liquid is metered into the bag using a highly accurate Coriolis mass flow meter or weigh load cell. Whatever the GWR transmitter reads as level at that time is "configured" to be the volume as determined by the standard. An additional volume of fluid is then added into the bag through the standard and the new level reading of the GWR level transmitter is "configured" to the new total volume, as measured by the standard. Typically, this is done 20 times and this table, which can be saved in the GWR transmitter, becomes the “strapping table.” From that point on, a specific measured “level” will correspond to a specific “volume.” This strapping table takes into account major factors affecting accuracy described above, such as bag positioning, differences in velocity of the microwave pulse in air vs. plastic bag, the curve of the probe, the shape of the bin/tote, and the curvature of the top of the bag where the level is.

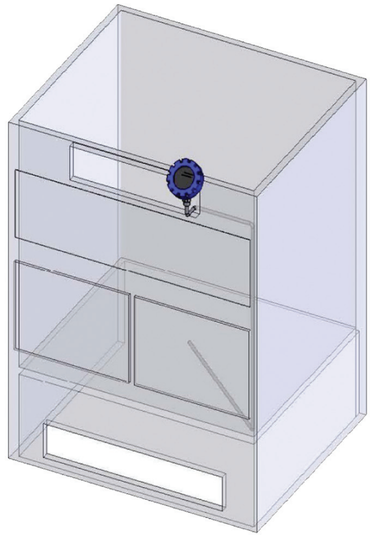

Figure 3. Guided wave in a stainless steel bin.

Figure 4. Bent rigid probe for a stainless bin.

Totes/Bins with Flexible Cable Probes

Plastic/polymeric totes/bins offer the advantage that they are non-conductive, allowing the rigid rod probe to rest directly on the sidewall of the bin/tote. Since no stand-offs are required, the bag tends to lie more uniformly against the probe. This allows for a more repeatable velocity and signal strength of the microwave pulse, and therefore, better measurement repeatability.

Two options were investigated in the placement of the wave guide/probe:

1. Probe on the <u>outside wall</u> of the tote/bin
2. Probe on the <u>inside wall</u> of the tote/bin

Since the microwave pulse can travel through the plastic/polymeric sidewall of the tote/bin, the first applications suggested that the place of the probe be on the <u>outside wall</u> of the tote/bin and attempt to measure the level of the liquid in the bag <u>through the wall of the tote/bin and then through the wall of the bag.</u> With this design, the probe was not in contact with the bag and it was anticipated that there would be:

1. Less chance of damage to the bag by the probe

2. Less chance of folding or deformation of the bag since the probe did not contact the bag

3. Better repeatability tote/bin to tote/bin and bag to bag

After testing the probe on the <u>outside wall</u>, the following was observed:

1. There was no chance of damage to the bag by the probe.

2. There was less folding and deformation of the bag as compared to having the probe in contact with the bag.

3. The gain (signal strength) of the GWR transmitter had to be greatly increased from the typical factory setting of 90 to more than 220 in order to propagate through the thick tote/bin walls. This increase in signal strength made it very susceptible to interference from conductive objects on the outside of the bin/tote. To minimize this interference and to keep from measuring false levels as people passed close to the probe, a grounded conductive shield had to be placed around the outside of the probe.

4. The 12 mm diameter rigid rod probe could not be accurately bent to match the outside contours of the tote/bin.

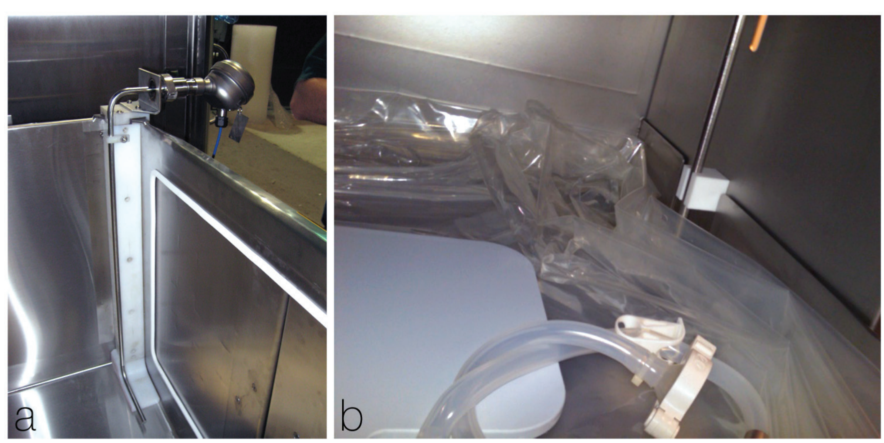

Figure 5 (a and b). Bent rigid probe in a stainless steel tote.

