



How humidity effects paper-based medical packaging

*With summer arrived in much of the world, many hospitals find themselves once again experiencing problems with the effects of high temperatures and relative humidity (RH) on the integrity of medical packaging and the sterility of medical devices. **For MDMs, the challenge is to supply the best possible packaging to withstand heat and humidity, and to provide easy-to-follow storage recommendations for end users.***

In this post, we'll address the **nine most pressing questions about the effect of moisture on paper-based medical packaging.**

1. What are hospitals' main concerns about paper packaging and moisture?

The two main concerns we hear from hospitals are, firstly, that high humidity may promote microbial growth and thereby contaminate medical devices in their packaging, and secondly, that packaging above recommended RH may lead to loss of microbial barrier.

One of the issues that hospitals report is that packaging exposed high RH requires re-sterilisation of medical devices, which in turn causes delays in surgical schedules. In addition, storage of devices and materials in hospitals during the summer months is a critical point in maintaining sterility.

Supplier IFU (instruction for use) and national recommendations on environmental conditions give guidance, but in the summer, hospitals may find themselves facing environmental conditions which are outside of the recommended ranges.

2. Why is paper so sensitive to moisture and humidity?

Paper is a natural hygroscopic material and thus likes to absorb or desorb moisture from the environment until equilibrium is met. If paper is stored in an area with high



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RH, it will cause an increase in moisture content in the paper. If paper is stored in a low RH area, a decrease in moisture content in the paper will be caused. The relationship between temperature and the amount of water in the air is very important and is described by the Mollier diagram.

3. How should storage recommendations be determined?

Start with your material supplier. Many material suppliers perform their own tests to provide information about how the materials behave in various environmental conditions. Usually they conduct testing of microbial barrier and paper parameters at different RH and temperatures.

If you decide to perform your own tests, these would typically include stability tests and transit tests at selected environmental conditions and time periods.

BillerudKorsnäs' standard storage recommendation is 30-60% RH and 10-30°C.

4. What should we do when environmental conditions are outside of the recommended ranges?

Contact your material suppliers. Some will perform their own tests conditions outside of their recommended ranges to support their customers. BillerudKorsnäs has begun perform tests at RH up to 90%. To learn more about the effects of RH on paper, please get in touch with us.

5. Are storage conditions part of hospital tender negotiations?

Yes, they can be. Some hospitals have started requesting Instructions for Use (IFU) for storage conditions outside of the recommended ranges.

6. Can microbial growth in packaging at high RH be a problem in hospitals?

At BillerudKorsnäs, we have undertaken an extended literature survey and have not found any evidence, articles, or literature which would indicate a risk for microbial growth on medical paper-based packaging at high RH. To learn more about the effects of RH on paper packaging, please get in touch to hear about the results of our own testing of the effect of high humidity on paper packaging.



7. Are issues with microbial growth on secondary or tertiary packaging during transportation or storage common?

Yes, many hospitals report issues with fungi contamination on secondary or tertiary packaging upon arrival to the hospital. This is often due to the content of recycled fibers in the packaging. To avoid such issues, we recommend requesting packaging produced from 100% virgin fibers.

8. How is microbial barrier affected by high RH?

BillerudKorsnäs' initial testing confirms that paper packaging exposed to high RH of 80% for one week maintains its microbial barrier. Microbial barrier of paper is ensured thanks to multiple layers of fiber structures of different sizes and lengths which create a labyrinth of pores that is difficult for bacteria to pass through.

9. What happens to paper packaging that is exposed to RH up to 90%?

BK performed tests to investigate effect of high relative humidity up to 90% on paper parameters. The result confirmed that most of paper parameters important for microbial barrier will improve after absorbing moisture at higher relative humidity. We'd love to share the results with you. Please get in touch.

BillerudKorsnäs has a wealth of expertise and experience in paper packaging for medical devices. We're known for our flexibility and are well-positioned to customise a solution for your particular needs, so please don't hesitate to contact us. We look forward to hearing from you.



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