

Leak Testing and Product Design in the medical sector

What are the factors that can influence the leak testing on a medical device?

MODENA, ITALY, May 31, 2021 /EINPresswire.com/ -- Technology is evolving day by day, and there are many changes coming.

Due to the rapidly changing technology, people's lives are getting better day by day. Nowadays, technology is not limited to just one domain. Instead, it is widely spread.

One of the most useful innovations includes making new medical devices and fixing the old ones so they can perform better. You might be thinking that how hard it can be to improve an old medical device. But let me tell you one thing, it is "quite" hard because changing these devices affect the [leak testing](#).

The things that affect the leak testing of a device

Considerable improvements in a medical device can affect the leak testing. Some of them are specified below.

- **Altering the shape of a device**

Altering or changing the shape of an existing medical device will affect the leak testing. The reason for this is its dimension. As you tend to change the shape of an existing medical device, you change its dimension. Change in dimension alters the part volume. For those of you who do not know, part volume is directly proportional to the leak rate. A changed leak rate will also affect the previous standards of the device, and for new standards, and fixtures you would need to make a new program. Creating a new program is not easy as it seems and requires various tests and verified documentations.

So, the shape does matter and you need to know the basics for it.

- **Replacing the material**

As time passes, medical devices tend to wear out because of frequent usage. Due to this wearing-out, device testers may think of fixing the medical device by replacing its material.

- **Although replacing or changing the material of a device is a very economical method to fix a worn-out medical device, it comes with a very heavy price, which is a significant change in leak testing.**

- Different materials tend to have different densities, and that is why one material can be more elastic than the other.

- Elasticity is another factor that messes up with the leak rate.

Moreover, changing the material of a device will also cause it to change its temperature. And as leak testers are sensitive to temperatures, it would also affect the leak rate in an undesirable way.

- Changing the color of a medical device

Changing the color of a medical device can affect its heat-absorbing, transferring, and reflecting properties. All of these properties tend to affect the leak rate test. And to get a suitable leak rate, you must make another new program, which is not very easy to make.

All of these elements are too small to be paid attention to, but they can seriously affect the leak testing.

Hence, the device manufacturers must put their label on the device, which should state that a person should contact them before making any significant changes in the product.

Taking this step would significantly help [medical device testers](#), and it will be deemed a more responsible step towards humanity.

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