A stainless steel flexible cable probe proved to be a better solution.

5. On a standard GWR installation in a metallic vessel, the top of the vessel acts as a "launch surface" enhancing the microwave pulse down the probe toward the surface of the liquid. However, in a plastic/polymeric vessel, there is no "launch surface" at the top and a much less efficient system resulted. We mounted a metallic, conductive "launch surface" at the top of the probe to give the microwave pulse a "push" down the probe.

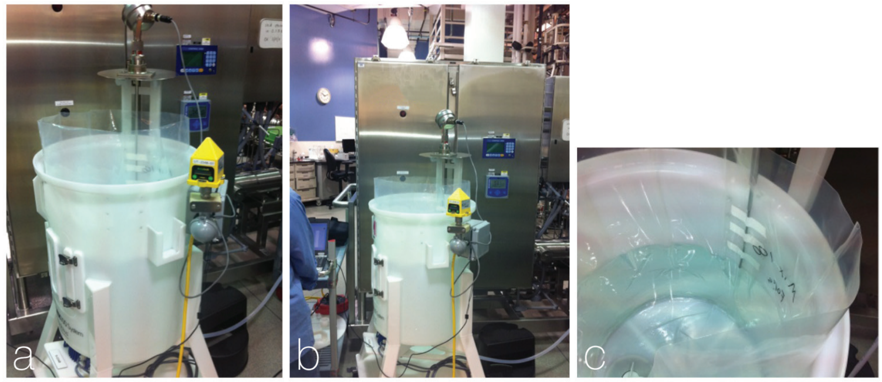

Figure 6 (a, b, and c). Cable on the inside of a 100 liter polymeric tote.

6. With the installation of the 6 mm diameter flexible cable probe on the outside wall of the tote, we observed typical level measurement repeatability, bag to bag, of approximately **3%** of total volume after strapping the first bag and tote.

The licensed facility wanted to improve the repeatability of the level measurement in the tote; 3% of total volume was close to the maximum error limit based on their User Requirement Specification (URS).

4 mm Flexible Cable Probe on the Inside Wall of the 100 Liter Tote

After testing the GWR sensor on the outside of the vessel wall, performance data proved the sensor could not measure well through the polymeric wall of the 100 L Millipore Mobius® tote system. We then installed a 4 mm diameter flexible stainless steel cable probe to inside of the 100 liter polymeric material tote and attached the guided wave radar transmitter to a polymeric stand mounted above the tote as shown in Figures 6a, 6b, and 6c. The stand also had a 20 square inch diameter launch plate at the top of the probe.

The flexible cable probe ran the full length of the inside sidewall and exited through a hole drilled in the bottom of the tote. We intentionally positioned the flexible cable probe on the opposite side of the tote from other electrical devices, conduit and the magnetic mixer to prevent electrical noise, and more importantly, to prevent false level reflections (also known as "ghost levels.")

After testing the 4 mm diameter flexible cable probe on the inside wall of the tote, as shown in Figure 6, it was observed:

1. There was a very small chance of damage to the bag by the probe during bag installation and removal. Damage to the bag and subsequent breach off sterility is possible should a strand of the e cable fray from the flexible probe. Risk is further minimized by placing the flexible probe in a polymeric spine as shown in Figures 8b and 8c.

2. There was substantially less folding and deformation of the bag as compared to having a 12 mm diameter solid rod probe in contact with the bag.

3. The gain (signal strength) of the guided wave radar transmitter had to be slightly increased from the typical factory setting of 90 to approximately 140 in order to measure through the bag wall. This smaller increase in signal strength did not make the probe susceptible to interference from conductive objects on the outside of the tote. A grounded, conductive shield did not have to be to be placed around the outside of the probe in order to minimize interference and to keep the probe from measuring false levels from people passing close to it.

