Catheter bonding Process Improvements with High-intensity Ultraviolet Curing Systems

María del Mar Ortega Meléndez
Manufacturing Competitiveness
Iván M. Avilés, Ph.D.
Industrial Engineering and Systems
Polytechnic University of Puerto Rico

Abstract *— Ultraviolet (UV) curing is a common process used in medical devices manufacturing for bonding operations. Light-curable adhesives provide rapid cure, great adhesion, and good chemical resistance for sterilization processes. This project studies the effect of the implementation of a new UV curing technology for manifold catheters manufacturing. The upgrade consists of moving from the current mercury light bulb UV to an LED bulb. Benefits from improvements include energy savings, improved process performance, and reduction of maintenance activities. Process performance is evaluated by its capability of meeting the tensile force design spec of 3.38lbf. Key Process Inputs (KPI) that affect the tensile strength output are UV Intensity and Process Cure Time. A Design of Experiments explored the lower and upper limits of adhesive curing time and intensity parameters, and their impact on tensile values.*

Key Terms *— Adhesives; LED; UV Cure; Catheters; Medical Devices.*

PROBLEM STATEMENT

This project will study the effect of the implementation of a new ultraviolet (UV) curing technology for epoxy adhesive curing operations on the Catheter Top Assembly. This project will design a new process characterization driven by an update to the UV bonding equipment used in the Catheter Top Assembly line. The current curing process uses the American Ultraviolet Lesco MKIII SuperSpot. This equipment is determined to be upgraded to the Dymax MX-150 Spot Cure system. The fundamental difference between the two systems are the source of UV energy. The Lesco uses a 100W Mercury bulb to produce a wide spectrum of UV light (320-460nm), while the Dymax system uses an LED bulb that produces a narrower band of UV light (~365nm). Additionally, the Dymax system has an integrated user interface that allows for recipe control and feedback that will make the process easier to operate and maintain.

Research Description

The UV bonding process is comprised of a UV light source, light guide, cure box, nitrogen purge box and Loctite adhesive. Although there are three different stations that use UV curing, the application and bonding processes are virtually the same and will all be contained within the description of the UV bonding process as described in Figure 1.

Figure 1
UV Bonding Process

Research Objectives

This test study's purpose is to explore the lower limits of adhesive curing time and intensity parameters and their impact on tensile values. These results will help identifying potential failure points and minimum values required to meet our tensile outputs. Test results that characterize the UV Bonding process, used in the Catheter Top Assembly manufacturing line, will be used to define optimum process conditions and control limits for critical process inputs. The impact on tensile strength will be considered and the critical process inputs determined.

Research Contributions

By updating the UV technology for the bonding cure, it is expected to improve the manifold bond process and equipment which includes:

- Increase process reliability and longer equipment life.
- Better curing properties to be determined by bonding tensile strength.
- Reduction of uncured and over cured defects.
- Reduced process cycle time.
- Reduce maintenance costs and time compared to current technology.

LITERATURE REVIEW

Sealants and adhesives are used in many different industries, their main purpose is to bond and or seal joints of materials; but these can also provide vibration damping and corrosion protection. Adhesive manufacturers continue to develop and improve formulations in order to meet new increasing customer specifications, including cleaner environmentally conscious materials with lower volatile organic compound (VOC) emissions and biodegradability. However, the most increasing trend is the need for faster processing and efficiency, thus reducing energy consumption [1]. One of the most common methods to cure an adhesive is thru ambient cure or applying a heat source used to increase the temperature of the substrates to dry coatings and complete a full cure. Depending on the application and type of adhesive the cure time can range from minutes to hours, or even days. The need to reduce cure times and energy consumption opened the door to new technologies using the light electromagnetic spectrum sources to initiate and accelerate adhesive cure. This is where the application of industrial ultraviolet lamps is added to the equation. Light-curing adhesives contain photo initiators that absorbs light to break down into functional groups, this initiates polymerization which is the curing reaction. Depending on the intensity and spectral range of the light source, a light pulse of less than one (1) second may be enough to fully cure the adhesive and permanently bond components. These products allow faster cures with greater depth of cure.

