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(54) **HOUSING FOR AN EARPIECE AND METHOD FOR PRODUCING A HOUSING FOR AN EARPIECE**

(57) The invention relates to a method for producing a housing for an earpiece configured to be at least partially inserted into an ear canal of a user, the method comprising:
- determining a three-dimensional model (1) of a user-specific ear canal geometry,
- expanding at least part of an outer surface of said model (1) relative to the user-specific ear canal geometry by an offset, and
- fabricating the housing based on the model (1),
wherein the expanding of the outer surface comprises:
- determining a first position at the outer surface of the model (1) within a cartilage region of the ear canal;
- determining a second position at the outer surface of the model (1) within a bony region of the ear canal,
wherein, at least partially within the offset surface, the model (1) is provided such that the offset gradually decreases between the first position and the second position.

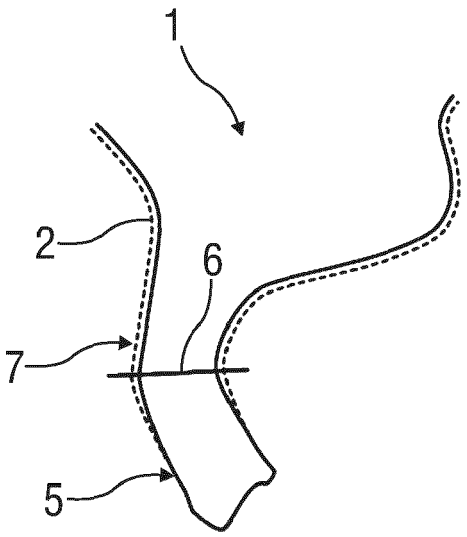

FIG 4

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Description

Technical Field

[0001] The invention relates to a method for producing a housing for an earpiece and to a housing for an earpiece.

Background of the Invention

[0002] In a conventional manual manufacturing process of a custom housing for a hearing device, such as a custom shell or a custom mold, one important step is waxing, also known as global waxing. In that process, a silicone impression would be manually cut (this cutting is also referred to as detailing) to be sized such that it meets the goals of the application, e.g. components would fit into a shell of the corresponding size. After such detailing, the detailed impression would be dipped in a basin of liquid wax, once, twice or maybe more, with the intent of increasing its size. Such a waxed detailed impression would then be slightly bigger than the actual impression of the ear canal, providing increased sealing and/or better retention, ideally both. The amount of waxing depends on tissue compliance, user experience, and the application in mind for the shell or mold.

[0003] In an improved digital manufacturing process of custom shells for hearing devices known in the art, a processing step analogue to the global waxing is also performed: after detailing, after the detailing step, the detailed model undergoes offsetting, by a selectable amount, which results in oversizing of the shape much similar to (repeated) submersion into liquid wax in the manual process.

[0004] This process has various downsides:

1. Global offsetting does not distinguish individual areas. Deep-reaching areas, e.g. starting from the second bend of the ear canal to the eardrum, will be offset the same as regions further out the canal, up out into the concha or even the cymba. Tissue, however, is fundamentally different between those regions: the deep-reaching areas comprise a so-called bony area. Little to no cartilage, merely only the skin, covers the bony structure of the skull. Oversizing a custom shell or mold and hence exerting pressure is uncomfortable, or even painful, in those areas. This is in contrast to the regions further out, where cartilage of increasing thickness allows for increased sealing, oversizing, and exertion of pressure.

2. Global offsetting as described above, will not increase the size to at skin-contact areas only, but also in all other areas. As a matter of fact, the intention is to increase fit, to improve sealing, which necessitates offsetting of the shape-parts that are in contact with the skin, with the "wall" of the ear canal. However, global offsetting (or likewise submersion into liquid wax) will offset all areas, not skin-contact parts only, e.g. inside the shell, towards the eardrum in the canal and to the outside of the ear.

