Dermabond Automation- Mini Swab Assembly Machine

John Bernis Vazquez Manufacturing Engineering Angel Gonzalez Lizardo, Ph.D. Industrial Engineering Department Polytechnic University of Puerto Rico

Abstract — This project covers the development, design and process control of Dermabond Mini Swab Assembly Machine. The project focused primarily on a solution based on the automation and process control application. This report covers the entire process of the Mini Swab Assembly machine, the available solutions and a practical approach towards the end product.

This project hold promise for reducing cost increase labor productivity, and optimized the current process due to the automation, product quality and process capability. Design considerations associate with the automation process addressed specific with the creation of a process control in one of the stations of the automated machine using the Coriolis meter technology.

Key Terms — Automation, Coroilis Mass Flow Meter, Dermabond, Mini Swab Process.

INTRODUCTION & PROCESS BACKGROUND

Dermabond adhesive is used to repair lacerations and to close surgical incisions and is manufactured in Ethicon LLC a Johnson & Johnson at San Lorenzo Puerto Rico. (See Figure 1)



Figure 1
Dermabond Ampoule

The formulation is filled and sealed in glass ampoules, which will dry- heat sterilized using existing sterilization cycle. The sterile ampoules, are assembled using Tubes, Tips and filters components and packaged in a rigid blister package.

The Dermabond Mini product is made in a manual process that required one operator for the manual Mini Assembly machine and one operator for parts inspection per shift.

Actually, in order to comply with the manufacturing demand, that line is running three shifts per day. The actual machine cycle time is 20.69 parts / minutes. (See Figure 2)

Step

2-small pile of ampoules may accumulate next to the loading station
3-When the Accept Bin reaches
The pre-set value for maximum number of parts the machine will fault and prompt the operator to empty the accept bin.
4-Place all rejected parts into a separate bin to be sorted
5-Continue normal

production until the

6-Process Inspection

production Lot is complete.

1- Ampoules loading station

and inspect the Mini Swabs for the criteria (CTQ) 8-If any failures are detected, perform a 100% inspection of the entire UOM 9-QA inspection for Non-Certified Associates 10-Rework of any failures, excluding ampoule breakage, Removing the ampoules from the butyrate tube and cycling back through the assembly process. 11-Inspection checks will be performed every 1,500 units that constitute a UOM until

the batch is complete

7-Randomly select 20 swabs

Figure 2 Mini Process Flow

The existing Mini Swab Assembly Machine accept labeled individual plastic tubes fed through a hopper and vibratory bowl, filled ampoules manually inserted into tubes, tip/filter assemblies fed through a vibratory bowl, and methanol sprayed using an EFD pump/spray system.

The tubes are placed on a rotating dial where the ampoules are manually inserted into the plastic tubes. Once loaded with an ampoule, the dial will rotate and a tip will be sprayed with methanol and inserted into the tube. This assembly is then inspected for overall height and offloaded at either accept or reject station based on height check and methanol spray results. (See Figure 3)

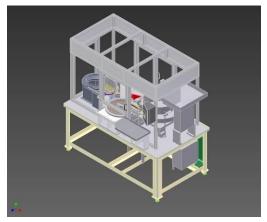


Figure 3
Manual Mini Assembly Machine

CORIOLIS MASS FLOW METER FOR NATURAL GAS MEASUREMENT, STAPPERT, KARL

Coriolis is one of the fastest growing technologies in the Oil and Gas market [1]. Newer designs and technology developments since the early1990's have enabled Coriolis to measure gases that are extremely light, heavy, dirty, clean, sweet, sour, hot, cold, and/or in a partial two phase state. (American Gas Association)AGA Report Number 11 specifically concentrates on the measurement of natural gas mixtures within the normal and expanded compositional ranges called out by AGA Report Number 8, Compressibility Factors for Natural Gas and Other Hydrocarbon Gases. The low flow sensitivity of Coriolis meters has been dramatically improved in recent years allowing the technology to easily achieve flow turndowns of 30:1 or more at pressures of 300 psi with turndown increasing as pressure increases.

