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Datasheet for the decision of 5 June 2023

Case Number: T 0990/21 - 3.5.03

Application Number: 16847347.8

Publication Number: 3351020

IPC: H04R25/00

Language of the proceedings: EN

Title of invention:
Bone conduction transducer system with adjustable retention force

Applicant:
Med-El Elektromedizinische Geraete GmbH

Headword:
Bonebridge/MED-EL

Relevant legal provisions:
RPBA 2020 Art. 12(8), 13(1)
EPC Art. 83

Keyword:
Decision in written proceedings - (yes): no request for oral proceedings + oral proceedings neither necessary nor expedient
Sufficiency of disclosure - main request (no)
Admittance - auxiliary request (no): amendment not suitable to overcome the issues raised by the board + giving rise to new objections

Decisions cited:
G 0002/21, T 1924/20

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Case Number: T 0990/21 - 3.5.03

D E C I S I O N
of Technical Board of Appeal 3.5.03
of 5 June 2023

Appellant: (Applicant)	Med-El Elektromedizinische Geraete GmbH Fuerstenweg 77 6020 Innsbruck (AT)
Representative:	Downing, Michael Philip Downing IP Limited Grosvenor House 7 Horseshoe Crescent Beaconsfield, Bucks. HP9 1LJ (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 26 February 2021 refusing European patent application No. 16847347.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	K. Bengi-Akyürek
Members:	K. Peirs
	C. Almberg

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division to refuse the present European patent application. The sole claim request subject to the appealed decision was deemed not to be allowable under Article 83 EPC.

II. A communication was issued under Rule 100(2) EPC including the board's negative preliminary opinion concerning the allowability under Article 83 EPC of the sole claim request.

III. With a written reply, the appellant submitted arguments on the board's negative preliminary opinion, and also submitted a further claim request. Oral proceedings were not requested at any stage of these appeal proceedings.

IV. The appellant requests that the decision under appeal be set aside and, as a **main request**, that a patent be granted according to the claims of the request referred to in point I above or, as an **auxiliary request**, according to the claims of the further claim request mentioned in point III above.

V. Claim 1 of the **main request** reads as follows (board's feature labelling):

(a) "An external component suitable for a bone conduction hearing implant system of the type comprising an implanted bone conduction transducer with an implant magnet, the component comprising:

(b) an external housing for fixed attachment on the skin of a hearing implant patient over the implanted bone conduction transducer;

(c) a housing interior located within the external housing and containing:

(d) i. an electromagnetic drive coil fixed within the housing interior and configured for conducting electrical current to develop implant communication signals for the bone conduction transducer,

(e) ii. a coil core made of a non-magnetized ferromagnetic material fixed within the drive coil, the coil core including opposing longitudinal ends and opposing longitudinal sides, and

(f) iii. at least one spacer container located adjacent to one of the longitudinal ends of the coil core and configured for holding a removable spacer piece;

(g) wherein the housing interior further comprises at least one of:

i. a pair of opposing pole piece containers located adjacent to the opposing longitudinal ends of the coil core and any spacer containers, each pole piece container being configured to hold a removable ferromagnetic pole piece, and

ii. a pair of opposing side piece containers located at the opposing longitudinal sides of the coil core, each side piece container being configured for holding a removable ferromagnetic side piece;

(h) wherein the coil core and any pole pieces and side pieces are configured to magnetically interact with an implant magnet in the bone conduction transducer in the absence of electrical current in the drive coil to hold the external housing in the fixed attachment on the skin of the hearing implant patient over the bone conduction transducer; and

(i) wherein electrical current in the drive coil magnetically interacts with the coil core and any pole pieces and side pieces to generate the implant communication signals to the implant magnet to create a mechanical vibration signal in the bone conduction transducer".