4. Although we initially used tape to attach the 4 mm diameter flexible cable probe to the tote wall (as seen in

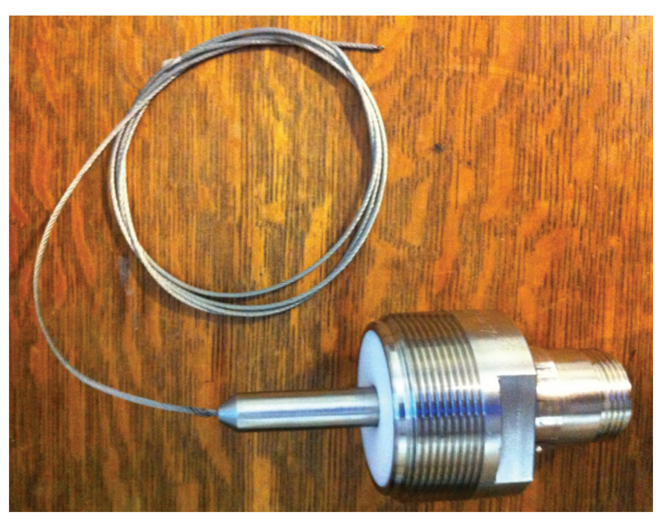

Figure 7. 1.6 mm flexible cable.

Figures 6a and 6c), the owner eventually drilled several holes on either side of the flexible cable probe and secured it to the tote wall with nylon tie wraps.

In summary, with the 4 mm diameter flexible cable probe on the inside of the plastic/polymeric tote, we were able to obtain repeatability, after strapping the first bag and tote, of about **1%** of total volume.

Note that the above tests were run on a preformed bag that sat upright in the tote and matched the contour of the tote - *see Figure 6a*. We later ran tests on folded bags that would be pre-inflated with sterile gasses before filling with similar results (as seen in Figures 8a and 8c).

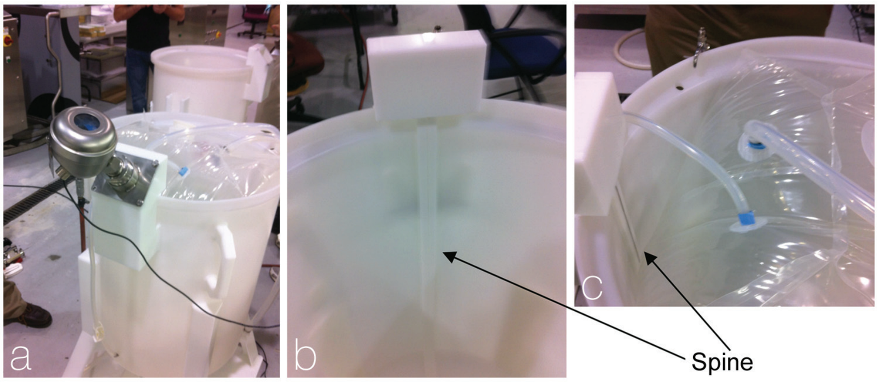

Figure 8 (a, b, and c). 1.6 mm flexible cable inside polymeric totes.

1.6 mm Flexible Cable Wave Guide Probe on the Inside Wall of the 150 Liter Tote

Since the owner wanted to achieve 0.5% or better repeatability, we developed a 1.6 mm diameter flexible cable probe for testing on ahe 150 liter polymer totes as shown in Figure 7.

This probe was mounted to a prefabricated polymeric stand at the top of the 150 liter tote as shown in Figure 8a. The 1.6 mm diameter cable probe was secured to the tote wall via a "spine" fabricated of the same material as the tote. The cable probe was inserted into a groove on the spine (as seen in Figures 8b and 8c).

After testing the 1.6 mm diameter flexible cable probe on the inside wall of the tote, it was observed:

1. There was minimal chance of damage to the bag by the probe during bag installation and removal because the flexible probe was positioned in a protective spine.

2. There was substantially less folding and deformation of the bag as compared to having a 4 mm flexible cable probe in contact with the bag.

3. The gain (signal strength) of the guided wave radar transmitter had to be slightly increased from the typical factory setting of 90 to 190 in order to measure through the bag wall. This increase in signal strength did make the probe more susceptible to interference from conductive objects placed on the outside of the tote.

4. The 1.6 mm diameter flexible cable probe was placed in a groove in the "spine" to secure the cable to the tote sidewall - *see Figures 8b and 8c.*

In summary, with the 1.6 mm diameter flexible cable probe on the inside wall of the plastic/polymeric tote, we were able to obtain repeatability after strapping the first bag and tote of about **0.5%** of total volume.

Note: the aforementioned tests were run with folded bags that were pre-inflated with sterile gasses before filling.

1.6 mm Flexible Cable Probe on the Inside Wall of the 200 Liter Tote

We also conducted tests of a 1.6 mm diameter flexible cable probe for use on a 200 liter polymer tote.

