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Patent application no. 20201071
Mode Sensors AS

Reference is made to the official action dated 27th April 2023.

Enclosed you will find an amended specification including a new set of claims.

Claim amendments:

The claim amendments do not introduce any added subject matter, but are intended to remove unclarities and ensure that there is support for the claims in the specification as filed. The only except Ion is claim 8, which is a new claim having support in paragraph 28.

We note that the Examiner has several of the same objections as the PCT Examiner. Consequently, we have brought the claims into correspondence with the claims that we filed at the EPO when recently entering the regional phase. These amendments should fix the issues raised by the Examiner. We will also address objections made by the PCT Examiner below.

The parameter α is now referred to as a frequency dependent parameter. Thus, the objection that amended claim 1 extends beyond the application as filed due to this feature has been overcome. We will explain this change in detail below.

Claim 1 has also been amended such that it is the total impedance absolute value which is curved fitted to the data model. This amendment addresses an objection raised by the PCT examiner that amended claim 1 extends beyond the application as filed. By the new amendment this objection has been overcome.

In relation to the objections to claims 5 and 6, we refer to point 4.6.2 of the EPO Guidelines for Examination on interpretation of relative terms:

When the use of a relative term is allowed in a claim, this term is interpreted by the division in the least restrictive possible way when determining the extension of the subject-matter of the claim. As a consequence, in many cases, a relative term is not limiting the extension of the subject-matter of a claim.

Thus, if the relative term was never limiting then it's removal cannot be a new technical teaching contrary to the requirements of Art. 34(2)(b) PCT.

The objection against claim 5 and 6 is thus moot in view of the amendments made to these claims.

We are of the opinion that the amendments address the unclarity objections. To solve this issue we have made the following amendments to claim 1:

"…the method comprising:
performing a first measurement cycle by:
a) applying a current corresponding to a cycle of different predetermined frequencies in time series on an outer pair of the electrodes;
b) measuring a resulting variating potential at each predetermined frequency over an inner pair of the electrodes;
c) calculating a measured impedance from the corresponding measured variating potential at each predetermined frequency;
d) calculating a total impedance absolute value from the corresponding measured impedance at each predetermined frequency; and
e) storing each total impedance absolute value against its corresponding frequency for the first measurement cycle in a memory;
performing one or more subsequent measurement cycles by repeating steps a) to e), wherein each of the one or more subsequent measurement cycles is performed after a predetermined period of time after the first measurement cycle…"

We submit that it is now clear how the first and subsequent measurement cycles are performed and how they are utilised in the rest of the method to determine if there has been a change in cell volume. Basis for the above amendment can be found in paragraph 40 of the application as filed.

The new claim 2 recite:

"reading respective frequencies belonging to a plurality of selected total impedance absolute values of the first measurement cycle; and
reading respective frequencies belonging to the plurality of selected total impedance absolute values of the one or more subsequent measurement cycle;
determining differences between each frequency value for the same total impedance absolute value for the plurality of selected total impedance absolute values; and
calculating an average frequency difference between the first and the one or more subsequent measurement cycles."

Basis for the above amendment can also be found in paragraph 40 of the application as filed.

With regard to the objections raise against the curve-fitting feature this has been overcome by amending claim 1 to refer to the measured impedance in place of referring to the measured potential.

Claim 4 has been amended in the same respect by referring to the measured impedance in place of referring to the measured potential.