[0005] The first downside has been addressed manually in the past. For example, the tip area, i.e. the bony region, may be inside offset (negatively offset) as a first detailing operation. The intent is to basically counteract later global waxing of the detailed shape. Only then would the normal detailing start. Obviously, this applies only to deep-reaching devices, reaching to or past the second bend and hence actually extending into the bony area. In particular, this may affect a custom shell or a custom mold which may be fabricated from titanium or acrylic or a thermoplastic material. For instance, a shell for IIC (Invisible In the Canal) devices, which are thin-walled and at least partially invisible in the canal, or a housing for a RIC (receiver in the canal) device may be directly printed in an additive manufacturing way (3D printed), e.g., titanium or acrylic. When printed in titanium, this is often followed by post-processing for a smoother appearance. Unlike acrylic shells, titanium shells do not need any lacquering. Hence, they may be offset (globally wax) a bit more, correcting for the layer which would be normally added by lacquering. They may also be offset a bit more in tendency in order to increase the fit-rate needed to deliver on the at least partially invisibility promise of IIC devices.

[0006] The second downside may be addressed by offsetting the undetailed model, i.e. the input ear model shape, instead of offsetting the detailed model, the entire shape resulting from shaping of the undetailed model. One could be tempted to modify the model prior to template application. However, doing such a kind of negative offsetting of the tip area on the model is wrong, too: the model shape should not be changed. It is the input of the process, the anatomical information about the customer's ear, and used for quality checking and acoustic computations (such as AOV - acoustically optimised vent), and more. So, changing it for this purpose is clearly bad advice. Models should only be edited to fix defects and clean up the scan data. In particular, the original model, which may be based on an ear impression, needs to be kept as the ground truth, as the relevant anatomical information about the customer's ear, namely but not exclusively for quality control and acoustic computations. In order to address the first downside, or both downsides in a combined manner, a different approach is thus needed.

[0007] EP 1 345 470 A2 describes a body-worn device being manufactured by preparing a digitised three-dimensional representation of an individual's body area where the body-worn device shall be applied. From such a digitised three-dimensional representation there are characteristic features of the individual's area which can be automatically determined as digitised. In dependency from such determining, the digitised representation is amended in a detailing step. The result is a digitised rep-

resentation. This detailed digitised representation controls the shell manufacturing process the resulting shell of which is assembled to the body-worn device.

Summary of the Invention

[0008] It is an object of the present invention to provide a novel method for producing a housing for an earpiece configured to be at least partially inserted into an ear canal of a user and to provide a novel housing for an earpiece, configured to be at least partially inserted into an ear canal of a user.

[0009] The object is achieved by a method according to claim 1 or 8, and by a housing for an earpiece according to claim 13.

[0010] Advantageous embodiments of the invention are given in the dependent claims.

[0011] According to an aspect of the present invention, a method is proposed for producing a housing for an earpiece configured to be at least partially inserted into an ear canal of a user, the method comprising:

- determining a three-dimensional model of a user-specific ear canal geometry,
- expanding at least part of an outer surface of said model relative to the user-specific ear canal geometry by an offset, and
- fabricating the housing based on the model.

[0012] According to the invention, expanding of the outer surface comprises:

- determining a first position at the outer surface of the model within a cartilage region of the ear canal;
- determining a second position at the outer surface of the model within a bony region of the ear canal,

wherein, at least partially within the offset surface, the model is provided such that the offset gradually decreases between the first position and the second position.

[0013] The three-dimensional model may be determined by measuring an ear canal of a user. This may be achieved by taking an impression of the ear canal using a moldable material, e.g. silicone, and scanning the impression. Likewise, it is possible to determine the three-dimensional model by inserting a probe into the ear canal for directly scanning the ear canal. The scan data may be converted into a point cloud model or triangle mesh with thousands of points or triangles. This model may then be digitally processed in a software, e.g. by expanding, i.e. adding an expansion layer on top of a surface of the model, and/or by detailing, i.e. virtually cutting the model for locally reducing a size of the model, e.g. at a distal end and/or at a medial or proximal end and/or inwardly, e.g. to provide space for internal components of the earpiece, e.g. a receiver, one or more microphones, sensors, circuitry and/or venting. The optimum placement for these internal components may also be determined in the software, taking into account the user's anatomy and audiological needs. The finished build of the model may then be used to fabricate the housing shell, e.g. by 3D printing.

[0014] In an exemplary embodiment, the second position marks the beginning of a first portion of a contact surface of the model near a medial end of the model.

[0015] The medial end may be defined as an end facing a tympanic membrane inside the ear canal when the housing shell is at least partially inserted into the ear canal.

