How to Achieve Clinically Dry Medical Device Lumens

Study creates a method for establishing a medical device dryness standard and uses it to test the effectiveness of a lumen drying technology for robotic devices

Michael Salloum, DrPH, FACHE, principal investigator
Witt/Salloum/Price & Associates Consulting

CENORIN

Table of Contents

Abstract 3

Study Objectives **3**

Methods **3**

Device Populations **3**

Inclusion/Exclusion Criteria **4**

Sampling Plan/Study Design **4**

Procedures **5**

Metrics and Measures **6**

Discussion **8**

Conclusion **8**

References **9**

Abstract

What does 'dry' mean, why does it matter, and how do you test for it?

Dryness is a concept that challenges many sterile processing professionals. It's a particular concern in healthcare facilities because residual moisture can inhibit the sterilization process and because it provides a potential conduit for contamination in sterilized packs and inside device channels.[1] For these reasons, medical device instructions for use typically require that devices including endoscopes and other devices with channels and lumens be "thoroughly dried" before sterilization or high-level disinfection.[2] But what does this mean? How is it measured?

Other critical sterile processing functions use testing tools and measurable standards to verify compliance.[3] They set a clinical standard and provide confidence that the protocols in use help to mitigate as much as possible the risk of contamination. The reproducible, universally applicable nature of the tests is vital for patient safety.

Unfortunately, there is no such universal test for dryness at this time, in part because of the complexity of assessing it and because very few drying studies have been conducted.[4] There has also been little oversight of instrument drying in the industry as a whole, which has created less urgency to establish a standard. However, in an attempt to reduce infection rates, more regulatory attention is being paid to the sterile processing environment and to thorough drying per manufacturers' instructions for use as an essential element of the infection prevention chain of control.

The purpose of this study was to determine the effectiveness of a novel lumen drying system and its directed air flow process for drying reusable medical device lumens. We wanted to assess whether the internal channel surfaces of robotic arms connected to the system reached a consistent, measurable standard of dryness in a predetermined amount of time. The study required two phases: a phase to develop a benchmark and measurement tool to determine whether a medical device was sufficiently "dry," and a second phase to test the system's effectiveness at achieving this benchmark.

We decided that the word "dry" was not specific enough for the process we were developing. A new term would need to be coined in order to establish a standard that would not be open to interpretation or context. The term "**Clinically Dry**" was applied to the target we were hoping to achieve. For the purpose of this study Clinically Dry is a condition in which an instrument's weight, taken prior to use or processing of any kind when the device is new, would be the ideal weight used to identify if it harbored any retained moisture or bioburden. This dry weight would be the weight that was closest to the manufacturer specifications as possible. This was the first step in developing a new standard that could be easily reproduced and verified.

Study objectives

Once we defined meaningful, specific terminology to describe this level of dryness, we set out to achieve the following goals:

1. **Determine scientifically what qualifies as 'Clinically Dry' and 'Not Dry'.** We did this by developing the clinical parameters for a definition of Clinically Dry and applying this definition to a matrix that would be used to measure compliance.
2. **Develop a static metric that can be applied universally for measuring Clinically Dry**. To do this, we investigated retained moisture properties to increase measurement accuracy, and studied the properties of directed air flow in the dryer cabinet to ensure adequate end-to-end temperature tracking.
3. **Determine if the directed air flow process of the lumen drying unit has a measurable effect on reaching the Clinically Dry standard.** We explored the effects of directed sustained airflow on drying lumened instruments and investigated whether sustained pressure-regulated air at different intervals has a measurable effect on the system's effectiveness.
4. **Examine the effect on the drying cabinet's air temperature controls after installing the lumen drying system, and the effect that opening the door has on the lumen dryer's temperature controls, the directed airflow channels, the drying cabinet temperature, and the terminal dryness of the lumens**.

Methods

Reusable robotic devices with lumens are in widespread use for minimally invasive procedures and surgeries in the U.S. and around the world. Lumened devices pose a significant drying challenge during reprocessing. For these reasons, and because thorough drying is a requirement of their reprocessing instructions for use, Endowrist® robotic arm lumens (Intuitive, Sunnyvale CA) were selected as the lumened devices for this study.