VI. Claim 1 of the **auxiliary request** reads as follows (board's highlighting of amendments vis-à-vis claim 1 of the main request):

"An external component suitable for a bone conduction hearing implant system of the type comprising an implanted bone conduction transducer with an implant magnet, the component comprising:

an external housing for fixed attachment on the skin of a hearing implant patient over the implanted bone conduction transducer;

a housing interior located within the external housing and containing:

i. an electromagnetic drive coil fixed within the housing interior and configured for conducting electrical current to develop implant communication signals for the bone conduction transducer,

ii. a coil core made of a non-magnetized ferromagnetic material fixed within the drive coil, the coil core including opposing longitudinal ends and opposing longitudinal sides, and

iii. at least one spacer container located adjacent to one of the longitudinal ends of the coil core and configured for holding a ~~removable~~ spacer piece removable with respect to the at least one spacer container;

wherein the housing interior further comprises at least one of:

i. a pair of opposing pole piece containers

located adjacent to the opposing longitudinal ends of the coil core and any spacer containers, each pole piece container being configured to hold a ~~removable~~ ferromagnetic pole piece removable with respect to the pole piece containers, and

ii. a pair of opposing side piece containers located at the opposing longitudinal sides of the coil core, each side piece container being configured for holding a ~~removable~~ ferromagnetic side piece removable with respect to the side piece containers;

wherein the coil core and any pole pieces and side pieces are configured to magnetically interact with an implant magnet in the bone conduction transducer in the absence of electrical current in the drive coil to hold the external housing in the fixed attachment on the skin of the hearing implant patient over the bone conduction transducer; and

wherein electrical current in the drive coil magnetically interacts with the coil core and any pole pieces and side pieces to generate the implant communication signals to the implant magnet to create a mechanical vibration signal in the bone conduction transducer".

Reasons for the Decision

1. *Decision in written proceedings*

The appellant did not request oral proceedings. Since the board does not consider the conduct of oral proceedings to be expedient either (cf. Article 116(1) EPC), the decision is handed down in written proceedings (Article 12(8) RPBA 2020).

2. *Technical background*

2.1 The present application relates to bone-conduction hearing devices, in particular of the "active implantable" type. In this type, bone conduction is achieved by a transducer that is implanted under the patient's skin. This saves space in the external component compared to other types of bone-conduction devices.

In the "magnetic bone-conduction hearing implant" type, for instance, the external component comprises not only a magnet to interact with a magnet screwed into the patient's skull but also a sound-producing element. An important advantage of bone-conduction hearing devices of the "active implantable" type is therefore that their external component will typically have a shallow design.

2.2 The hearing device of the present invention can be implemented as shown in Figure 3 of the present application (reproduced below).

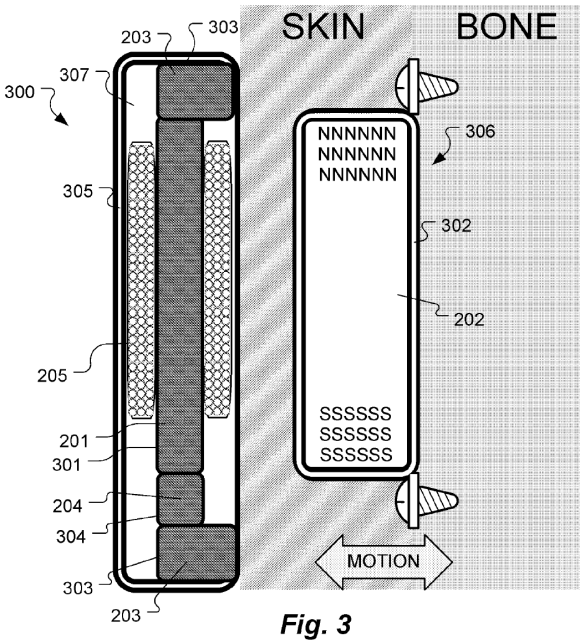

Fig. 3

The device comprises

- an implanted part 302 with a bone-conduction transducer 306 and
- an external part 300 that is held with a magnet (e.g. pole pieces 203 inside container 303) in a fixed position over implanted part 302.