[0016] In an exemplary embodiment, the offset gradually decreases between the first position and the second position down to zero.

[0017] Leaving a first portion of the contact surface near the medial end which may be configured to contact a bony area within the ear canal unexpanded avoids building up pressure where it might hurt the user of the hearing device, while the expanded areas, in particular areas intended to be in contact with the cartilaginous part of the ear canal, may improve fitting and sealing. In an exemplary embodiment, the method further comprises a detailing step, comprising reducing a size of the model at a distal end and/or at a medial or proximal end and/or inwardly.

[0018] The distal end may be defined as an end pointing away from the tympanic membrane when the housing shell is at least partially inserted into the ear canal.

[0019] In an exemplary embodiment, the detailing step is performed after expanding.

[0020] In an exemplary embodiment, the first position is located in an area of the model reproducing the ear canal from a first bend to a second bend of the ear canal, in particular at the second bend.

[0021] In an exemplary embodiment, the model is expanded with a uniform offset distal from the gradual decrease.

[0022] In an exemplary embodiment, the housing is a shell, in particular a custom shell. In an exemplary embodiment, the housing is a mold, in particular a custom mold.

[0023] According to an aspect of the present invention, a method is proposed for producing a housing for an earpiece configured to be at least partially inserted into an ear canal of a user, the method comprising:

- determining a three-dimensional model of a user-specific ear canal geometry,
- expanding at least part of an outer surface of said model by an offset relative to the user-specific ear canal geometry, and
- fabricating the housing based on the model.

[0024] Furthermore, a detailing step is provided, comprising reducing a size of the model at a distal end and/or at a medial or proximal end and/or inwardly, wherein the detailing step is performed after expanding.

[0025] In an exemplary embodiment, the model may

be uniformly expanded prior to detailing. In other embodiments, the model may be locally and/or gradually expanded, e.g. as described above.

[0026] In an exemplary embodiment, the housing shell is made of titanium. Alternatively, the housing shell may be made of an acrylic material.

[0027] In an exemplary embodiment, the housing shell is used to produce an earpiece for an Invisible In the Canal hearing device.

[0028] According to an aspect of the present invention, a housing for an earpiece is proposed, configured to be at least partially inserted into an ear canal of a user, wherein the housing comprises an outer surface at least partially expanded relative to a user-specific ear canal geometry by an offset. The offset gradually decreases between a first position at which the is configured to be positioned within a cartilage region of the ear canal and a second position at which the is configured to be positioned within a bony region of the ear canal.

[0029] In an exemplary embodiment, the housing may be produced by any one of the methods described above.

[0030] Further scope of applicability of the present invention will become apparent from the detailed description given hereinafter. However, it should be understood that the detailed description and specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

Brief Description of the Drawings

[0031] The present invention will become more fully understood from the detailed description given hereinbelow and the accompanying drawings which are given by way of illustration only, and thus, are not limitative of the present invention, and wherein:

Figure 1 a schematic view of a model of a user-specific ear canal geometry which may be based, e.g., on an ear canal impression,

Figure 2 a schematic view of the model after expanding,

Figure 3 a schematic view of the model after shaping or detailing, and

Figure 4 a schematic view of an embodiment of the model with a gradual offset.

[0032] Corresponding parts are marked with the same reference symbols in all figures.

Detailed Description of Preferred Embodiments

[0033] **Figure** 1 is a schematic view of a model 1 of a user-specific ear canal geometry. The model may be based, e.g., on an ear canal impression taken from the user and/or an ear canal scan.

[0034] The model 1 may be generated and processed in a method for producing a housing for an earpiece configured to be at least partially inserted into an ear canal of a user, the method comprising:

- determining a three-dimensional model 1 of the user-specific ear canal geometry,
- expanding at least part of an outer surface of said model 1 by an offset relative to the user-specific ear canal geometry, and
- fabricating the housing based on the model 1.

[0035] In particular, the housing may be provided as a housing shell or a mold.

[0036] In a detailing step, a size of the model 1 may be reduced at a distal end and/or at a medial or proximal end and/or inwardly.

[0037] The steps of expanding and detailing may typically be performed in a software for processing the model 1.

[0038] In an exemplary embodiment, instead of globally expanding the detailed model 1, i.e. the result of shaping, the undetailed model 1, i.e. the input of shaping, is expanded.