Device populations

There were 48 lumened device populations (totaling 742 sampling groups) studied under this protocol. All were robotic lumened reusable Endowrist devices, which were grouped by lumen diameter, lumen length, condition (new, refurbished, end of life) and by whether or not they had undergone repairs. Each of these conditions could impact the drying process and data. See the table below for details.

TABLE 1: Device Populations

Group #	Population Description	Group #	Population Description
1.	**Robotic lumened reusable Endowrist 8mm < 31cm long** new	25.	**Robotic lumened reusable Endowrist 8mm 33cm-34cm long** new
2.	refurbished w/o repairs	26.	refurbished w/o repairs
3.	end of life count w/o repairs	27.	end of life count w/o repairs
4.	new w/ repairs	28.	new w/ repairs
5.	refurbished w/ repairs	29.	refurbished w/ repairs
6.	end of life count w/ repairs	30.	end of life count w/ repairs
7.	end of life count, refurbished w/o repairs	31.	end of life count, refurbished w/o repairs
8.	end of life count, refurbished w/ repairs	32.	end of life count, refurbished w/ repairs
9.	**Robotic lumened reusable Endowrist 8mm 31-32cm long** new	33.	**Robotic lumened reusable Endowrist 5mm < 20cm long** new
10.	refurbished w/o repairs	34.	refurbished w/o repairs
11.	end of life count w/o repairs	35.	end of life count w/o repairs
12.	new w/ repairs	36.	new w/ repairs
13.	refurbished w/ repairs	37.	refurbished w/ repairs
14.	end of life count w/ repairs	38.	end of life count w/ repairs
15.	end of life count, refurbished w/o repairs	39.	end of life count, refurbished w/o repairs
16.	end of life count, refurbished w/ repairs	40.	end of life count, refurbished w/ repairs
17.	**Robotic lumened reusable Endowrist 8mm 32cm-33cm long** new	41.	**Robotic lumened reusable Endowrist 5mm >20cm long** new
18.	refurbished w/o repairs	42.	refurbished w/o repairs
19.	end of life count w/o repairs	43.	end of life count w/o repairs
20.	new w/ repairs	44.	new w/ repairs
21.	refurbished w/ repairs	45.	refurbished w/ repairs
22.	end of life count w/ repairs	46.	end of life count w/ repairs
23.	end of life count, refurbished w/o repairs	47.	end of life count, refurbished w/o repairs
24.	end of life count, refurbished w/ repairs	48.	end of life count, refurbished w/ repairs

Inclusion/Exclusion Criteria

In order to sort the devices into study groups, specific inclusion and exclusion criteria were established for each group. As an example, the inclusion and exclusion criteria for Group #1 are shown in Table 2.

Table 2: Inclusion/Exclusion Criteria Sample

Robotic lumened reusable Endowrist 8mm <31cm new	
Inclusion Criteria • 8mm terminal end • Lumen is less than 31cm in length • Not refurbished • Undamaged • No previous repair history • Not at end-of-life count • Dry weight listed in manufacturer specs	**Exclusion Criteria** • Not 8mm at terminal end • lumen is greater than 31cm in length • Refurbished • Damaged • Past repair by 3rd party vendor • At last use before end-of-use cycle • Dry weight not available from the manufacturer specs

Sampling plan and study design

There were separate collections for each of the 48 sampling groups, totaling 742 sampling groups. There were 385 DaVinci Endowrist® robotic lumened reusable devices in this inventory. Testing and analysis were conducted on these units and a total of 742 cycles were run.

The sampled instruments were all part of the facility inventory. None of the units in the study population included loaner or outside equipment that was not part of the facility's internal inventory.

All instruments used in this study were withheld from use in the clinical setting until reprocessed through the department's documented steam sterilization workflow**.** There was no need to obtain consent from any clinical patients for this study because all units were reprocessed after data collection for this study was completed. They were put through the facility's approved steam sterilization process before returning them to use in the operating room.