All in all, it can be argued that Coriolis technology solves more problems and offers even more value for gas than liquid measurement. This is because gases are compressible, and with more traditional gas technologies (orifice, turbine, rotary,

and ultrasonic) process pressure, temperature, and gas composition must be accurately measured or controlled, the devices regularly maintained Orifice oilers checked; rotary gears, particle jamming, and gear oilers;

Ultrasonic flow tubes, flow conditioners, testing performed on the technologies that are sensitive to gas density and flow profile. Since Coriolis measures the flowing mass of fluids its and transmitters checked and adequate gas flow plates, flow tubes, and transmitters checked; Turbine bearings, flow tubes, transmitters, and gear accuracy is independent of fluid composition, flow pulsations and flow profile/swirl. The meter is more accurate over a wider range of operating conditions and is less costly to install and maintain and many applications and especially in 300 ANSI applications and higher

Coriolis is a smaller line-size technology: the largest offering from any vendor for gas applications is a150mm (6") pipe diameter. The pressure drop and flow range of a Coriolis meter draws a direct relationship to the actual flow area through the meter when comparing it to other metering technologies; i.e. the flow area trough a turbine meter is area not displaced by the turbine internals and rotor, the flow area of an orifice meter is that of the orifice diameter. Because of this relationship a Coriolis meter will typically be one pipe size smaller than a turbine meter and several sizes smaller than an orifice while having similar pressure drops at flowing pressures in the 300 ANSI class and above.

THEORY OPERATION

A Coriolis meter is comprised of two main components, a sensor (primary element) and a transmitter (secondary) [2]. Coriolis meters infer the gas mass flow rate by sensing the Coriolis force on a vibrating tube or tubes. The conduit consists of one or more tubes which are vibrated at their resonant frequency. Sensing coils located on the inlet and outlet sections of the tube(s) oscillate in proportion to the sinusoidal vibration. During flow

the vibrating tube(s) and gas mass flow couple together due to the Coriolis force causing a phase shift in the signals produced by the sensing coils. The phase shift, which is measured by the Coriolis meter transmitter, is directly proportional to the mass flow rate. (See Figure 4)

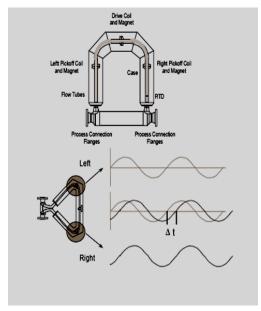
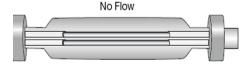


Figure 4 Coriolis Mass Flowmeter

The vibration frequency is proportional to the flowing density of the fluid [3]. For gas applications the flowing density is not used for gas measurement but can be used as an indicator to change in a Coriolis meter's flow factor. (See Figure 5)



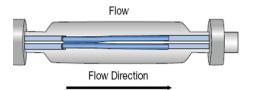


Figure 5 Coriolis Flow Factor

In the meter on the top (viewed from the side); there is no flow through the tubes, so they vibrate toward and away from each other in phase. As material flows through the tubes of the meter on the bottom, the Coriolis effect causes the upstream side of the loop to fall slightly behind the downstream side, which the motion sensors detect as a time shift.

This technology or application has the ability to measure several process variables all at the same time opens up completely new application fields [4]. Mass flow, density and temperature (the primary measured variables) can be used to derive other variables such as volume flow, solid contents, concentrations, and complex density functions.

Automation Level

For this assembly process, an automation level is one that allows the upgrade or improvement for a single device or element; it consists of programmable controllers and microcomputers that manage the functional logic (e.g. PLCs) of the system, the single device control and the interface with the sensors.

The concept of automated systems can be applied to various levels of factory operations. Automation is normally associated with the individual production machines. However the production itself is made up of subsystems that may themselves be automated.