The type of lamp chosen for the cure impacts greatly and it is crucial for optimal curing of adhesives. Most, light-curing adhesives systems have been formulated to cure using ultraviolet light sources, however some are design to cure under visible light but with longer curing times. For a light-curing reaction to occur, it is important that the wavelength spectrum of the curing lamp overlaps the absorption spectrum of the photo initiator [2]. Depending on the adhesive formulation, photo initiators have a typical absorption spectrum that ends at 370 to 480 nanometers. The objective of this research study is to complete an upgrade to the current UV curing technology that uses a mercury light bulb, which produces a wide spectrum of UV light (320-460nm). Figure 2 shows a graphical representation of the electromagnetic spectrum for UV light and visible light.

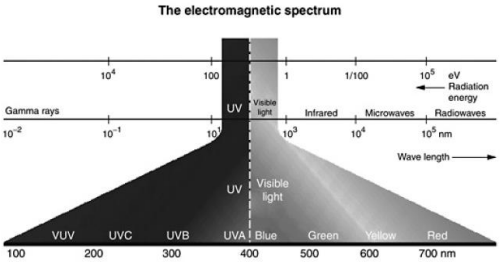

Figure 2
Industrial UV Lamps Poduce Energy across the Full Spectral Range of the Optical Region [3]

The U.S. Department of Energy (DOE) estimates that by switching to LEDs the country could save $120 billion in energy costs over the next twenty years [4]. LEDs have many other good characteristics like compact size, resistance to breakage and vibration, good performance in cold temperatures, and do not require any warmup time when turned on, which is a great feature when applying to high volume production. Recent research studied the differences between LED lamps and mercury-based lamps. The results showed that a homogeneous light distribution allows a higher photonic efficiency. The diffuse and uniform emission of the fluorescent mercury lamp partially compensates its lower energy

efficiency; however, LED lights, with an optimized array, provide an improvement of the light homogeneity and energy efficiency, creating higher curing reaction rates [5]. This research study shows that upgrading to an LED UV lamp provides significant advantages over traditional mercury-based illumination sources, specifically its higher energy efficiency, which produces a narrower band of UV light (~365nm).

The materials to be bonded are another consideration. To ensure that light energy reaches the adhesive, at least one of the components to be bonded must be translucent within the adhesive's absorption range. The industry distinguishes between two lamp types: spot lamps and area lamps. Spot lamps are used for punctiform or linear bonding. Area lamps are chosen for batch exposure of large surfaces. This means that depending on the application, different lamps may serve the purpose best. The goal should always be to expose the entire surface to be bonded with the same intensity [6]. The application for this research study will be focused for a spot cure on medical device manufacturing processes. The types of adhesive most used for assembly of medical devices include cyanoacrylates, light curable acrylics, epoxies, urethanes, and dual (UV/moisture cured) silicones [7]. The adhesive to be UV cured for this research study is a light-curable acrylic which provides substrate versatility, "on demand" rapid cure, adhesion to hard to bond plastics, and good chemical resistance for sterilization processes [8].

METHODOLOGY

In order to test the implementation of the new UV cure system for the catheter assembly line, the first step is to identify all the variables that affect the adhesive cure. As shared in the process overview and as learned during the literature research, light intensity, time of cure, and the type of adhesive affect the cure of the adhesive. The catheter design has requirements of tensile strength for each bonded joint. The effectiveness of the cure will be measured based on the ability to meet the design spec for tensile strength. Additionally, to the tensile strength, visually surface defects like voids, bubbles, and adhesive tackiness will be also evaluated.

As described in the literary review, the material, and components to be bonded affect the process output. In this case, material transparency affects the capacity of the adhesive to absorb the UV light, of the polymer to form, and the curing reaction to start. Catheters that share manifold design and material type will be tested together under worst case circumstances. These worst-case catheters are determined by the colorant used in the manifold. This test will feature three (3) different catheter manifold parts, purple, grey and clear. For which the purple manifold, will simulate a worst-case scenario during challenge testing since it can filter up to 85% of UV Light source. Table 1 shows the different manifold colorants and their UV light filter capacity. This will be addressed by adjusting the UV intensity under the feasibility test.