Procedures

The first phase had two goals: to establish key values necessary for successful data collection, and to establish a trial workflow using an ultrasonic system without the redundant instrument wash cycle, which could help reduce overall reprocessing time.

One key value that was needed was the length of time the devices should be exposed to pressurized air after being washed in the ultrasonic system. It was important to document the effect of having a specific amount of exposure to pressurized air after ultrasonic processing, which could help us develop a repeatable, compliant process. Exposure times were determined before the instruments were connected to the lumen drying system so that we could measure the effect of different amounts of time (10, 15, 30 seconds) on the dry weight recorded later on the clean side.

During this phase we also developed a testing protocol to verify compliance with the exposure time that could be executed on the clean side. This verification protocol proved to have an almost 98% accuracy rate. The test included two steps:

1. Each device was weighed after being removed from the lumen drying system and the weight was compared to the dry weight reference for that device. Any weight that was outside the anticipated zone indicated a residual.
2. A residual swab product confirmed moisture/protein residual with a color change. Any remaining moisture resulted in both a weight outside the range for the device and a change in color on the swab, which confirmed residual in the lumen.

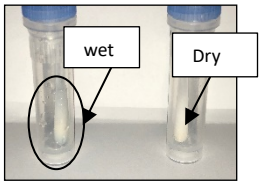

Figure 1: Moisture Swab

Decontamination area procedures

The devices (robotic arms) were identified in the testing process as either part of the *experimental group* (first log in of the day) or the *control group* (second log in of the day) by means of their unique serial numbers. The department instrument tracking system was updated to include these unique identifiers so that each Endowrist device could be electronically tracked. Once the device was scanned into the decontamination workstation, the system indicated which group the device was assigned to and the tech knew which workflow pathway to follow.

All robotic arms that were identified as part of the control groups were processed in the existing department workflow. The arms were pre-cleaned and placed in the ultrasonic washer. After being removed from the ultrasonic wash they were placed in the instrument washer as per procedure. Each device was then removed on the clean side and exposed to pressurized air for random, nonstandard non-measured times before being placed in the dryer cabinet.

At the same time, arms that were identified for the experimental groups were pre-cleaned and placed in the ultrasonic washer. These arms were then removed, exposed to various amounts of timed (10, 15, 30 seconds) and monitored pressurized air while still in the decontamination workflow, and then connected to the lumen drying system in the drying cabinet with the timer started on the directed airflow channels.

It's important to note that every Endowrist device in the study went through both pathways to ensure that complete sampling was achieved.

Clean side procedures

While the Endowrist lumens were processed with the lumen drying system in the drying cabinet, the cabinet was also being used to dry other types of instruments. A log sheet was placed on the clean side to record each time the door was opened and what items were removed. This manual log was used to ensure compliance with scanning test and non-test instruments into and out of the dryer on the clean side for comparison later.

In this phase, once the predetermined time was reached, the door was opened, the time recorded on the manual log, the dryer device rack identification was recorded and then all devices in the rack were scanned into the electronic tracking system at the workstation. This process was developed so that we had multiple touchpoints where time-sensitive data was being collected to confirm recorded time accuracy.

Once at the prep workstation the tech would remove each device from the rack one at a time and place it on the scale for weight measurements. The weight was recorded twice to ensure accuracy and then the tech would use the residual swab tester to determine if any moisture remained in the lumen. The weight was then compared to the reference log. Each

instrument had its weight entered into the data collection worksheet along with the results of the swab tests. This data was later used to determine the "dry weight range" that would be used in the next phase of the study. The collected weights were compared to the original dry weights taken before processing. Then manufacturer specs for each Endowrist model were recorded as a baseline and the values collected were used to establish a range for each model that ensured the highest compliance. This gave us a metric we could reproduce in determining if a device was "clinically dry."

After completing the Endowrist weights, we were able to establish a scale for each Endowrist model and a weight range that would allow us to measure how dry the device was by assessing its weight after processing in the lumen dryer.

Metrics and measures

As a means of confirming the adequate dry value of each lumen, all the devices were processed in the department's low temperature sterilizer. The rationale behind this added step was to use the built-in moisture sensors of the low temperature system to gauge the effectiveness of the measuring and testing process used in the initial phase of the study.