Propose Process Improvement Stations Overview

The Conveyor will be tooled with individual fixtures on each link of the system. Each link and fixture will be 4 "long and each fixture will hold four completed assemblies. The fixtures will hold a row of four tubes toward the back of the tool and a row of four tips & filters toward the front of the tool. As the product passes through the assembly process the Tip assembly will be will be pressed on top of the Tube. The fixtures will be made from Hard Coat Anodized Aluminum. (Figure 6)

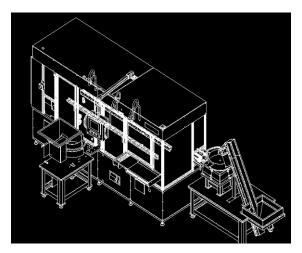


Figure 6 Mini Swab machine

In-Feed Tube

The first station on the machine to begin producing the assembly will be the Tube in-feed station. This station will automatically feed the Tubes into the system and load them into the fixtures on the indexing link system. (See Figure 7)

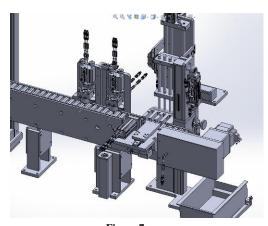


Figure 7
In Feed Tube Station

Amp In-Feed

After tubes have been placed into the machine and indexed clear of the Tube Load Station, Amps will be installed into the tubes. Amp will be fed into the system via, semi automated process Tubes will move into the system in an up arrangement and deposited into the tubes in the machine nest. A set of four contact pins will be used to verify the height of each amp. In the event that an amp fails the height inspection, no further operations or product

components will be loaded and the components will be rejected at reject station. (See Figure 8)

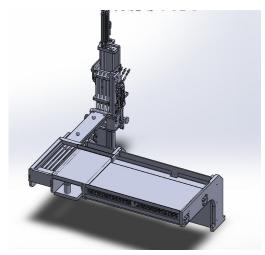


Figure 8
Tubes Reject Station 1

Reject Station

After the product indexes clear of the Amp Infeed station it will enter into the Reject Station. This station will pick and place any Tubes that have failed for height or orientation and Amp that have failed their height inspection. Rejects will be removed from the machine nest and placed in the reject Bin. (See Figure 9)

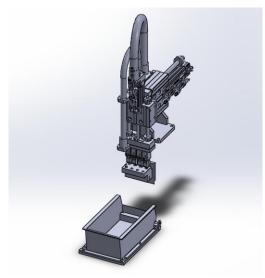


Figure 9
Tubes Reject Station 2

Filter In - Feed

The station will automatically feed the filters into the machine and load them into the fixtures on the indexing link system. (See Figure 10)

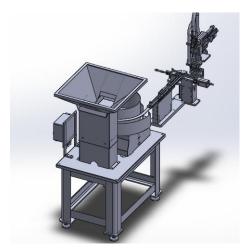
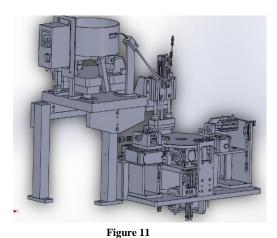


Figure 10 Filter infeed station

Tip In - Feed

This station will automatically feed Tips into the machine and load them over filters in the machine nests. (See Figure 11)



Tip In-Feed Station

Filter Insert &Inspection

Consist in an assembly which will install the filters into tips and inspect depth of installation. (See Figure 12)

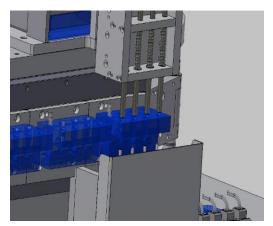


Figure 12
Filter Insert & Inspection Station

Reject Station

After the product indexes clear of the Filter Insert & Inspection Station it will enter into the Reject station. This station will pick and place any components that have failed the press assembly and will drop it in a Reject Bin.