[0039] Taking such an oversized version of the model 1 as the starting point for shaping will naturally lead to oversizing of the model exactly in the contact areas.

[0040] **Figure 2** is a schematic view of the model 1 after expanding, resulting in an expansion layer 2 being added to the outside of the model 1.

[0041] **Figure 3** is a schematic view of the model 1 after shaping or detailing, i.e. virtually cutting, i.e. reducing, the model 1 to be sized such that components can be fit into it and to reduce a length at a tip 3 of the model 1, i.e. the area which will extend the deepest into the ear canal. Shaping or detailing will however not alter contact surfaces 4 of the model, i.e. surfaces which will be in contact with the ear canal walls.

[0042] In an exemplary embodiment, the expansion layer 2 is not uniformly applied to the entire model 1. Instead, the expansion layer 2 is applied with a gradual decrease of thickness from a desired offset down to a reduced offset, e.g. zero, leaving a first portion 5 of the contact surface 4 near the tip 3 which will contact a bony area within the ear canal unexpanded. Hence, build-up of pressure is avoided where it would hurt.

[0043] **Figure 4** is a schematic view of an embodiment of the model 1 with a gradually applied expansion layer 2 as described above. A starting line 6 indicates where the expansion offset starts decreasing. The starting line 6 may for example be placed at a position of the contact surface 4 intended to contact the second bend of the ear canal.

[0044] The offset, i.e. the thickness of the expansion layer 2, may be configured to fall to zero at the latest

when it reaches the first portion 5 of the contact surface 4 near the tip 3 which will contact a bony area within the ear canal. The location of this first portion 5 may for example be determined individually for each hearing device user.

[0045] Detailing starting out from such a gradually expanded model 1 will naturally only oversize in a second portion 7 of the model 1 which will contact the cartilaginous areas of the ear canal, i.e. the portion 7 of the contact surface 4 other than the first portion 5 and reach reduced or zero oversizing in the first portion 5.

[0046] Such gradual expansion can be initialized automatically. For example, the gradual decrease of the expansion layer 2 may start between the first bend and the second bend, or only at the second bend, depending on where the bony region of the individual hearing device user starts.

[0047] In an exemplary embodiment, the housing of the earpiece may be made of titanium, e.g. by an additive manufacturing method such as 3D printing, based on the model 1. In an exemplary embodiment, the housing of the earpiece may be made of acrylic, e.g. by an additive manufacturing method such as 3D printing, based on the model 1.

[0048] In an exemplary embodiment, the housing is configured to form part of an IIC (Invisible In the Canal) device. In an exemplary embodiment, the housing is configured to form part of a RIC (Receiver In the Canal) device.

[0049] In a control software for controlling the processing of the model, there may be an option provided to allow for manual setting of the gradual decrease, either only by providing a starting line 6 together with a transition distance, or an ending line together with a transition distance, or by both providing a starting line 6 and an ending line, where the offset should have reached zero or in fact a different second offsetting value.

[0050] The described method may be part of a method for manufacturing a body-worn electronic device adapted to the shape of an individual's body area, e.g. as described in EP 1 345 470 A2, which is hereby incorporated by reference in its entirety.

[0051] This method for manufacturing a body-worn device, e.g. a hearing device, adapted to the shape of an individual's body area, e.g. an ear canal, may comprise:

- preparing a digitized, three-dimensional representation of said area;
- automatically determining at least one characteristic feature of said representation;
- producing a shell in dependency of said at least one characteristic feature;
- assembling said device with said shell.

[0052] Detailing may comprise at least one of cutting, surface treating, offsetting, fixing, relaxing and increasing at least a part of the digitized representation, whereby such actions may be performed digitally. The detailing step is for example described in paragraphs [0045] to [0047] of EP 1 345 470 A2 and may comprise (virtually) cutting the model 1, in particular at a distal end and at a medial or proximal end, thus creating partial surfaces which may differ from the measured ear canal geometry. Further, detailing may include defining components to be arranged in the model 1 of the housing for an earpiece. Surface offsetting is described in paragraph [0047] of EP 1 345 470 A2. This surface offsetting may in particular be replaced by the one or more of the methods described above with reference to the figures.