This probe was mounted to a prefabricated polymeric stand at the top of the tote and the 1.6 mm diameter cable probe was secured to the tote wall via a "spine" fabricated of the same material as the tote. In addition, we used the same mounting bracket design and spine design as on the 150 liter poly totes previously shown.

After testing the 1.6 mm diameter flexible cable probe on the inside wall of the tote, it was observed:

1. There was minimal chance of damage to the bag by the probe during bag installation and removal because the flexible probe was positioned in a protective spine.


Figure 9. 6 mm flexible cable for mounting inside of a tote.

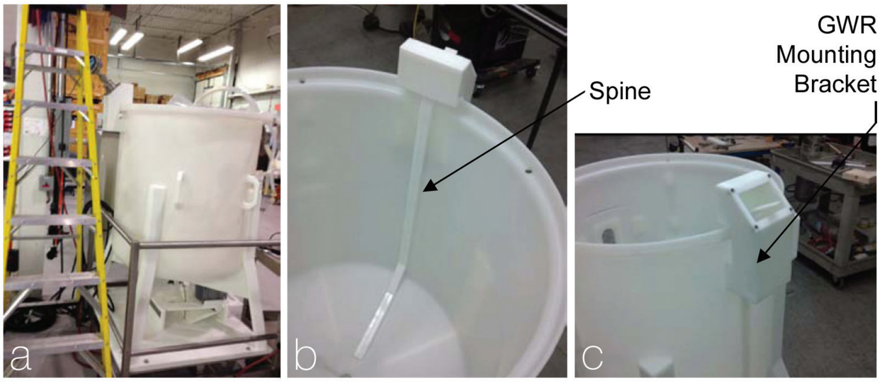

Figure 10 (a, b, and c). 6 mm flexible cable in a 500 liter polymeric tote.

2. There was substantially less folding and deformation of the bag as compared to having a 6mm flexible cable probe in contact with the bag.

3. The gain (signal strength) of the guided wave radar transmitter had to be slightly increased from the typical factory setting of 90 to approximately 220 in order to measure through the bag wall. This increase in signal strength did make the probe more susceptible to interference from conductive objects placed on the outside of the tote.

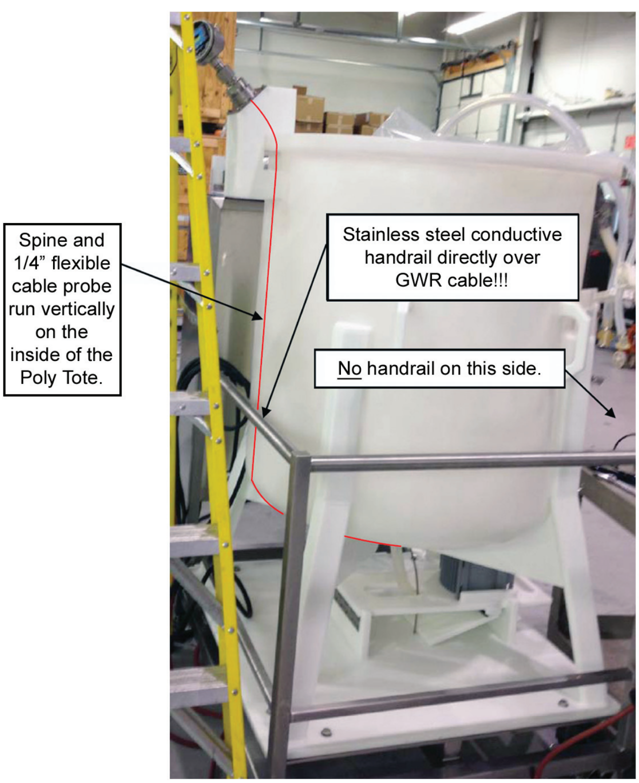

Figure 11. Ghost level due to handrail.

4. The 1.6 mm diameter flexible cable probe was placed in a groove in the "spine" to secure the cable to the tote sidewall.

In summary, with the 1.6 mm diameter flexible cable probe on the inside wall of the plastic/polymeric tote, we were able to again obtain repeatability after strapping the first bag and tote of about 0.5% of total volume.

1.6 mm Flexible Cable Probe on the Inside Wall of the 500 and 1,000 Liter Totes

We then conducted tests of a 1.6 mm diameter flexible cable probe for testing on a 500 liter and 1,000 liter polymer and stainless steel totes. The 1.6 mm flexible cable did not perform at all due to the lower energy pulse from it.

It must be noted that the 1.6 mm diameter flexible cable probe should not be used on totes requiring a flexible cable greater than 36 inches in length.