Table 1
Manifold Material Description

Manifold Material	Colorant	Color Guide	UV Light Filter Capacity
Lexan 124R Polycarb	Pms 2593, ltl spec l1146	Purple	85%
Lexan 124R Polycarb	Rtp spec s-92128	Grey	28%
Lexan 124R Polycarb	None	Clear	0%

Test Conditions and Process

The test will be conducted in the same clean environment that current manufacturing for catheter assemblies occurs. This testing is to be conducted under challenge conditions that are meant to run outside or on the cliff of potential failure and no nitrogen used. The objective of this test is to define Normal Operating Conditions (NOC) and Edge of Failure (EOF) for the manifold catheters bonding process. The NOC is the controlled range of variation for the process during normal operating conditions (i.e. routine production). The EOF is the range that lies outside of NOC where the process is known to make non-conforming parts.

This test study will explore the lower limits of our time and intensity parameters and their impact on tensile values. These results will help us identify potential failure points and minimum values required to meet the tensile outputs. One consideration for this process, is whether to flood the cure area with nitrogen to create a better curing environment, as it is under the current manufacturing process. Compress nitrogen, in this case, removes oxygen from the area which can act as an inhibitor for UV curing. Oxygen impacts the effectiveness of UV curing in some adhesives and sealants. Reducing the oxygen level by adding an inert gas like nitrogen to the cure area, increases the curing performance. To create worst case conditions, nitrogen will be removed from the curing process for testing.

Table 2
Test Methods for UV Curing of Manifolds

Test Name	Test Objective/Purpose
Feasibility Testing	Verify that at the lower limit for process settings and variable UV intensity parameters, the units pass attribute testing and are statistically capable for variable testing.
Edge of Failure	Test parts around the perceived low end and upper limits of the process range to give insight to the tensile strength at lower and higher UV doses.

The test methodology process for each sample will be as follows:

1. An exhaust tube will be inserted into the manifold as shown on Figure 3.

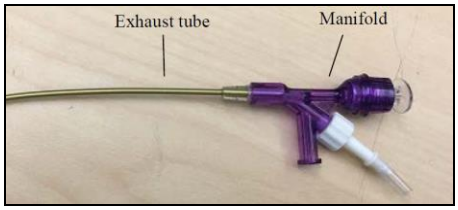

Figure 3
Manifold and Exhaust Tube Assembly Example

2. 30 cc of Loctite 3943 will be added to the manifold inside the port holes to the exhaust joint location as shown on Figure 4.

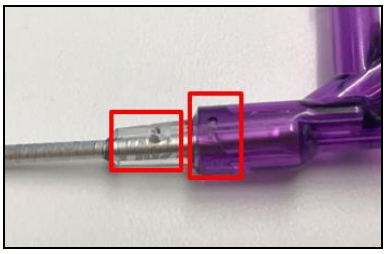

Figure 4
Adhesive Deposit Location

3. Parts will be fixed 12.7mm from two UV light guides in the same orientation as used in the corresponding UV cure box. UV cure box guarantees unit positioning for every cure.
4. The UV cure Dymax system is activated per the time in the test parameters described on Tables 3 and 4 for Feasibility Testing, and Table 5 for Edge of Failure Testing.
5. Completed parts are then inspected under a microscope at 10X for visual surface defects like voids, bubbles, and adhesive tackiness.
6. Part will be tensile tested to be challenged against the spec 3.38lbs of force per the approved Manifold to Catheter Pull Test Method using an Instron Load Tester.

Test Sampling Plan

Sampling plan for this study is based on internal requirements and procedures. The required performance levels (in terms of the confidence and the max percent defective rate) are set by different quality systems SOPs and/or work instructions. The performance level may also be shown as the minimum reliability (or conforming rate) required. The Process FMEA Risk Index for the process under evaluation is used to determine the required level of performance. For this test study, we will use failure mode of tensile failure, uncured bonding. The catheter manufacturing Process FMEA dictates a Risk Index of 1 for this failure mode. A Risk Index of 1 requires a level of performance with a 95% the confidence and a 5% max percent defective rate. Per internal sampling plan, a variable data process with this performance level requires a minimum sample size of n=15 with a Ppk of 1.15. Feasibility Test for UV intensity will

be run three (3) times for a total of 45 samples, with n=15 for each manifold color. Edge of Failure test will be run one (1) time for a total of 90 samples, with n=30 for each manifold color.