Final assembly (install Tips into Tubes)-After successful completion of the assembly of the Filter into the Tip, the product will move on to the final assembly step. The tips will be lifted, **methanol sprayed**, and pressed onto the Tube. (See Figure 13)

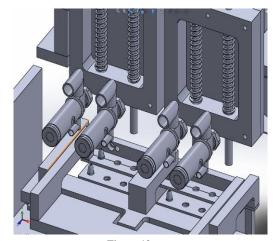


Figure 13 Methanol Spray Nozzles

Final Height Inspection

Completed swab that has passed all of the assembly steps will be inspected for correct over all height (OAH). (See Figure 14)

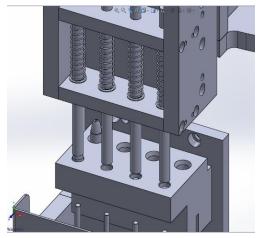
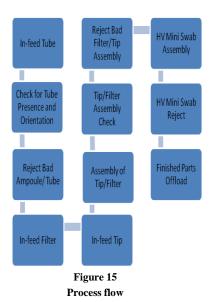


Figure 14
Final Height Inspection

Additional Reject Station

Completed product that has passed all of the assembly steps will be off- loaded onto a flat belt conveyor. The conveyor is expected to be constantly running at a slow pace. (See Figure 15)



Propose Design Assembly Tip/Filter station process control (Methanol) / Coriolis Mass flow meter. (See Figure 16)

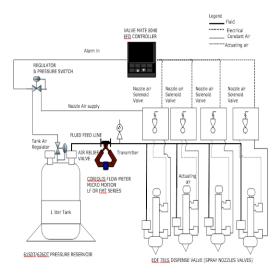


Figure 16
Propose Design Assembly

- Reservoir 615DT Methanol
 - Capacity 1 liter
 - Maximum operation pressure -6.9 bar / 100 psi
 - Maximum Operating- 50 C
- 781S Dispense Valve (Spray Nozzles)
- Four (4) Solenoid valve
- Fume extractor (FUMEX)
- Coriollis Mass flow meter (Micro Motion & Tasmitter)
- Level switches
- Instrumentation selection

One of our primary concerns was to keep the Methanol consumption below 1 liter in an 8 hour shift if we do this, the machine will not fall under the requirements of "Standard for spray application using Flammable or combustible Material" NFPA 33.

Based on the testing performed, a sufficient solvent bond can be achieved by using 1 liter of Methanol in an 8 hour shift, but we want you to be aware that this is less than what you are currently using on your existing Swab Assembly Machine. On the existing machine the dial on the EFD valve is possibly set high to ensure that there is sufficient methanol output for a good bond.

From our testing we are planning to use the following Methanol spray for the solvent bond

station. There is sufficient Solvent bond strength using .0297 ml of Methanol spray per tip. This will keep us inside the minimum of less than one liter per 8 hours. (NFPA 33 does not apply) The application pressure (Pressure Pot) will be 10psi. The spray time will be .025 seconds.

The distance from the end of the spray nozzle to the tip will be 1/2 Inch +/- 1/8 inch. Using these parameters the system could produce up to 33,600 Parts in an 8 hour period at a system rate of 70 parts per minute. Current NFPA code forces us to recognize that we must not use an excess of 1 liter of methanol in and 8 hour period.

CONCLUSION AND RECOMMENDATIONS

In order to be available to perform with the implementation of the Propose Design Assembly Tip/Filter station process control (Methanol) / Coriolis Mass flow meter is very important to evaluate what will be the accuracy of the selected instrument which is Coriolis Mass flow meter.

Coriolis mass flow meters are the most accurate of the industrial flow measurement technologies and the only flowmeter that could measure true liquid mass flow directly.

Coriolis flowmeters see use in continuous and batch processes.

One of the points to evaluate is that the Coriolis mass flow meters cannot accurately measure two – phase slug flow .Slog flow is the condition where a slug of liquid is followed by slug of gas, generally in rapid secession.

A gas slug is one of a number of high pressure bubbles of gas and liquid.

Errors as large as 58 % has been reported and in one test 2 % to 4 % reported out of range.

Research compares the response time Coriolis to other flow measurement technologies. Latency and response time are critical parameters for flow meters using in batching applications, especially in batches in short duration .If the flowmeter is used for filling process which required 1 second to be accurate the that flow meter better have very low latency and fast response time. As per the research Coriolis Mass flow meter have difficulties dealing

with batch shorter than ½ second, and many meters have difficulty with batches as long as 20 seconds.

In order to have the expected accuracy to e perform trials due to is recommended to perform a "proof of principal" in order to confirm the accuracy based on the cycle time of the Mini Swab assembly machine.

