



## 3D Scanner Applied to Patients Under 18 Years of Age: Has the Time Come to Rewrite the Regulations for Use?

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### Abstract

The arrival of 3D digital scanning systems for patients' ears has revolutionized one of the most classic fields of Audiology, that is, the manufacture of custom silicone molds for the patient's ear. This is an efficient and clean system due to the accuracy it provides. But while performing 3D ear scanning for children, we face a big obstacle. That obstacle is that the instruction manuals of the manufacturers of the 3D Scanner indicate that it is used only for those over 18 years of age. In other words, we must give up one of the most important fields of our profession which is Pediatric Audiology.

This aspect is treated in this opinion article from the perspective of the authors' own experience and reflects their personal contribution in this field throughout their 30 years of work and experience, making classic silicone molds and the new 3D molds by scanning. Our opinion article is intended to suggest a change in the current use of 3D scanning with children.

The exact copy of the ear is a tremendously important aspect while examining patients with severe and/or profound deafness, especially at an early age. But there are some teenagers of 12, 14 or 16 years old, who have a wide enough conduit to be able to use the Otoscan 3D, especially if they have been using tight molds since they were little. And there are also adult patients with a very small ear canal, which makes scanning impossible.

For this reason, our proposal and recommendation is to change the instruction manuals for use from 2021 so that the limitation is not based on age, but on the diameter of the ear canal. In this way, the responsibility of the manufacturers of the equipment is safeguarded (which is one of their main concerns and basis of the reason, in the event of possible legal claims), and allows flexibility in use based on a technical/audiological criterion, instead to be based on a mere question of ages.

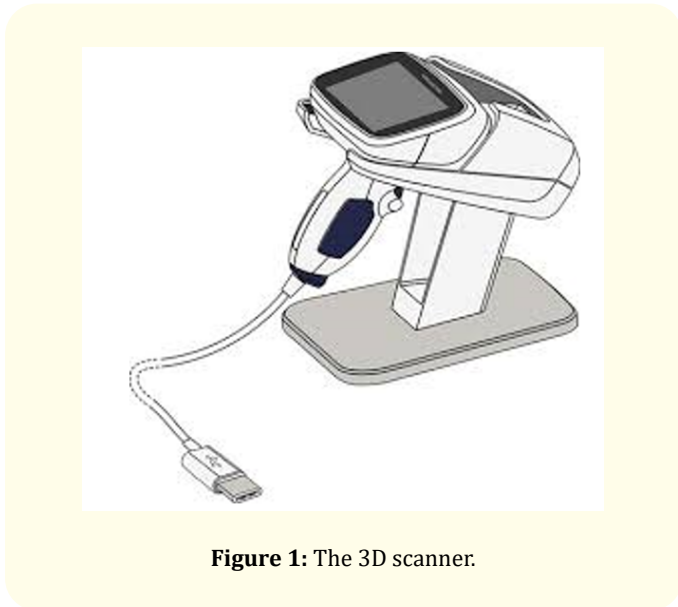
**Keywords:** 3D Scanner; Children and Otolaryngology; Audiology and Regulation; Current Affairs in Audiology

### Introduction

In recent years, Audiology and Anaplastology have evolved very rapidly related to taking measurements of patient's ears. This is mainly due to the arrival of digital 3D scanning systems that are replacing traditional techniques for making molds with silicones.

Currently, it is not necessary to inject the liquid silicone into the patient's ear by means of a syringe or injection gun. The measurement can be taken with a 3D Laser beam that digitizes the shape and volume of the ear canal. This scan is later visualized in 3D software that allows us to analyze all the perspectives and angles ro-

tating 360 degrees around the mold. It allows us a view from the inside and outside of the ear to see the pinna of the ear (Figure 1).