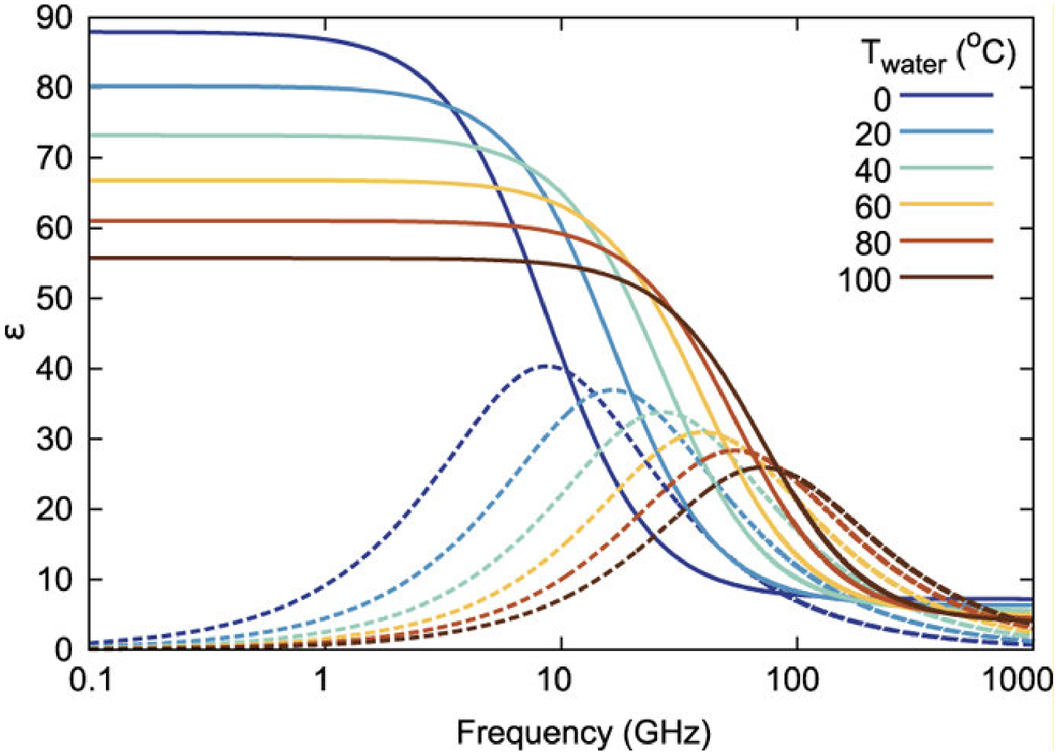
Claim 8 has been restructured to recite method steps.

Whether the factor α is frequency dependent or not

The Examiner notes that the factor α is, as disclosed in the application documents, based on the cell membrane capacitance and further notes that the capacitance depends on a dielectric constant which in turn depends on frequency.

In the following we explain that the Examiner is right in that the dielectric constant indeed depends on frequency, but we also explain to what extent the dielectric constant depends on frequency at all, that all of this depends on several factors, and that in this context the change in the dielectric constant is not relevant for the factor α, and that α therefore <u>in practice</u> will be frequency independent in the context of the present invention.

First of all, the dielectric constant is a material constant. The value and the frequency dependence depend on the material. In the context of the invention, the material is substantially water.
Water is a dipole and has therefor indeed a strong frequency dependence, but this dependency is in the GHz range, not in the low kHz range which is the frequency range according to the invention. Within this low kHz range is almost no change of the dielectric constant. According to paragraph [0038] of the application as filed "the frequencies used for the measurement are typically … 1kHz to 500 kHz." Also drawing 7 shows a similar frequency range. In this frequency range (1kHz to 500kHz) and at body temperature (35°C to 40°C), the change in the value of the dielectric constant is neglectable. The frequency must be increased to around 5GHz before there is any significant change.
The graphs below, which can be found in the article "Water: Promising Opportunities For Tunable All-dielectric Electromagnetic Metamaterials" (https://www.nature.com/articles/srep13535), clearly shows the above.



Therefore, the dielectric constant can be considered as frequency <u>independent in the frequency range</u> used for impedance measurements of live tissue. It is therefore of no consequence to the present invention whether the parameter α is considered frequency dependent or frequency independent. We have therefore chosen to revert to the original wording and define the parameter as frequency dependent.

Absolute value of total impedance and curve fitting

Both the calculation of the absolute value of the total impedance and the curve fitting are done according to well-established techniques. Hence, this has not been described in detail in the specification. An example, namely, the least mean square technique is mentioned. It is, however, clear from the description that this is just an example of such techniques. Paragraph 25: "…such as the least mean squares technique".