RESULTS AND DISCUSSION

As described in the research description, the UV bonding process for catheters manufacturing is comprised of a UV light source, light guide, cure box, nitrogen purge box and Loctite adhesive. Potential sources of variation, as defined in the research description, were monitored, and controlled during this study to evaluate their effect on the Manifold to Exhaust Tube Tensile Strength process output. This study was able to test high and upper limits of the process inputs and measure their effect on the process outputs. Figure 5 offers a summary of the process variations effect on the tensile strength output.

Potential Source of Variation	Effect on Process Output: Manifold to Exhaust Tube Tensile Strength (>3.38lbs)	Control Method (if applicable)
UV Intensity	Too intense: • Material degradation Not intense enough: • Low tensile and uncured adhesive	Preventative Maintenance (PM), Equipment Recipe Control, Uncured Adhesive Inspections
Material Variation	Dark Colorant: • Requires more UV intensity to cure parts Light/No Colorant: • Requires less UV intensity to cure parts	NA
Equipment Calibration	Incorrect UV Intensity reading can lead to fluctuations in output.	Routine Calibration, PMs
Operator Assembly	Glue application and placement of part in the cure box can influence curing and tensile consistency.	EFD Recipe Control, Operator training, and certification

Figure 5
Process Inputs, Outputs, and Sources of Variation

This next section is a summary of the test results that characterize the manifold bond operation to define process conditions and control limits for Key Process Inputs (KPI). The impact on the process outputs below is considered and the critical process inputs determined. Experiments began with an initial feasibility test featuring all three manifold types: purple, grey, and clear, with variable UV intensity levels. Through testing, to create worst case scenarios, nitrogen was removed from the process and no negative impact was identified. Upon further investigation during testing, it was identified that most of the curing area is underneath the polycarbonate surfaces, shielded from the nitrogen. This would indicate that the nitrogen would provide little to no impact to the adhesive curing process since it cannot come in contact within the cure area to remove oxygen. This confirms that nitrogen is not a key process input for the manifold bond process.

Feasibility Test

This test was conducted to explore the lower limits of our time and variable UV intensity parameters and their impact on tensile values. These results will help identify potential failure points and minimum values required to meet our tensile outputs. This testing was conducted under challenge conditions that were meant to run outside or on the cliff of potential failure. Process parameters used in the test are listed in Table 3.

Table 3
Feasibility Test Parameters

Parameter	Value
UV Intensity (W/cm2)	1.0
Intensity Value (%)	10%, 30%, 50%, 70%, 90%
Cure Time (s)	8
Manifold Color	Purple, Grey, Clear
Sample Size (n)	45
Target Output (lbf)	3.38

A Full Factorial DOE was performed for UV intensity with five (5) levels and Product Color with three (3) levels against the tensile strength output of minimum 3.38lbf. All test parts met or exceeded the required tensile strength output of >3.38 lbs. All samples were inspected for surface defects and no signs of voids, bubbles, or uncured adhesive was found. By analyzing the DOE results P-value for all factors are 0.00; this means that there is strong of significant association between the response variable and the term. This confirms that the material colorant affects the process output due to the UV filtering capacity. The purple colorant manifold test parts performed with the lowest tensile strength force in comparison with the much higher grey and clear test parts.

Based on these findings, a second test was performed only for the purple manifold product, it was selected for this test as the worst-case scenario for its ability to filter out the highest percentage of UV light, resulting in the lowest total UV dose. This second test was made to confirm tensile capability at variable the cure times of the units and determine Normal Operating Conditions (NOC) range for the time parameter. Process parameters used in this follow up test are listed in Table 4.

Table 4
Purple Manifold Feasibility Test Parameters

Parameter	Value
UV Intensity (W/cm2)	1.0
Intensity Value (%)	10%
Cure Time (s)	10, 15, 20, 25, 30
Manifold Color	Purple
Sample Size (n)	30
Target Output (lbf)	3.38
Target Ppk	1.15 or greater

For this additional purple manifold feasibility test, all test parts met or exceeded the required tensile strength output of >3.38 lbf and minimum Ppk of 1.15, even at the lowest intensity value with variable cure times. All samples were inspected for surface defects and no signs of voids, bubbles or uncured adhesive was found. Figure 6 shows the process capability sixpack analysis for the purple manifold feasibility test with variable curing times.