In addition, drive coil 205 with coil core 201 is used to transmit a signal from the external to the implanted part, where bone-conduction transducer 306 will produce sound through bone conduction.

2.3 To keep external part 300 properly placed over implanted part 302, magnets 203 must be appropriately tuned to the thickness of the user's skin. A magnet that is too strong will cause discomfort for the user, especially when current is flowing through the drive coil. If the magnet is too weak, the external unit may fall off inadvertently, e.g. due to sudden movements.

2.4 The present application addresses this appropriate tuning of the magnets. It suggests to use a modular magnetic arrangement to provide an adjustable force of magnetic attraction between the implanted and the external part. This modular magnetic arrangement is implemented by the "spacer container(s)" as in **feature (f)** and the "opposing pole/side piece containers" as mentioned in **feature (g)**. These containers are able to hold modular elements in the form of, respectively, a "spacer piece" and "ferromagnetic pole and side pieces", all of which are removable. By adding or removing these modular elements, the magnetic attraction force between the implanted and the external part can allegedly be tuned.

3. *Main request: claim 1 - construction*

An important aspect during the appeal proceedings concerned the interpretation of the terms "external component" of **feature (a)** and "removable" of **features (f) and (g)**.

3.1 The appellant was of the opinion that the "external component" of feature (a) could relate to a component that is not completely finalised. In particular, it stated that, "once an appropriate combination of modular pieces is selected and assembled, the housing [of the external component] is typically sealed before supply to the patient" (cf. statement setting out the grounds of appeal, page 10).

In the board's view, such a semi-finalised product is not "suitable for a bone conduction hearing implant system" as required by feature (a) because it is simply not (completely) ready to be used in cooperation with an implant magnet. The skilled reader must therefore necessarily regard the "external component" of claim 1 as the *finalised* product that does not require any further manufacturing steps to operate properly.

3.2 Whether such a finalised product can encompass the sealed housing referred to by the appellant depends on how the skilled reader would construe the term "removable" of features (f) and (g). The appellant opined that, within the context of claim 1, the term "removable" placed before the term "piece(s)" should be understood as "removable with respect to the container(s)", and referred to paragraph [0025] of the description of the present application as filed. It considered it to be, "to a degree, immaterial as to whether the external housing is sealed after the

selection of a desired combination of internal components" because "sealed units can be opened (as per wristwatch casings, for example), whether the content is subsequently modified or not".

The board does not share the appellant's opinion and points out that a skilled reader of a patent claim would, for many reasons, interpret the claims based essentially on their own merits (cf. **T 1924/20**, Reasons 2.7). In that regard, the board holds that the skilled reader would construe the term "removable" in features (f) and (g) in the sense that the modular elements in the form of the "spacer, pole and side pieces" of these features can be removed, not only from their respective "containers", but from the "external component" entirely. This is because the skilled reader would understand that removing these modular elements from their respective containers would typically involve accessing the housing interior of **feature (c)**. This would normally require opening the external component of feature (a). As a result, the skilled reader would find it natural that the term "removable" implies the possibility to remove the spacer, pole and side pieces referred to in features (f) and (g) from the external component. To ensure that the external component stays "suitable for a bone conduction hearing implant system", the skilled reader would also recognise that this should be done *without* damaging the external component.

Returning to the appellant's "sealed-housing" configuration, the board notes that opening a sealed unit would, by design or by technical necessity, typically damage the unit to an extent that cannot be (easily) repaired. During normal use, a unit that is sealed off by a resin or silicone coating, e.g. to make

it waterproof, should therefore, at least in principle, not be opened. Particularly for the opened "wristwatch casings" referred to by the appellant, the board considers that the level of precision and expertise required to restore even a seal of minimal degree in the form of a mere "water resistance" would normally be beyond the skill of an ordinary practitioner. Consequently, the board can only conclude that the appellant's "sealed housing" is not part of the claimed scope, because it constitutes a housing in which the spacer, pole and side pieces are not "removable" within the meaning of features (f) and (g).