The PCT Guidelines states the following:

> 5.33 An independent claim should clearly specify all of the essential features needed to define the invention except insofar as such features are implied by the generic terms used; for example, a claim to a "bicycle" does not need to mention the presence of wheels. If a claim is to a process for producing the product of the invention, then the process as claimed should be one which, when carried out in a manner which would seem reasonable to a person skilled in the art, necessarily has as its end result that particular product; otherwise, there is an internal inconsistency and therefore lack of clarity in the claim. In the case of a product claim, if the product is of a well-known kind and the invention lies in modifying it in a certain respect, it is sufficient if the claim clearly identifies the product and specifies what is modified and in what way. Similar considerations apply to claims for an apparatus.

and:

> 20.14 If, however, the applicant can show convincingly that the subject matter in question would, in the context of the claimed invention, be so well known to the person skilled in the art that its introduction could be regarded as an obvious clarification and, therefore, as not extending the content of the application, it is permissible.

Point 20.14 of the Guidelines is about adding subject matter. In this case, we are not suggesting any additions to the specification, as we deem that to be unnecessary. The specification provides sufficient information for the person of skill to look up well-known methods for performing the calculation and curve-fitting. The person of skill would easily find a number of such techniques without undue burden. We are therefor of the firm opinion that it is not necessary to define these techniques in the claims.

The above is also reflected in the EPO Guidelines:

> 5.2 Absence of well-known details
> For the purposes of sufficient disclosure the specification does not need to describe all the details of the operations to be carried out by the person skilled in the art on the basis of the instructions given, if these details are well-known and clear from the definition of the class of the claims or on the basis of common general knowledge (see also F-III, 1 and F-IV, 4.5).
>
> 4.3 Background art
> The applicant may cite documents in the application which relate to standard technical knowledge (background art neither addressing the same technical problem nor necessary to complete the disclosure of the claimed invention). Such citations typically relate to well-known tests for measuring certain parameters mentioned in the description or to the definitions of terms of established meaning that are used in the application. Usually they are not relevant for assessing the patentability of the claimed invention, unless for example they contain relevant information which the applicant does not mention in the description.

4.4 Irrelevant matter
Since the skilled person is presumed to have the general technical background knowledge appropriate to the art, the examining division does not require the applicant to insert anything in the nature of a treatise or research report or explanatory matter which is obtainable from textbooks or is otherwise well-known.

1. Sufficiency of disclosure
A detailed description of at least one way of carrying out the invention must be given. Since the application is addressed to the person skilled in the art, it is neither necessary nor desirable that details of well-known ancillary features are given, but the description must disclose any feature essential for carrying out the invention in sufficient detail to render it apparent to the skilled person how to put the invention into practice. A single example may suffice, but where the claims cover a broad field, the application is not usually regarded as satisfying the requirements of Art. 83 unless the description gives a number of examples or describes alternative embodiments or variations extending over the area protected by the claims

A number of decisions of the EPO BoA substantiates these Guidelines.

In T 0485/00 the Board discussed if the person of skill would still be able to carry out the invention despite the lack of description of measurement methods. The conclusion was that the methods described in prior art were well known to the skilled person and that "measuring the surface area of the resulting product by two or three well-known methods does not represent an undue burden for the skilled person" (Point 1.6 of the decision).

In T 1040/03 the Board came to the conclusion that the person of skill would include conventional features, such as splines, a clamp, an actuator electrical contact means etc. to facilitate radial movement on a rotating member. It was not necessary to include these features in the description, as "the skilled person would be capable of putting the method into effect without the burden of exercising inventive skill" (point 2.2 of the decision.

In T 1608/13 the question was if the specification contained enough information to enable the person of skill to determine certain parameters (sieving coefficients). The Board came to the conclusion that the person of skill "interprets it [the patent document] in the light of the common general knowledge in the technical field concerned" and that "in the absence of a specific measuring method [...] the skilled person would first look for applicable standards in the field" (point 3.3).

Our case is particularly similar to T 1608/13. In our case the person of skill is told by the specification to use known methods for determining a total value of the impedance and perform the curve fitting. The person of skill would then look up such methods in a textbook or similar. This does not place an undue burden on the skilled person. The skilled person in this field is very familiar with mathematical and statistical methods, as such methods are regularly used when determining parameters in the field of impedance measurements. The person of skill is also very familiar with computing techniques used to perform such methods. Contrary to what the Examiner states, it is indeed very relevant what kind of information a person of skill would find in textbooks.

We enclose a copy of Chapter 14 of the textbook "Numerical Recipes in C – The Art of Scentific Computing", by Press, Flannery, Teukolsky and Vetterling, issued in 1988. We have included the whole of Chapter 14 to show the level of detail presented to the person of skill. We will, however, only refer to the highlighted passages.