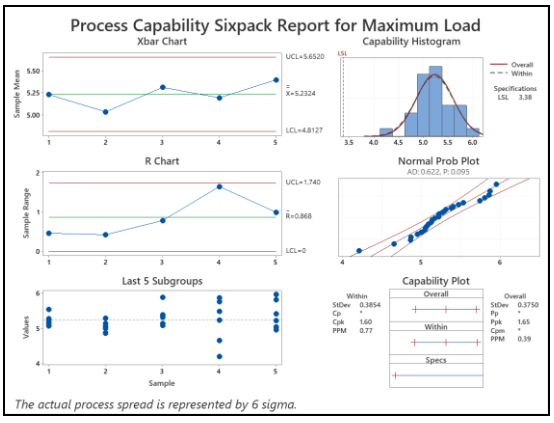

Figure 6
Process Capability Sixpack Analysis for Purple Manifold

When analyzing the failure modes, it is expected to see an adhesive failure, this means the bonded joint area broke at the documented tensile force. However, some tensile failures occurred due to the exhaust tube breakage instead of the bonded joint. Failures due to a break in the exhaust tube, occurs prior to adhesive failure, which means that the limiting factor in this build was not the quality of adhesive curing, but rather the tensile strength of the proximal exhaust tube. This feasibility test was successful in showing that even under worst case conditions, adhesive curing is still capable at meeting required tensile values.

Edge of Failure Test

Test parts around the perceived low end and upper limits of the process range to give insight to the tensile strength at lower and higher UV doses. These results will help us identify potential failure points and minimum values required to meet the tensile outputs. Process parameters used in the test are listed in Table 5.

Table 5
Purple Manifold Feasibility Test Parameters

Parameter	Value
UV Intensity (W/cm2)	1.0
Intensity Value (%)	Low 8%, High 80%
Cure Time (s)	Low 10, High 30
Manifold Color	Purple, Grey, Clear
Sample Size (n)	15 for each manifold type
Target Output (lbf)	3.38
Target Ppk	1.15 or greater

For the Edge of Failure test runs, all test parts met or exceeded the required tensile strength output of >3.38 lbs and minimum Ppk of 1.15. All test runs passed normality test with a P-Value >.05. All samples were inspected for surface defects and no signs of voids, bubbles or uncured adhesive was found. This feasibility test was successful in challenging high and lower process input limits for all manifold types, this means that even at process limit ranges, adhesive curing is still capable at meeting required tensile values under the new LED UV curing system.

Table 6
Edge of Failure Results Summary

Manifold-Edge	Tensile Output Mean (lbf)	Ppk
Purple-Low	4.03	1.49
Purple-High	5.05	1.93
Grey-Low	5.18	3.28
Grey-High	10.22	1.85
Clear-Low	23.52	1.41
Clear-High	33.79	1.46

Equipment and Process Evaluation

While completing the equipment acquisition phase, the process requirements and needs for improvements were evaluated. The needs from improvements were defined as improved equipment reliability, process performance, and maintenance activities. When comparing the current equipment in use, versus the new equipment to implement, it is evident to the project the benefit of this upgrade. Increased in lamp bulb life, reduction of process cycle time and better space utilization are some of the immediate benefits that the Dymax UV Curing system provides. Figure 7 shows in detail each equipment specification that was assessed and compared and the identified benefit.

Spec	Current Equipment: Lesco Super Spot MKIII*	New Equipment: Dymax Blue Wave MX-150**	Upgrade Benefit
Picture			Digital Touch Screen Improved user interface Curing programs can be easily entered, stored, and recalled when needed
Dimensions	8.5" x 11" x 13.5"	5.14" x 7.19" x 7.35"	Smaller footprint, allows for better workstation space utilization
Lamp Bulb Type	100W DC Mercury Vapor	LED Bulb	More energy efficient
Lamp Bulb Life	2,000 hrs	>5,000 hrs	Better equipment reliability Less maintenance cost Longer useful life
UV Output	20 W/cm2	24 W/cm2	Higher intensity improves adhesive curing
Warm Up Time	15-30 min	No warmup needed	Less setup/changeover time Improved process cycle time
Warranty	1 Year	1 Year	N/A
Equipment Cost	$ 6, 250	$ 6, 850	Higher inversion during equipment acquisition is offset by energy, cycle time, and maintenance costs savings
Light Bulb Replacement Cost	$ 550	$1, 304	

Figure 7
Equipment Comparison and Benefits from Implementation[9][10]

Process performance is normally measured by yield output and percent of defects. For the manifold bond operation 6 months of data were gathered to compare process performance and fall out. Figures 19 and 20, show a graphical representation of the proportion of manifold bond defects for current production and for the test runs performed under Feasibility and Edge of Failure testing. During the test runs no samples were failed due to surface defects, meaning it had 100% yield output. The data from July thru December 2020 for the manifold bond operation under current production shows an average defect proportion of 0.69%. This is not a high fallout in comparison with other production processes, but the new process implementation offers an improvement to that fallout. Figure 8 shows the current manufacturing process P-chart for manifold bond visual defects.