During this process the instruments were tracked using the department's tray tracking program and the appropriate cycle was run for each tray. Each cycle had its parameters recorded using the electronic worksheet used to collect the study data, which was entered in the department tray tracking software per standard department procedures.
During the initial phase testing, there was a noticeable spike in cycles aborting due to moisture. These aborted cycles were in the control groups where lumens were only exposed to pressurized air for either 10 seconds or 15 seconds. Moisture failures resulted in 115 of the loads aborting.

Survey instruments and microbiological testing

The online data collection worksheet was added to the department intranet site for universal access. All department staff were also given training on the completion of the survey form and then a competency assessment was administered under timed conditions to ensure skills competency was met. Each member of the staff participating in the study collection process successfully passed the assessment before starting data collection for the study.

Microbiological testing lab procedures were specifically developed for this study. CRE strains of three different gram-negative bacteria (Escherichia coli ATCC BAA-2469, *Pseudomonas aeruginosa* ATCC BAA 2110, and *Klebsiella pneumoniae* ATCC BAA-1705) and three non-CRE strains of bacteria (*Escherichia coli* ATCC #8739, *Pseudomonas aeruginosa* ATCC #9027, and *Klebsiella pneumoniae* ATCC #4352) were used. Side-by-side traditional culturing was done.

Quality control

During the testing all devices intended for patient use were processed through the hospital-approved steam sterilization workflow. After the study protocol was established and the data collection began, there was a decrease in the number of moisture errors reported by operating room staff. At first, this was thought to be anecdotal, but after analyzing the data, a pattern emerged.

Fewer moisture errors

The data showed that there was in fact a relationship between the measuring process we used to make sure the robotic arms were dry and the dramatic reduction in errors reaching the OR during the course of the study. Specific quality metrics showed a steep decrease in the number of reported events of retained moisture reaching the back table; from 20 recorded incidents in a 7-day period before the study, to only 4 reports during the entire month the study was underway. *This was a 95% reduction*.

In addition, there was a sudden reduction in staff complaints of retained moisture in the lumens during the setup of the robotic arms. Before the study there had been as many as 14 complaints in a month, and during the study there were only 2 in 30 days; *an 85% reduction*. These reductions occurred despite the fact that the devices were processed by steam sterilization, the current hospital practice, rather than with the low-temperature system used for the study.

Fewer inspection errors

Another error reduction noted during analysis had to do with missed end-of-life identification in the decontamination area. The process of tracking end-of-life devices for data collection purposes had the added benefit of closing the loop on the inspection process during decontamination. Whereas the month before a total of 22 error events were recorded, not a single expired Endowrist device went to the OR for the duration of the study.

Improved satisfaction and turnaround times

After this pattern was discovered, a survey was circulated asking the OR scrub staff working in the robotics rooms to rate on a scale of 1 to 10 their satisfaction with the current level of service they had been receiving during the study period. The average score was an 8. In the comments section, the number one comment by far was "unbelievable improvement." This survey was also sent to the surgical staff and first surgical assists who had cases in the robotics rooms at least twice a day. The results mimicked the scrub staff survey, with a satisfaction average score of 8 and comments focused on the dramatic reduction in contaminated equipment. This group also indicated they were very pleased with the faster turnaround times on the robotic sets. Pre-study, the average time for turnaround (documented by the tray tracking system reports) had been more than 90 minutes; but during the lumen drying system study the average time dropped to just over 55 minutes, *a reduction of almost 61%*.

Temperature protocols

Temperature monitoring was a critical element in this study. As part of Objective 4, we needed to document whether repeatedly opening the drying cabinet door to remove other items would have any effect on the lumen drying system's 30-minute cycle and/or the Endowrist arms connected to its directed airflow channels.