As an aside, the board notes that its interpretation of the terms "external component" and "removable" is also in line with what the skilled reader would gather from the application as a whole. Paragraph [0006] of the description expresses the need to address the "delicate matching" of the magnetic attraction between the external component and the implant magnet. From paragraphs [0031] and [0032] together with Figure 5 of the present application, it appears that the present invention tunes this magnetic attraction by adding or removing (optional) modular elements to or from the "external magnetic arrangement". Furthermore, paragraphs [0022] to [0025] of the present application teach that external housing 305 (cf. Figure 3 of the application, reproduced in point 2.2 above) comprises several dedicated containers for holding different kinds of removable modular elements. The skilled reader would readily understand that these dedicated containers would be the ones to be used when tuning the magnetic attraction in the way taught by paragraphs [0031] and [0032] together with Figure 5 of the present application as filed. Expressions such as "the core element only" and "plus side elements" used

in paragraph [0031] and such as "just a coil core" and "addition of side pieces" in paragraph [0032] of the description make it apparent that the optional modular elements should be added or removed with respect to the "external magnet arrangement" *as a whole*, that is to say with respect to external housing 305. There is also nothing in the application as filed to suggest that external housing 305 should be sealed after a proper selection of modular elements has been found. Instead, paragraph [0022] of the original description describes external housing 305 as being "fixedly attachable on the skin of a hearing implant patient". It is also shown as such in Figure 3 of the application. By doing so, the application as a whole teaches nothing else than that external housing 305 is indeed the *finalised* product, ready to be used "for a bone conduction hearing implant system".

3.3 The board emphasises, however, that the subject-matter of claim 1 is not restricted to an "external component" for which an appropriate combination of "spacer, pole and side pieces" is selected and assembled once. Rather, the "external component" of claim 1 could well be modifiable during a patient's lifetime. In particular, the board does not share the appellant's view that "the implanted or subcutaneous portion of the device is typically not replaced", at least not for certain patients. The reasons for this are as follows. The skilled reader would, based on their common general knowledge, readily understand that the "bone conduction hearing implant system" mentioned in feature (a) belongs to the "active implantable" type of bone conduction devices, which, as set out in point 2.1 above, is characterised by a shallow design. Incidentally, one of the most prominent (and first) examples of an "active implantable" bone-conduction

device is the appellant's Bonebridge™ device, available since 6 June 2011. The Bonebridge™ device can be implanted in children above five years of age. It is typically tuned to the patient's unique anatomy, such as skin thickness or morphological features (cf. paragraph [0018] of the present application as filed). During a child's development, its anatomy will change. Moreover, its implant may need replacement during growth until adulthood. For such a patient, a modifiable "external component" would indeed make technical sense for the skilled reader. One such external component could then accommodate, during the patient's growth, for varying skin thicknesses and/or multiple implanted devices that are put in place.

3.4 The appellant also submitted that the construction that the external component would be modifiable during its lifetime was not predicated on the technical problem mentioned in paragraph [0006] of the original application, which the appellant paraphrased as "how to securely retain a magnetically held, vibrating, external component about a patient without compromising quality".

The board can, however, not recognise how this technical problem would affect the way in which the skilled reader would construe claim 1: the appellant's technical problem is not stated in claim 1 and is, from the board's perspective, also not derivable from effects directly and causally related to features (a) to (i) (cf. **G 2/21**, Reasons 25).

4. *Main request: claim 1 - sufficiency of disclosure*

4.1 The board recalls that sufficiency of disclosure is given only if the invention defined in the independent

claims can be carried out by the skilled person over the "whole claimed scope" without undue burden using their relevant common general knowledge and further information in the underlying application. This "whole claimed scope" covers in particular the "modifiable external component" construction set out in point 3.3 above. It does, however, not cover the appellant's "semi-finalised product" addressed in points 3.1 and 3.2 above.