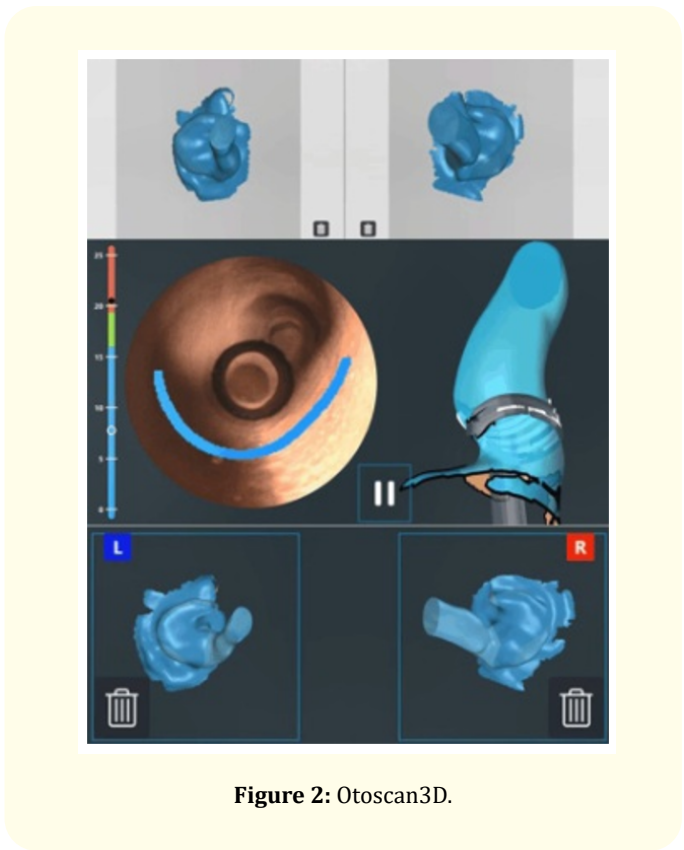
**Figure 1:** The 3D scanner.

We can also carry out tests with the components of InTheCanal hearing aids (ITC), to see if the microphone, headphone, battery, amplifier body, etc. will fit inside and in what position.

This new technique for reproducing the patient's anatomy using laser and 3D software has the advantage of allowing us to plan retouching and changes on the computer screen. And it is leaving behind the classic injected silicone mold system. By working with Otoscan 3D, we get cleaner, faster and more versatile systems. And we can provide solutions to the cases of our patients in the same visit in which we take the measures, thus avoiding trips and repeated visits (Figure 2).

Although the progress has been very important, there are still some limitations on the part of the equipment manufacturers. Especially in relation to the use and application with children and young patients. Technical drawbacks, such as the diameter of the tip of the laser beam that we place in the child's ear, are expected to be solved in the future by reducing its diameter.

But there is an added drawback due to the legal limitations of use. This is a conceptual issue and not a technical one. The current application age is limited to 18 years of age and older (See figure 3: page 6 of the Otoscan 3D User Manual [1], Section 2.4: Expected



**Figure 2:** Otoscan3D.

patient population: "Otoscan is indicated for use on patients 18 years of age and older presenting for inspection of the external ear channel").

This leaves out pediatric patients. However, many fellow audiologists apply Otoscan 3D for children or adolescent patients in hearing aid or bath protection molds (perhaps without knowing this technical/legal detail? [2]).

Of course, the use in young people does not present technical problems in the hands of a professional with experience in the handling of children. Although the tip of the laser beam in current models is not very fine [3] and it is the diameter in relation to the child's ear canal that will really determine if it is possible to scan the mold in children under 18 years of age.

On the other hand, if we do not apply the scanner to children when making personalized molds, we have to use the old system as an alternative: silicones.