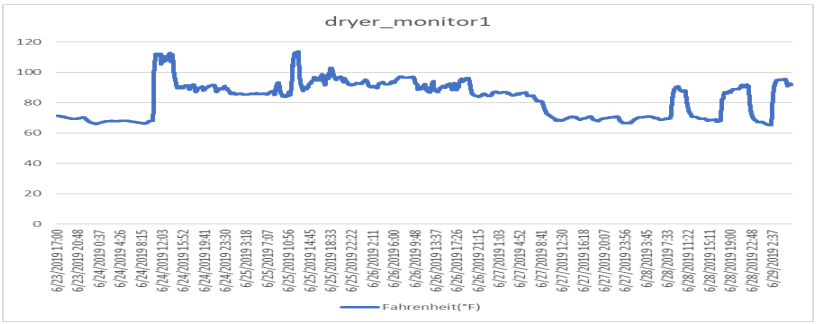

Figure 2: Cabinet Temperatures During Cycle

We discovered that there was a significant drop in ambient temperature in the chamber when the door was opened for as little as 4 seconds. This resulted in an average drop of 2 degrees every 2 seconds. We also noted that once the door was closed it took more than 3 minutes to begin to recover the lost temperature, and that 84% of the time the chamber didn't return to the target temperature. This was because the loss in sustained temperature was cumulative as the door was opened repeatedly, and this further impeded the recovery process. As you can see in Figure 2, the chamber never returns to the sustained target temperature.

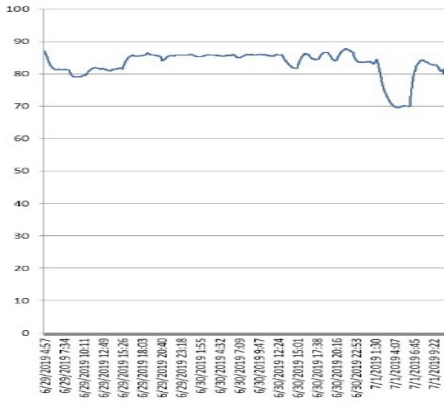

Figure 3: Temperature in Airflow Channels

Figure 3 illustrates that the directed airflow channels of the system inside the dryer chamber are more successful at maintaining temperatures in the target zone despite the chamber door being opened to remove other devices. In addition, there was no evidence of any decline in sustained airflow pressure. Since the drying process was dependent on temperature maintenance and sustained airflow, the data supported the hypothesis that directed airflow successfully dried the inner lumen surfaces regardless of the ambient chamber temp fluctuations and the opening of the chamber door.

Drying time variations

Evidence indicates that this lumen drying technology also offers a significant benefit in terms of drying time. The data from the experimental group showed a steep decline in drying time when compared to the control group. Control group lumens were laid flat on the dryer shelf, per hospital procedures. They were initially removed at the same time as the arms attached to the directed air channels (at 30 minutes). It should be noted that 100% of the control group failed; none of the control group arms reached the Clinically Dry threshold in 30 minutes. They were returned to the dryer shelf and tested every 15 minutes until each arm met the dry weight target. *For more than 96% of the control group lumens, the amount of time required to reach their dry target weights was more than 70 minutes.* Less than 2% dried in less than 70 minutes and about 2% were still not dry after 70 minutes.

Thermal conductivity is the property of a material to conduct heat. Heat transfer occurs at a higher rate across materials of high thermal conductivity (such as metals) and is impeded by insulation on a device. When you consider that drying is

dependent on conduction of heat from the outside of the lumens to their interior surfaces, it's not surprising that they wouldn't be dry in 30 minutes from sitting passively on a shelf. Three factors are against it: the variability of the chamber temperature from repeated openings, the inconsistent/weak flow of circulated chamber air through the channels, and the fact that these arms are insulated by design. Furthermore, simply elevating the temperature would not be the answer. Increasing the exterior temperature would do nothing to expedite the drying of the inner lumen and in fact could cause significant permanent damage to the device and shorten its useful life. As this study shows, effective drying requires a directed flow of air through the lumen for a measured amount of time, under specific pressure and temperature conditions that are immune from the effects of repeatedly opening the cabinet door.