Other important analysis is to evaluate the calibration process of the Coriolis Mass flowmeter.

Conceptually, calibrating a strain gauge load cell tank is straightforward. One places traceable test weight on the vessel and records the reading on the scale display.

Calibrating Coriolis mass flow meters for flow rate measurements is very difficult to perform, especially because is not traceable standard for flow rate.

In general, such calibration of the flow rate for Coriolis Mass flowmeters is best left to the manufacturing that has the sophisticated lab system to calibrate the instrument.

In the Mini Swab assembly machine which will work as a batching system the flow rate is not an critical parameter or variable but is critical the quantity of flow .

The most typical method of calibration Coriolis for use in batching system involves fluid over a giving length of time into an accurate weight tank, and then comparing the reading of the weight scale to that totalizes of the Coriolis meter. Various issue a rise this method. First is a most accurately measure time.

Another advantage is the Ability to batch from empty, since the batch to batch operation required cleanouts between runs, batching from empty condition where pipelines and system are empty. (See Table 1)

Table 1
Advantage vs. Disadvantage

Advantages

- 1- Cost is generally lower than a load cell system
- 2- Easier to retrofit into existing applications that load cell system.
- 3- Measures pound mass (vs. other flowmeters which are volumetric devices)
- 4- Allows for simultaneous multiples feeds
- $\hbox{5-Precise measurement over broad range}.$
- 6-Inmune to the effects of tank agitation.

Disadvantages

- 1- Device is difficult to calibrate compared to the load system.
- 2-Meter must be totally full of liquid while testing which often requires complex piping arrangements.
- 3-Have dynamic response limitations cannot measure extremely short batches accurately
- 4-Short batches with pumps that cause large flow pulsations are not accurate measurement.

Pressure drop is proportional to the flowrate squared. High flowrates result in higher pressure drops but greater accuracies. At lower flowrates, pressure drop is lower, but accuracy is lower as well. (See Figure 8)

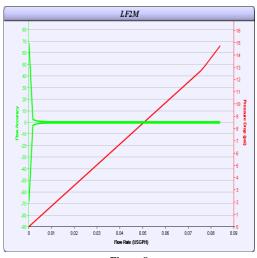


Figure 8
Flow Rate vs. Accuracy

During the evaluation of the suggested application the following concern to be evaluated during the Proof of principal or lab test.

Is very important to understand the measure couldn't accurate if the single shot (Trigger) is 20 millisecond if the trigger is 20 millisecond the accuracy measurement will be between 10 % to 20 % of error.

One if the recommendation is that the initial flow rate or shot perform in high speed, and then processed in a proprietary digital signal processing chain to give a flow measurement every 10 milliseconds. Thus no flow rate data is "lost". The output of the meter is a continuously integrated flow rate.

The longer the integration of the flow rate measurement, the more accurate it becomes. This is true even if the flow is in pulses such as in this application.

Two values can be looked at in this application. After each spray, and will have a valid indication of gross errors such as a plugged nozzle and the individual readings can be averaged to together in a "rolling average" algorithm to give an accurate running total of the process fluid used. If individual spray values are not needed, the meter can be set with long averaging (damping) to give this value directly.

Based on the estimates consumption calculations 0.2287 grams in 20 milliseconds is approx. 11 ½ grams / second. Fluid is low viscosity. The high speed valve needs to be able to manage the pressure fluctuation and the meter needs to be set for bidirectional totalizing.

The selected Mass flow meter is the CMFS 015 sensor with 800 Enhanced core (with 500 barriers) together with the Ethernet module.

As part of the advantages of this automation machine it can be concluded that were covered the CTQ's (Critical to Quality) in terms of quality, labor and process control. (See Figure 9)



Figure 9
Common Defect

The implementation of a process control in the Dermabond process gives the opportunity to characterize the amount of Methanol that we are using in our process creating a process specification.

After the investigation and research some of the improvement or the following advantages that to be obtained.

- High accuracy
- Direct measurement of mass and volume
- Measure accurately across wide variations in temperature, pressure, flow rate.
- Do not require process shutdown for maintenance or meter verification.
- Minimize instrumentation and therefore minimize potential leak points.
- Meet custody transfer accuracy requirements for most process fluid in most countries in the world.
- Are available with custody transfer security enhancements and other specializations.