4.2 In reply to Reasons 10 of the appealed decision stating that the present application does not give at least one way of carrying out the invention, the appellant referred to several paragraphs of the description of the present application as filed. The present application (e.g. paragraphs [0018], [0031] and [0032]) may arguably teach the skilled person how **features (f) and (g)** allow to select an appropriate combination of "spacer, pole and side pieces" and provide for an "adjustable force" via a "modular magnetic arrangement". However, for the following reasons, the board is not convinced that the examining division's concerns indicated in Reasons 10.1 of the appealed decision regarding the "containers" of features (f) and (g) are unjustified.

4.2.1 In view of the terms "holding" and "hold" in features (f) and (g), the board does not doubt that these containers must be *real* physical entities. Nonetheless, the examining division rightly posed the question "*how one could remove e.g. the optional spacer piece 204 from its container 304, if the application does not mention any way of accessing the internals of the housing*". The appellant could not convince the board in this respect that the skilled person would indeed be able to fabricate a housing that may be

opened periodically for servicing of internal components. The reasons for this are set out in the following:

For this servicing of internal components, the housing must allow to remove the "spacer, pole and side pieces" of features (f) and (g). The present application, however, provides no details on how these "spacer, pole and side pieces" should actually be "removable". The skilled person can therefore only rely on their common general knowledge. In the board's opinion, this would provide them with several options:

- First, the skilled person could carry out the removability of the "spacer, pole and side pieces" by designing the containers such that an appropriate orientation with respect to gravity already suffices for the "spacer, pole and side pieces" to fall out.

- Alternatively, the containers can be designed such that the removal of the "spacer, pole and side pieces" requires shaking, in which case the skilled person needs to assess what kind of acceleration could actually be appropriate for that shaking.

- As a further alternative, the skilled person could have recourse to basic holding arrangements such as a locking pin, an O-ring or a spring assembly as part of their common general knowledge. Moreover, they could design the containers such that a tool is required to remove the "spacer, pole and side pieces" (without damaging the "external component"; see the fourth paragraph of point 3.2 above).

The skilled person could, of course, again draw upon their common general knowledge to eliminate some of these alternatives based on how the "external component" might be typically used. As an example, the skilled person would probably consider some of these alternatives to be a liability due to the risk of losing the "spacer, pole and side pieces". This could happen when the patient is engaged in a physical activity such as riding on horseback, running, trampoline jumping or swimming. From this perspective, the implementations using a "locking pin" or a tool may seem to have some advantages. Nevertheless, the skilled person also has to take into account that the external unit will be typically shallow (cf. point 3.3 above). This, in turn, limits the alternatives involving a locking pin or using a tool. From this example, it is apparent that there are indeed several practical ways available to the skilled person based on their common general knowledge to access the interior of the external housing of feature (b), as correctly emphasised by the appellant.

More importantly, however, this example also illustrates the constraints that are involved in designing the "containers" of features (f) and (g) such as to ensure removability of the "spacer, pole and side pieces". These constraints imply, in the board's view, a level of complexity that causes the manufacturing of the "external component" of claim 1 to be beyond a matter of "routine trial and error". Therefore, the board cannot agree to the appellant's statements that "no complex decision making is required" or that "no undue burden falls upon the skilled person". In conclusion, the board is not convinced that the skilled person would be able to implement the "containers" of features (f) and (g) merely based on the knowledge of

the application combined with the skilled person's common general knowledge.