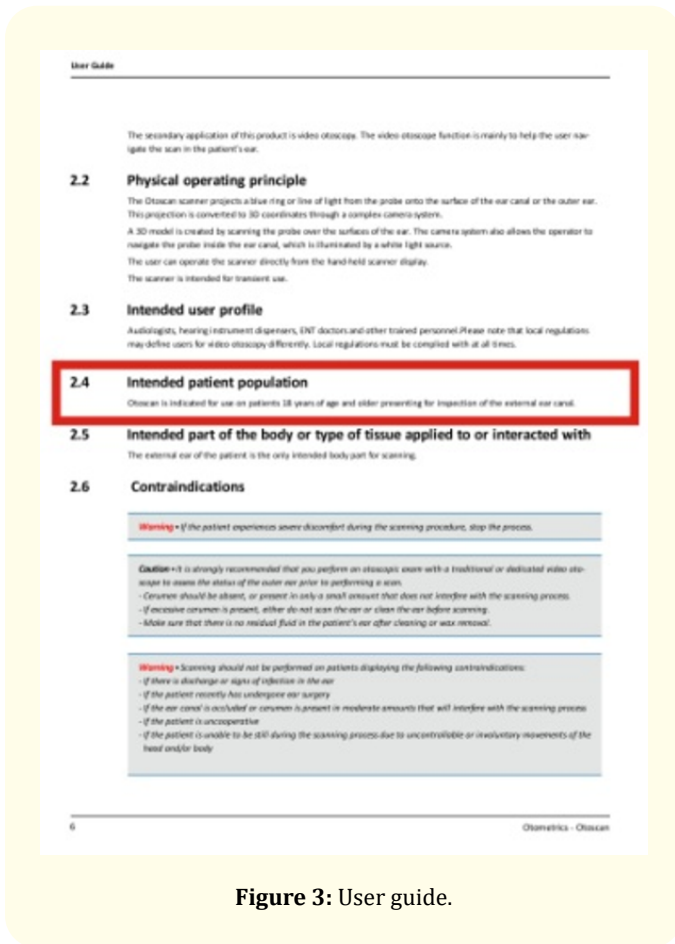


Figure 3: User guide.

This implies a greater degree of risk due to the previous placement of the protector called "OtoBlock" in the small infant canal. And we must also inject the silicone with a pediatric syringe (or with a gun and pediatric cannula adapter [4]). And finally the mold extraction maneuver. All of this is obviously more complicated than a 3D scan with just the laser beam (Figure 4).

The obstacle here is not the technical issue (that is, reducing the diameter of the laser tip), but a legal obstacle and the risk of complaints that could be filed against the manufacturer in cases of misuse of this type of instrument. In this case, they are multinational corporations with global distribution on all continents, so manufacturers try to establish a recommendation level that works for all countries. But perhaps (and here is the important part of the matter we are dealing with) the reference of use according to age

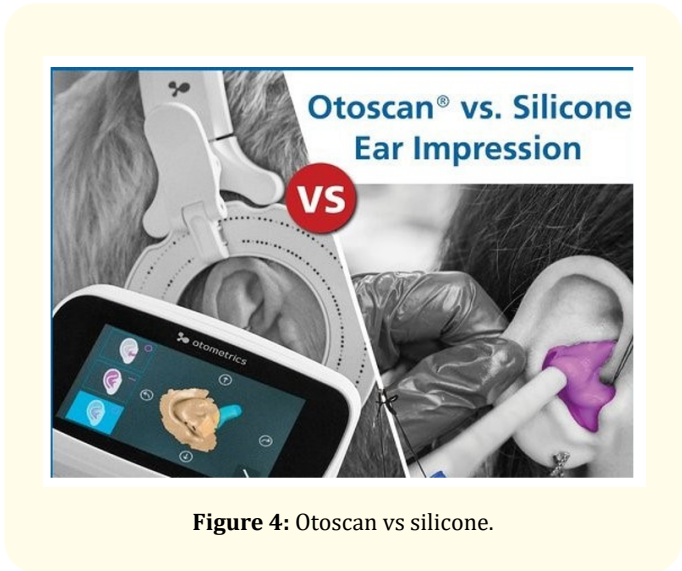


Figure 4: Otoscan vs silicone.

can be left open and without age limitation. And leave the limitation linked to the diameter of the duct.

This would not only allow us to treat patients under 18 years of age with good-sized auditory canals but would also allow, in parallel, to recommend the discarded cases of patients over 18 years of age who have canals with physical characteristics that are limiting due to their diameter.

At this point we must ask ourselves, is it time for audiologists to recommend that manufacturers modify the limiting texts and incorporate a more fluent expression? For example: "Otoscan 3D is indicated for use for patients with a minimum diameter of the ear canal equivalent to 1.5 times the diameter of the scanner tip".

### Conclusion

Therefore, we propose a new standard for patient selection that is not based on "The age limitation that the manufacturer carries out due to a legal prudence of self-protection, to avoid risks of legal complaints, but based on technical and anatomical factors, that is, the diameter".

Perhaps a debate, based on the use of the professionals experiences become necessary. Perhaps we already have enough cases of measurements with Otoscan 3D to be able to face a revision of the texts of the recommended use manuals. Logically this is something that should be driven by the manufacturers themselves, but it can

also be something that starts with the opinion and perspective of the Audiologists who use the equipment. Maybe audiologists are getting to the moment when we shouldn't just use what manufacturers give us, but also ask them for real solutions for patients in our clinics?

The collaboration of audiologists who do not belong to the manufacturer's own research teams can help us all to sit around the table and talk about this issue and reach an agreement that benefits patients who are currently left out of the group that we can serve with Otoscan 3D.

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