[0053] The step of automatically determining the at least one characteristic feature may comprise performing such determining by automatically investigating the digitized representation under the constraint of predetermined geometrical rules. Thereby, e.g. rules with respect to curvature, surface areas of cross-sections, etc., of the digitized representation are investigated under predetermined criteria so as to find at the digitized representation the location of the respective characteristic feature.

[0054] The determining step may comprise comparing the digitized representation with a digital representation of a standard of the body area. Thereby, both approaches, namely that of performing determining with automatic investigation under the constraint of predetermined geometrical rules and by performing a comparison are combined. For instance, it is by performing such comparison that it is easily established whether a digitized representation as provided is accurate enough or not. If e.g. a difference found by such comparing exceeds a predetermined level, there is at least a high degree of likelihood that the digitized representation does not represent individual's body area with an accuracy high enough. Further, if the actually treated digitized representation is close enough to the standard, characteristic features of the standard may be exploited as the respective characteristic features of the digitized representation actually treated and may thus be taken at least as a first approximation of such characteristic features to be automatically determined at the digitized representation.

[0055] The step of determining is not essential for the present invention. Instead, the subsequent steps may likewise be performed directly using data of an ear canal measurement.

[0056] The step of preparing the digitized representation may be performed by scanning a cast of the body area. The step of preparing the digitized representation may be performed by three-dimensional scanning of the body area directly.

List of References

[0057]

1 model
2 expansion layer
3 tip
4 contact surface

5 first portion
6 line
7 portion, second portion

Claims

1. A method for producing a housing for an earpiece configured to be at least partially inserted into an ear canal of a user, the method comprising:

    - determining a three-dimensional model (1) of a user-specific ear canal geometry,
    - expanding at least part of an outer surface of said model (1) relative to the user-specific ear canal geometry by an offset, and
    - fabricating the housing based on the model (1),

    characterized in that the expanding of the outer surface comprises:

    - determining a first position at the outer surface of the model (1) within a cartilage region of the ear canal;
    - determining a second position at the outer surface of the model (1) within a bony region of the ear canal,

    wherein, at least partially within the offset surface, the model (1) is provided such that the offset gradually decreases between the first position and the second position.

2. The method according to claim 1, wherein the second position marks the beginning of a first portion (5) of a contact surface (4) of the model (1) near a medial end of the model (1).

3. The method according to claim 1 or 2, wherein the offset gradually decreases between the first position and the second position down to zero.

4. The method according to any one of the preceding claims, further comprising a detailing step, comprising reducing a size of the model (1) at a distal end and/or at a medial or proximal end and/or inwardly.

5. The method according to claim 4, wherein the detailing step is performed after expanding.

6. The method according to any one of the preceding claims, wherein the first position is in an area of the model (1) reproducing the ear canal from a first bend to a second bend, in particular at the second bend.

7. The method according to any one of the preceding claims, wherein the model (1) is expanded with a uniform offset distal from the gradual decrease.

8. A method for producing a housing for an earpiece configured to be at least partially inserted into an ear canal of a user, the method comprising:

    - determining a three-dimensional model (1) of a user-specific ear canal geometry,
    - expanding at least part of an outer surface of said model (1) relative to the user-specific ear canal geometry by an offset, and
    - fabricating the housing based on the model (1),

    characterized in a detailing step, comprising reducing a size of the model (1) at a distal end and/or at a medial or proximal end and/or inwardly,
    wherein the detailing step is performed after expanding.

9. The method according to claim 8, wherein the model (1) is uniformly expanded.

10. The method according to any one of the preceding claims, wherein the housing is made of titanium.

11. The method according to any one of the preceding claims, wherein the housing is made of acrylic.

12. The method according to any one of the preceding claims, wherein the housing is used to produce an earpiece for a Receiver in the Canal (RIC) or an Invisible In the Canal (ITE) hearing device.

13. A housing for an earpiece, configured to be at least partially inserted into an ear canal of a user, wherein the shell comprises an outer surface at least partially expanded relative to a user-specific ear canal geometry by an offset, **characterized in that** the offset gradually decreases between a first position at which the shell is configured to be positioned within a cartilage region of the ear canal and a second position at which the shell is configured to be positioned within a bony region of the ear canal.