Coriolis flowmeters have successfully addressed these challenges:

 Coriolis meters can calculate °Brix (a form of concentration measurement) from inline process data. This reduces or eliminates the delays associated with manual sampling and laboratory analysis.

- Coriolis meters are immune to changes in temperature or viscosity. One meter can measure any fluid in any process condition.
- A wide turndown is inherent in Coriolis technology.
- A Coriolis multivariable device can replace several other instruments while providing equal or better measurement, and Coriolis solutions are available in a variety of footprints and mounting options.
- Coriolis solutions are easy to clean, require little maintenance, and have a low incidence of failure. The result is increased process uptime.
- Coriolis solutions provide accurate real-time measurement across a wide variety of process conditions, allowing manufacturers to shift set points closer to the target, reduce off-spec product, and reduce ingredient waste.
- Coriolis solutions enable tighter process control, allowing manufacturers to predict material use and manage inventories more accurately and efficiently.
- Coriolis solutions can be implemented with batching and filling enhancements to support packaging applications.

CORIOLIS MASS FLOW CALCULATIONS SUMMARY

The calculations were performed with some assumption explained in the table below. (See Table 2)

Table 2

Methanol Calculation Table

Fluid:	METHANOL	Units
Fluid State	Liquid	
Mass Flow Accuracy at Operating. Flow (+/- % of Rate):	0.5	lb/ft3
Density Accuracy at all Rates (+/-):	0.3121	
Pressure Drop at Operating Flow:	14.73859	
Sensor Minimum Pressure at operating conditions:	n/a	
Velocity at Operating Flow	5.71897	Ft/sec

Based on the manufacturing data the mass flow will work with these conditions parameters. (See Table 3)

Table 3
Manufacture Parameters

Flow rate (USGPH)	Operating	Units
Flow Rate	0.084	USGPH
Pressure	60	psig
Process Fluid Temperature	70	F
	70	F
Density	49.365	Lb/ft3
Viscosity	0.58	ср
Process pressure rating	1501	psig

As part of the "proof of principal" made by Micro Motion representative the following data were obtained. (See Table 4)

Table 4
Experimental Data

Flow	Mass flow	Pressure	Velocity	Re
Rate	Accuracy	Drop	(ft/sec)	
(USGPH)	+/- off	(psi)		
	rate			
0.084	0.5	14.739	5.719	603.288
0.076	0.5	12.72	5.148	543.004
0.067	0.5	11.308	4.576	482.721
0.059	0.5	9.896	4.005	422.438
0.05	0.5	8.484	3.433	362.155
0.042	0.5	7.072	2.862	301.872
0.034	0.5	5.659	2.29	241.589
0.025	0.5	4.247	1.719	181.305
0.017	0.5	2.835	1.147	121.022
0.008	0.514	1.423	0.576	60.739

Using Hazen-Williams formula for calculating head loss in pipes and tubes, Equation (1)

$$Pd = 4.52 \ q^{1.85} / (c^{1.85} \ dh^{4.8655}) \tag{1}$$

Where

Pd = pressure drop (psi/ft pipe)

c = design coefficient determined for the type of pipe or tube - the higher the factor, the smoother the pipe or tube

q = flow rate (gpm)

dh = inside diameter (inch)

REFERENCES

- Stappert, Karl "Title of the Reference", Coriolis Mass Flow Meters for Natural Gas Measurement, 2009.
- [2] Sparks, D, Smith ,R., Massoud- Ansari, S., Najafi, N. "Title of the Reference", Coriolis Mass Flow, Density and Temperature Sensing with a single Vacuum Sealed Mems Chip, 2004.
- [3] Fahlenbock, Terry, D., "Title of the Reference", *Coriolis mass flow meter: High accuracy for high flowrates*, 2005.
- [4] Smith, Richard, Sparks, Douglas, Riley, Diane, Najafi, Nader, Najafi., "Title of the Reference", A MEMS-based Coriolis Mass Flow Sensor for Industrial Applications, 2009