Already at the introduction to the chapter the person of skill is informed of the following:
The basic approach in all cases is usually the same: You choose or design a figure-of-merit function ("merit function," for short) that measures the agreement between the data and the model with a particular choice of parameters. The merit function is conventionally arranged so that small values represent close agreement. The parameters of the model are then adjusted to achieve a minimum in the merit function, yielding best-fit parameters. The adjustment process is thus a problem in minimization in many dimensions.

Then follows a review of the different methods, their strength and weaknesses:

- 14.1 Least Square as a Maximum Likelihood Estimator
  - Here the person of skill is informed of the strengths and weaknesses of this method in general (see the highlighted passages)
  - "Chi-Square Fitting", with a detailed set of equations
- 14.2 Fitting Data to a Straight Line
  - Including concrete examples
- 14.3 General Linear Least Squares
  - Which is a generalization of section 14.2
  - "Solution by Use of the Normal Equations", with detailed sets of equations
  - "Solution by Use of Singular Value Decomposition", also with detailed sets of equations
- 14.4 Nonlinear Models
  - "Calculation of the Gradient and Hessian", with detailed sets of equations
  - "Levenberg-Marqquardt Method". Here it is pointed out that this has become the standard of least-square routines.
- 14.5 Confidence Limits on Estimated Model Parameters
  - "General Case: Confidence Limits by Monte Carlo Simulations"
  - "Use of Chi-Square Boundaries as Confidence Limits"
  - "Probability Distribution of Parameters in the Normal Case"
- 14.6 Robust estimation. Here the statistical estimators are grouped into three categories:
  - M-estimates
  - L-estimates
  - R-estimates
  - A detailed explanation of these estimates is then given under the headlines:
    - "Estimation of Parameters by Local M-estimates
    - Numerical Calculation of M-estimates
    - Fitting a Line by Minimizing Absolute Deviation
    - Other Robust Techniques

The person of skill would among these methods chose one of those that will provide a sufficiently accurate estimate according to the strengths and weaknesses pointed out in the textbook.

This textbook is already more than 30 years old, and computer science has since developed. New methods and improvements of old methods have emerged, especially since computers have become increasingly more powerful. This means that methods that at one point in time would be too laborious to be useful may at a future point in time become highly practical. Consequently, it would deprive the applicant of rightful protective scope if the claim should be limited to specific methods.

It is important in this context that mathematical methods are not patentable as such. In fact, they are not considered technical per se. The present invention uses mathematical methods, but the invention is not about these methods as such.

In EPO BoA T 208/84 it was pointed out that (quote from Case Law of the BoA, 10th edition, page 13):
A basic difference between a mathematical method and a technical process can be seen, however, in the fact that a mathematical method or a mathematical algorithm is carried out on numbers (whatever these numbers may represent) and also provides a result also in numerical form, the mathematical method or algorithm being only an abstract concept prescribing how to operate on the numbers. No direct technical result is produced by the method as such. In contrast, if a mathematical method is used in a technical process, that process is carried out on a physical entity (which may be a material object but equally an image stored as an electric signal) by some technical means implementing the method and provides as its result a certain change in that entity. The technical means might include a computer comprising suitable hardware or an appropriately programmed general purpose computer. The board was, therefore, of the opinion that, even if the idea underlying an invention may be considered to reside in a mathematical method, a claim directed to a technical process in which the method is used does not seek protection for the mathematical method as such.

We have removed the reference to “per se known methods”. This reference is unnecessary as the person of skill would know how to make these calculations.

Measured variating potential:

We note that there is a small step missing in claim 1. We agree that there is an unclarity in the claim. Claim 1 now defines that from the variating potential a measured impedance is calculated. This is a simple calculation done using the equation given in paragraph 36. Strictly speaking, the impedance is not directly measured, but it is a direct result from the measured potential. To distinguish this impedance from the later defined total impedance absolute value we retain the term measured impedance.

Amendments of the description:

We have brought the description into conformity with the claims. The prior art cited is already mentioned in the description.

Translation of claims:

A translation of the claims into Norwegian is herewith enclosed.

Request grant of patent:

We request that the application now will be issued for grant.

Yours sincerely,
Bryn Aarflot AS

Arild Tofting