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Medical Device Enabled

INGRESS PROTECTION FOR MEDICAL DEVICES: WHAT TO CONSIDER

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SUMMARY

Nextern has developed the knowledge and resources to design devices to a standard known as Ingress Protection (IP), which ensures protection from environmental elements. We can determine the level of ingress protection based on the device's use case, develop design elements that will protect a device from certain levels of ingress, and test design elements to ensure the application functions as intended - protecting the device and users from harm.

INTRODUCTION

What the standards say:

According to **IEC 60601-1 Section 6.3**, devices with enclosures must be classified with a rating of protection against harmful ingress of liquids and solids. **Section 11.6** details the level of protection needed in different cases like normal use spills and leakage. Both sections point to a specific ingress protection rating defined by **IEC 60529**.

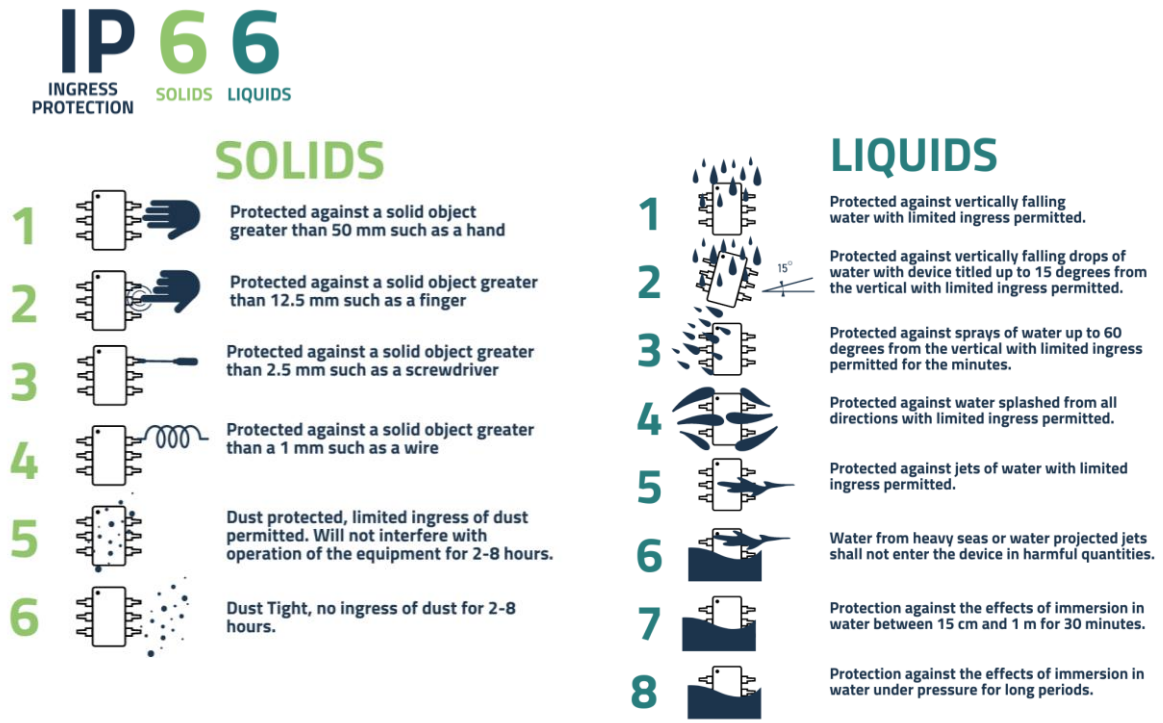
What you need to know:

Ingress Protection (IP) is a vital element to a device's usability. It determines if a device will short circuit if it's left out in a light rain or whether the device will make it safely to the bottom of the Mariana Trench (or anything in between). In terms of medical devices, IP ratings indicate if the device is safe from the expected normal use and beyond in homes or hospital rooms. It also describes if someone could stick their finger into a high voltage line inside the device or if it's completely dust-proof. **Essentially, IP Ratings describe how resistant a device is to both solids and liquids making their way inside and causing damage.**

BACKGROUND

As stated above, IP Rating is defined by IEC 60529, which describes a series of specified tests on a device. Based on the level of the tests a device passes, it's given a two-number rating, with the first number being its solid ingress resistance and the second being for liquids. The number in each rating type corresponds to the highest level of each set of tests the device was able to pass.

See below for a breakdown of the IP Codes.



PROBLEM

The question then becomes what level of ingress a device will need to protect against. For example, devices that are used in indoor controlled environments such as a clinic or doctor's office may only need an IP22 rating. Most devices that will be mounted in place outdoors may need an IP44 rating to protect against animals and heavy rain. Cellphones, as another example, are rated IP68 to protect against years of pocket dust and being submerged in water.

PROBLEM STATEMENT: Ingress protection needs to be present for most medical devices if devices may encounter liquids and have potential to cause harm or electrical shock to patients.

So how do we design and internally test a medical device for a certain level of ingress protection? And how do we test medical devices to be certain there is no risk for the patient?

CONCLUSION/SOLUTIONS

Ensuring your medical device meets the correct ingress protection (IP) standards involves several considerations. With careful gasket structure, precise tolerancing, mechanical joints and interference design we can make any two parts fit together in a way that will keep out liquid and solids. Developing these components and manufacturing processes consistently can come down to trial and error.

With Nextern's wide variety of 3D printing technologies, our team can repeatedly and rapidly prototype isolated features or whole devices until we find a design that holds up to the Ingress Protection standard that is necessary. We can then develop the production-level device and processes to guarantee the device will meet the same level of protection. But how do we confirm that these devices will withstand the environmental challenges they might face?

To reach liquid rating of 1 (IPX1), for example, the device needs to survive 10 minutes of light rainfall, a rating of 4 (IPX4) would mean it survived spray from small nozzles from all angles, and a rating of 7 (IPX7) means it survives being submerged in water for 30 minutes. To reach a solid ingress rating of 1 (IP1X) the device would need to protect itself from a large ball probe, a rating of 4 (IP4X) means it would keep out a wire, and a rating of 6 (IP6X) is only given to devices that keep out all dust as it's blown around in a large air chamber.

With test chambers designed to put a device through its pace and subject it to the level of ingress protection we're testing, we can verify that a device will survive not only up to, but exceeding the standard it needs for its use case.

Achieving ingress protection (IP) requires a combination of design, prototyping, and testing. Using precise engineering through validation, we can ensure that medical devices can withstand the harshest elements and provide reliable performance for critical healthcare solutions.