6 mm Flexible Cable Probe on the Inside Wall of the 500 Liter Poly Totes

We then conducted tests of a 6 mm diameter flexible cable probe for use on a 500 liter poly tote. The prototype probe is shown below in Figure 9.

After testing the 6 mm diameter flexible cable probe on the inside wall of the 500 liter poly tote (as seen in Figures 10a, 10b, and 10c), it was observed:

1. There was minimal chance of damage to the bag by the probe during bag installation and removal because the flexible probe was positioned in a protective spine.

2. There was still minimal folding and deformation of the

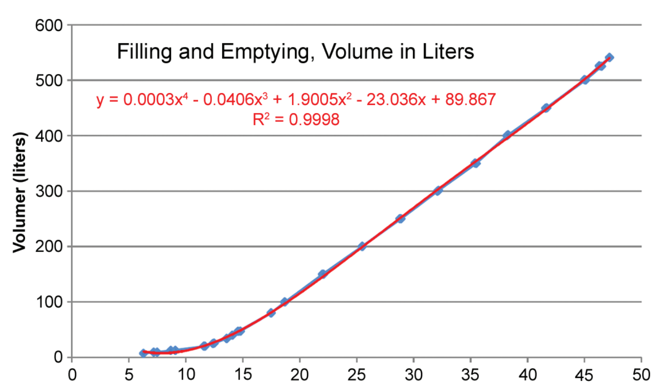

Figure 12. Strapping level vs. volume repeatability (500 liter).

bag as compared to having a 1.6 mm flexible cable probe in contact with the bag.

3. The gain (signal strength) of the guided wave radar transmitter had to be greatly increased from the typical factory setting of 90 to approximately 235 in order to measure through the bag wall. There was some interference or ghost levels on the outside of the poly tote due to the stainless steel handrail mounted about 1" from the outside of the poly tote and directly in front of the 6 mm flexible cable. See Figure 11. The handrail showed up as a ghost level and was impossible to tune out. We ended up rotating the poly tote 180° to position the flexible cable opposite the hand rail.

4. The 6 mm diameter flexible cable probe was placed in the spine to secure the cable to the tote sidewall. See Figures 10b and 10c.

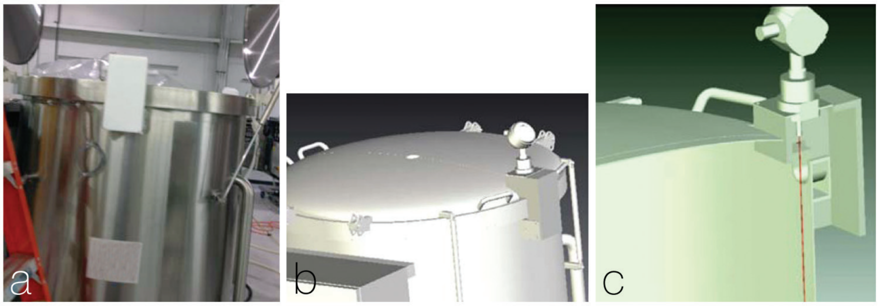

Figure 13 (a, b, and c). 1,000 liter stainless steel tote.

We then plotted the level vs. volume based on the filling and emptying "strapping table." The results for the 500 liter polymeric tote are shown in Figure 12.

In summary, with the 6 mm diameter flexible cable probe on the inside wall of the plastic/polymeric tote, we were able to again obtain repeatability after strapping the first bag and tote of about **0.3%** of total volume.

6 mm Flexible Cable Probe on the Inside Wall of the 500 Liter Stainless Steel Totes

We then conducted tests of a 6mm diameter flexible cable probe (Figure 9) for use on a 500 liter stainless steel tote.

After testing the 6 mm diameter flexible cable probe on the inside wall of the 500 liter stainless steel tote, the following was observed:

1. There was minimal chance of damage to the bag by the probe during bag installation and removal because the flexible probe was positioned in a protective spine.

2. There was still minimal folding and deformation of the bag as compared to having a 1.6 mm flexible cable probe in contact with the bag.

3. The gain (signal strength) of the guided wave radar transmitter had to be slightly increased from the typical factory setting of 90 to approximately 235 in order to measure through the bag wall. Since the tote is conductive, there was no interference or ghost levels on the outside of it.

4. The 6 mm diameter flexible cable probe was placed and taped on the "spine" to secure the cable to the tote sidewall.

In summary, with the 6 mm diameter flexible cable probe on the <u>inside</u> of the plastic/polymeric tote, we were able to again obtain repeatability after strapping the first bag and tote of about **0.25%** of total volume.