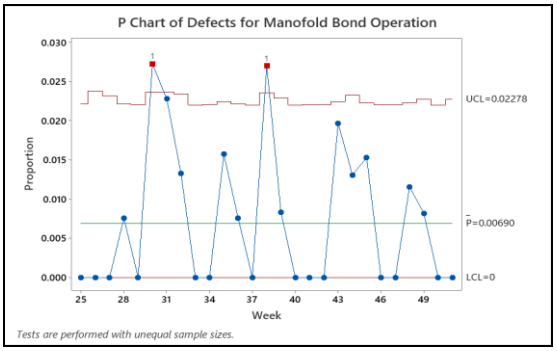

Figure 8
Manifold Bond Surface Defects Jul-Dec 2020

In summary, adhesive curing was achieved with no visual non-conformances under the higher and upper process limits. Key Process Inputs (KPI) that affect the tensile strength output are UV Intensity and Process Cure Time. Based on the Feasibility testing DOE at higher UV intensities better tensile strength. Process curing time variations for the purple manifold samples proved that the process is capable even with different times. With this we can define the Edge of Failure (EOF) parameters and the Normal Operating Conditions (NOC).

EOF limits are to be set as per the EOF test runs, while the NOC limits will be defined to provide process flexibility while still remaining

under the EOF limits. These tests proved that the current process parameters under the new UV cure system can provide the desire tensile output. Table 6 summarizes the identified KPIs and their process limit values.

Table 6
NOC and EOF Parameters Setpoints

Parameter	EOF Lower Limit	EOF Upper Limit	Nominal Setpoint
Cure Time	10 seconds	30 seconds	20 seconds
UV Intensity	1.0 w/cm2	10.0 w/cm2	7.0 w/cm2
Parameter	**NOC Lower Limit**	**NOC Upper Limit**	**Nominal Setpoint**
Cure Time	15 seconds	25 seconds	20 seconds
UV Intensity	5.0 w/cm2	9.0 w/cm2	7.0 w/cm2

CONCLUSION

Is the new UV curing technology capable of curing the 30cc of Loctite adhesive for all different manifold materials in the catheters manufacturing line? Is the process output complaint with the required specification of >3.38lbf? Is the process capable of absorbing process variation in curing time, UV intensity, material changes, and still meet the required tensile output? The answer to all these questions is yes. The Feasibility and Edge of Failure testing proved that the new equipment is capable of successfully curing the adhesive while meeting the tensile and surface defects requirements. The Key Process Inputs (KPIs) were determined to be UV Intensity and Curing time. The use of nitrogen in this case was proved to have no impact into the adhesive curing, so this variable could be an item to evaluate in the future. Elimination of the nitrogen use can potentially provide big cost savings to the catheters manufacturing process. This research was successful in characterizing and establishing the new process parameters for the Dymax LED UV cure system.

The research contributions for improved equipment reliability, process performance is evident with the equipment upgrade that the new Dymax Blue Wave offers in comparison with the current manufacturing process. One of the major items in terms of cost and time is the equipment maintenance activities, this new equipment provides longer UV lamp life which will directly impact the labor and costs incurred in maintenance work orders.

The manifold color variant was a variable identified during this process that proved to impact tensile output due to its ability to filter UV light. However, manifold design is a variable that cannot be changed of adjusted for the current product design and process, nor is within the scope of this study. The purple manifold product, D-120, is the catheter with the lowest tensile strength output. A potential future research can involve identifying a new manifold material or colorant that still provides the cosmetic design needs (purple color) but that has a lower UV filter capacity. In general, polycarbonate materials like the manifold in this study affect the curing performance, if the colorant variable can be addressed process capability can be improved and it can open the process to be applied in other catheter product families.

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