Discussion

This study successfully achieved the stated objectives:

- We established a functional definition for the term "**Clinically Dry**" that is based on metrics any department can implement.
- We successfully created a metric that can be universally applied and reproduced to measure the rate of compliance in reaching a Clinically Dry standard.
- We successfully applied the matrix of a dry weight schedule for the instruments as a means of measuring compliance to the established Clinically Dry benchmark.
- We determined the effect of opening the drying cabinet door on the temperature generation capability of the directed flow channels.
- We conclusively confirmed that the system successfully maintained uninterrupted flow at the target temperature ranges to achieve the desired level of dry, which was confirmed by the dry weight.

The data documents that directed airflow is not only more effective than standard drying practices; it's also more efficient. When using the lumen drying system there was a significant reduction in the length of overall processing time and in the number of events requiring repeated reprocessing due to failures. The ability to measure and achieve Clinical Dryness before sterilization reduced the number of aborted cycles, reduced retained moisture events in the operating room, and increased end user satisfaction.

Use of the system successfully reduced drying time by 40% and increased robotic arm reprocessing productivity by almost 40%. There was an associated reduced cost of hourly labor and reduced cost per cycle, all due to this improved performance.

Training for this process was performed in under an hour, and both competency and compliance testing were easily rolled out as department procedures. Department personnel reported over 92% satisfaction with the new workflow, which also contributed to higher employee engagement scores.

The data strongly indicates that there is a direct correlation between pressure-regulated air exposure time and the efficacy of the lumen drying system. The optimal combination was 30 seconds of pressurized air, then 30 minutes in the lumen drying system. Data also indicates that the correlation metric is universally applicable to all robotic arms. This reproducible method was designed using the specific "Clinically Dry" standard that was established for the study protocol.

The data also suggests that there is a correlational relationship between moisture retention in the lumens and aborted low-temperature sterilization cycles, and that retention of moisture outside the Clinically Dry parameters of the study's weight ranges results in an aborted cycle that prolongs the processing time and increases the likelihood of patient care delays.

Although a low temperature sterilization method was used in this study as way to confirm the achievement of Clinically Dry devices, most departments employ steam sterilization. It should be noted that all the reported quality control improvements in this study were achieved via the standard steam sterilization workflow.

'Clinically Dry' devices are achievable

Our research has shown that this new directed air system and the protocol developed for testing its efficacy provide an opportunity for facilities to achieve numerous clinical benefits. The study supports the conclusion that this is a reproducible protocol that can result in significant cost savings, improved reprocessing productivity for lumened instruments, and increased assurance in the sterile processing workflow.

Sterile processing departments have the potential to reap numerous real-world benefits from replicating this study's workflow and applying its Clinically Dry metric. For example, integrating a Lumen Drying System into the drying workflow can reduce the amount of time required to achieve Clinically Dry robotic arms to thirty minutes, which in some cases translates to as much as an hour less of

drying time per cycle. This time savings can reduce processing time overall by as much as 40%. This corresponds to a net savings, on average, of nearly $60,000 a year in operating costs and another $40,000 a year in cost avoidance (2019 dollars).

There are also productivity gains that can be achieved. Installing the lumen dryer's device rack and controls into the inner wall of an existing dryer cabinet enables users to dry up to 10 lumens at a time in the vertical position required by manufacturers' IFU.[6] Since we have confirmed the ability of the lumen dryer's directed air flow channels to maintain a target temperature range even when the door is opened repeatedly, the exposure time will not need to be lengthened. This translates to drying more lumened instruments in a shorter time, while simultaneously allowing full use of the cabinet for drying a complete load of other devices and instruments.

Departments can also reduce the number of OR-reported retained moisture events, which can also improve surgical customer satisfaction. The 95% decrease documented in our data suggests that this protocol can also improve quality control systems.

However, the most important benefit concerns patient safety. It is the potential for dramatically reducing a facility's risk of releasing contaminated lumened instruments, which are known for retaining moisture and being a major reprocessing challenge.[5] Having a protocol in place that allows a department to assure a clinical level of dryness can improve the quality of the end product and the confidence in a department's infection prevention program.

Finally, this study, if other hospitals duplicate it, has the potential to expand research data for the development of a clinical drying standard. This could ultimately lead to better detection and prevention of retained moisture in all reprocessing departments.

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