4.2.2 Moreover, the "absence/removal" of one or more of the "spacer, pole and side pieces" as addressed in Reasons 10.1 of the appealed decision is indeed a cause for "concern". The "removal" part of this concern has already been treated in point 4.2.1 above. Regarding the "absence" part, the skilled person would immediately understand that such an "absence" may be indispensable when trying to accommodate for a patient's changing anatomy (cf. point 3.3 above) by means of a stacked arrangement of the "spacer, pole and side pieces". Whereas the application does not mention such a stacked arrangement, the skilled person would certainly be aware of it based on their common general knowledge. Such an arrangement is also reflected in claim 1 by the term "at least one" according to features (f) and (g). The necessity to foresee such an "absence" may however jeopardise the crucial advantage of the "active implantable" class of bone-conduction devices mentioned in point 3.3 above, namely that of their shallow design. In Reasons 10.1 of the appealed decision, the examining division was correct in drawing the attention in this respect to whether the size of the "external device" is reduced accordingly.

The application is, however, silent about whether this shallow design is compatible with a stacked arrangement having multiple "spacer containers" and multiple pairs of "opposing pole and side piece containers" that can be present in the "external component" according to features (f) and (g), especially given that some of these containers may be left empty to accommodate later for the child's changing anatomy. If there is such a compatibility, the application fails to teach the

skilled person how to indeed achieve it. If there is no such compatibility, the skilled person may not be able to reconcile the need for accommodating for a patient's changing anatomy with the desire for a shallow design merely based on their common general knowledge. This applies in particular to how the skilled person could reconcile the requirement of a shallow design with the need to keep some of the "containers" of features (f) and (g) empty for future use.

In that regard, the appellant submitted, with reference to claims 2 to 4, 5, 8, and 9 as well as paragraphs [0021] and [0029] of the present application, that these "containers", by being "invariably present", necessarily require the internal dimensions of the external component to be fixed. The board notes that this is not mandatorily the case because the walls of the containers defining the external component's internal dimensions could well be made from a flexible material.

4.3 In conclusion, the present application lacks relevant information on some important implementation aspects of the claimed invention, without which the skilled person cannot carry out the claimed invention without undue burden. Hence, claim 1 of the main request on file does not comply with Article 83 EPC.

5. *Auxiliary request: admittance*

5.1 The **auxiliary request** was filed for the first time *after* the appellant had filed its statement of grounds of appeal (cf. points III and IV above). It may thus be admitted only at the board's discretion (Article 13(1), first sentence, RPBA 2020).

5.2 From the board's highlighting in point VI above, it is immediately apparent that the amendments underlying claim 1 of the auxiliary request essentially specify that the "spacer piece" of **feature (f)** and the "ferromagnetic pole and side pieces" of **feature (g)** are "removable" in the sense that they can be removed with respect to their respective containers. This may mean in particular that these "spacer, pole and side pieces" are

- either entirely removable from the external component or are

- removable only from their respective containers, while still remaining within the external housing of feature (b).

In the former interpretation, claim 1 of the auxiliary request expresses the same as claim 1 of the main request (cf. the fourth paragraph of point 3.2 above) and, hence, cannot overcome the issues raised by the board in point 4 above.

In addition, the board doubts that, for the latter interpretation, there is a direct and unambiguous disclosure in the application as filed (Article 123(2) EPC). In particular, the board could find no such disclosure in paragraphs [0022] to [0025] and [0027] of the original description or in "the claims as filed" as referred to by the appellant. Quite the opposite, properly addressing the "delicate matching" mentioned in paragraph [0006] of the description as filed requires, in the board's view, to add or remove modular elements to or from the external component *entirely* and not only from their respective containers: due to the limited space that will be typically available in the

shallow external component considered in the application as filed, a mere "reshuffling" of the modular elements inside this external component will in general not suffice (see also the last paragraph of point 3.2 above). Claim 1 of the auxiliary request therefore seems to give rise to a new objection.

5.3 The auxiliary request is therefore not admitted into the appeal proceedings (Article 13(1) RPBA 2020).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

B. Brückner K. Bengi-Akyürek

Decision electronically authenticated