14. The housing according to claim 13, produced by the method according to any one of the claims 1 to 12.

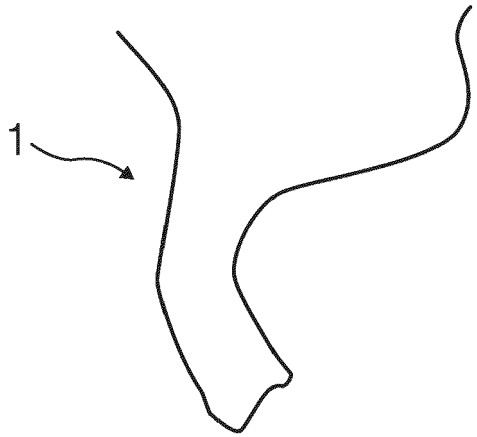

FIG 1

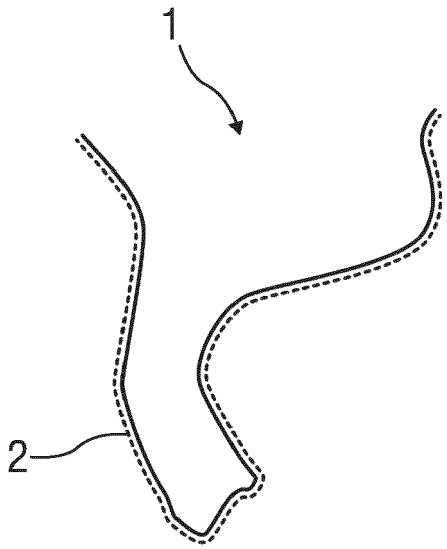

FIG 2

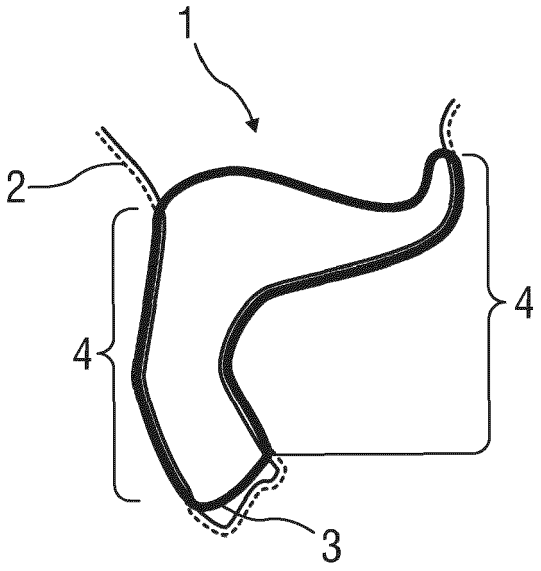

FIG 3

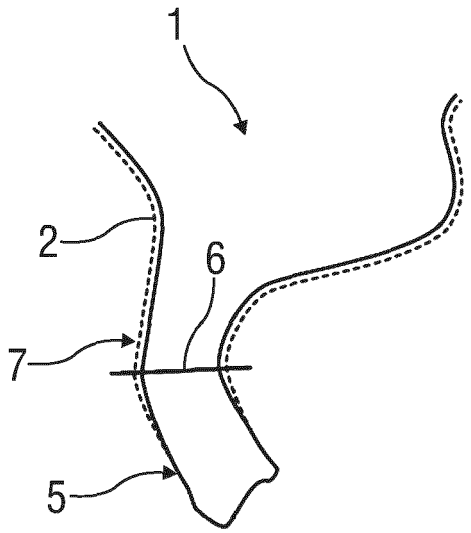

FIG 4

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EUROPEAN SEARCH REPORT

Application Number
EP 23 15 2231

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2019/007762 A1 (PAETSCH CHRISTOPHER R [US] ET AL) 3 January 2019 (2019-01-03) * paragraphs [0003], [0034], [0035], [0038], [0039], [0051]; figures 5A, 5B, 5C *	1-14	INV. H04R25/00
A	US 2020/186905 A1 (KARAMUK ERDAL [CH] ET AL) 11 June 2020 (2020-06-11) * paragraphs [0006], [0007] *	1-14	
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			TECHNICAL FIELDS SEARCHED (IPC) H04R

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	19 June 2023	Kunze, Holger

CATEGORY OF CITED DOCUMENTS

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