6 mm Flexible Cable Probe on the Inside Wall of the 1,000 Liter Totes

We then conducted tests of a 6 mm diameter flexible cable probe (Figure 9) for use on a 1,000 liter stainless steel tote.

This probe was mounted to a prefabricated polymeric stand at the top of the stainless steel tote - *see Figure 13a*. The 6 mm diameter cable was secured in a "spine" fabricated of the same material as the tote - *see Figures 13b and 13c*. In addition, we used the same mounting bracket design and spine design as on the 150 liter poly totes previously shown.

After testing the 6 mm diameter flexible cable probe on the inside wall of the 1,000 liter tote, it was observed:

1. There was minimal chance of damage to the bag by the probe during bag installation and removal because the flexible probe was positioned in a protective spine.

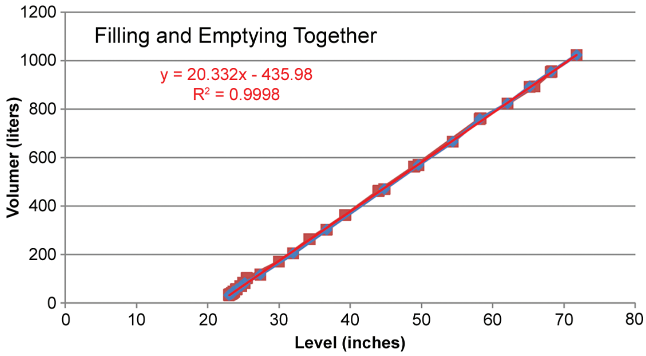

Figure 14. Strapping level vs. volume repeatability (1,000 liter).

Guided Wave Radar Technology	Repeatability
1,000 Liter Stainless Steel Bin, 12 mm Solid Rod	4% of Total Volume
100 Liter Plastic/Polymer Tote, 4 mm Flexible Cable on Outside Wall	3% of Total Volume
100 Liter Plastic/Polymer Tote, 4 mm Flexible Cable on Inside Wall	1% of Total Volume
150 Liter Plastic/Polymer Tote, 1.6 mm Flexible Cable on Inside Wall	0.5% of Total Volume
200 Liter Plastic/Polymer Tote, 1.6 mm Flexible Cable on Inside Wall	0.4% of Total Volume
1.6 mm Flexible Cable Greater than 36 inches in Length on Inside Wall	**DO NOT USE 1.6 mm**
500 Liter Plastic/Polymer Tote, 6 mm Flexible Cable on Inside Wall	0.3% of Total Volume
500 Liter Stainless Steel Tote, 6 mm Flexible Cable on Inside Wall	0.25% of Total Volume
1,000 Liter Stainless Steel Tote, 6 mm Flexible Cable on Inside Wall	0.25% of Total Volume

Table A. Repeatability summary.

2. There was minimal folding and deformation of the disposable bag.

3. The gain (signal strength) of the guided wave radar transmitter had to be increased from the typical factory setting of 90 to approximately 210 in order to measure through the bag wall. Because the tote was metallic, there was no interference with objects outside of the tote.

4. The 6 mm diameter flexible cable probe was placed and taped on the "spine" to secure the cable to the tote sidewall.

We then plotted the level vs. volume based on the filling and emptying "strapping table." The results for the 1,000 liter stainless steel tote are shown in Figure 14.

In summary, with the 6 mm diameter flexible cable probe on the inside of the 1,000 liter stainless steel tote, we were able to again obtain repeatability of about **0.25%** of total volume.

Summary

Summary of our repeatability experience for all tested probes and totes/bins can be found in Table A.

Guided wave radar level measurement is an acceptable, less expensive alternate to load cell systems. The typical cost of a GWR transmitter and cable probe is approximately 1/3 the cost of a load cell system.

In addition, guided wave radar transmitters have the option of periodic calibration verification performed on a bench dry calibration stand. The first calibration on a GWR in a 1,000 liter bin took approximately eight hours to perform and consumed over 2,000 liters of purified water. Calibration verification on a bench stand took less than 10 minutes and did not require water.

For GWR measurement lengths of less than 1 meter, we suggest the use of 1.6 mm flexible cable as the probe. For measurement lengths greater than 1 meter, we would suggest the use of a 6mmees flexible probe.

In all cases, the positioning of the wave guide probe between the tote wall and the bag wall provided the best repeatability of less than 0.5% of total volume.

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