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D E C I S I O N
of 16 April 2003

Case Number: T 0229/00 - 3.2.2

Application Number: 92914893.0

Publication Number: 0611291

IPC: A61B 8/12

Language of the proceedings: EN

Title of invention:
Method and apparatus for removing artifacts from an ultrasonically generated image of a small cavity

Patentee:
ENDOSONICS CORPORATION

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 56, 84

Keyword:
"Clarity (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0229/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 16 April 2003

Appellant: ENDOSONICS CORPORATION
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 1 October 1999 refusing European patent application No. 92 914 893.0 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
U. J. Tronser

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 1 October 1999 to refuse European patent application No. 92 914 893.0

The ground of refusal was that claims 1 and 8 contained subject-matter extending beyond the content of the application as filed (Article 123(2) EPC). The decision also noted that the subject-matter of claim 10 was not defined clearly (Article 84 EPC), and that the subject-matter of claims 11 and 12 did not involve an inventive step.

The examining division argued that the problem acknowledged by the applicant could not be solved by the apparatus defined in claim 10 and corresponding to Figure 6, and the apparatus defined in claims 11 and 12 was an obvious combination of the apparatus of the following documents:

D1: US-A-4 917 097

D2: US-A-4 875 372

II. On 17 November 1999 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on the same day. On 31 January 2000 a statement of grounds of appeal was filed.

III. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

- claims 1 to 3

- description pages 1, 1A and 2 to 29

- figures pages 1/7 to 7/7

as submitted at the oral proceedings before the Board on 16 April 2003.

IV. Independent claims 1 and 2 read as follows:

"1. An apparatus for imaging a cross section of a small cavity such as a coronary vessel, comprising a probe (44) adapted to be introduced within the small cavity, having an array of transducer elements (54), a source of electrical pulses for exciting the transducer elements to emit ultrasonic waves in an ambient environment of the transducer elements (54) within the small cavity, and a receiver for detecting electrical signals generated by mechanical oscillation of the transducer elements after excitation of the transducer elements by electrical pulses; wherein the apparatus is adapted for imaging a cross section of a small cavity including first and second areas, the first area having a larger diameter than the second area, and includes a first buffer (84) provided with means for storing N bytes of the electrical signals as an echo waveform; a second buffer (70) provided with means for storing M bytes of the electrical signals as a reference waveform; comprising M bytes of non-zero data, wherein N > M; said electric signals representing said reference waveform being derived from ultrasonic waves collected when the probe (44) is in said first area and said electric signals representing said echo waveform being derived from ultrasonic waves collected when the

probe is in said second area; means (86) for subtracting the reference waveform from the echo waveform in order to provide an imaging waveform stripped of any repeatable noise patterns; and an imaging device responsive to the imaging waveform for generating a visual image.".

"2. An apparatus for imaging a cross section of a small cavity such as a coronary vessel, comprising a probe (44) adapted to be introduced within the small cavity, having an array of transducer elements (54), a source of electrical pulses for exciting the transducer elements to emit ultrasonic waves in an ambient environment of the transducer elements (54) within the small cavity, and a receiver for detecting electrical signals generated by mechanical flexing of the transducer elements after excitation of the transducer elements by electrical pulses; wherein the apparatus is adapted for imaging a cross section of a small cavity including first and second areas, the first area having a larger diameter than the second area, and comprises a first buffer (84) provided with means for storing N bytes, a second buffer (92), and a sequencer (80) being adapted to select one of a first and a second distinct signal path in the receiver; the second buffer (92) being provided with means for storing electrical signals comprising M bytes, with N>M, as a reference waveform when the first signal path is selected, said electric signals representing said reference waveform being derived from ultrasonic waves collected when the probe (44) is in said first area; means (95) for subtracting the reference waveform from electrical signals when the second path is selected, which electrical signals include signals caused by echoes of the ultrasonic waves collected when the probe is in the

second area of the cavity, in order to generate an echo waveform; the first buffer (84) being provided with means for storing the amplified echo waveform; and comprising an imaging device responsive to the output of the first buffer for generating visual images"."

Claim 3 is dependent on claim 2.

V. The appellant argued as follows:

The amplifiers used in the receiver saturated for only a very short time period, ie for only the first 20 or 30 samples of the 500 to 600 samples of the signal, which did not affect the apparatus drastically, and consequently, the structure of Figure 6 did work, contrary to what the examining division held. Therefore, the examining division was wrong in stating that the problem acknowledged by the applicant could be solved only if the subtraction step was performed before the amplifying step.

Document D2 disclosed the use of a single store only for the reference waveform and the apparatus thereof always sensed an echo signal, in contrast to the application which required an echo-free signal for the reference waveform.

The prior art did not teach going first to a large diameter portion of a cavity to collect the waveform caused by the ringdown, and subtracting this from the waveform collected during inspection of a treatment site which had a smaller diameter.

Reasons for the Decision

1. The appeal is admissible.

2. The application was refused under Article 123(2) EPC, on the grounds that method claims 1 and 8 contained subject-matter extending beyond the content of the application as originally filed. These claims have been cancelled, so this objection no longer applies and the outstanding points to be discussed here concern the remarks of the examining division regarding the clarity of claim 10 (corresponding to claim 1 now on file) and the inventive step of the subject-matter of claims 11 and 12 (corresponding to claims 2 and 3 now on file).

3. *Amendments*

Claims 1 to 3 are based on claims 10 to 12 as originally filed. Claims 1 and 2 have been amplified to explain how the reference and echo waveforms are obtained in different areas of a cavity and stored in the respective buffers. The claims have also been clarified and rendered consistent with the description.

The description has been amended for consistency with the claims and to make clear that the prior art method of removing the ringdown signal, discussed on page 3 (references to the description pertain to WO-A-93/00036), was not part of the prior art. Other minor amendments were made in the description and the figures, and the amended application meets the requirement of Article 123(2) EPC.

4. *Clarity*

The examining division was of the opinion that since the apparatus of Figure 6 subtracts two signals after

they have been amplified, no sensible information will be available from the saturated amplifier chain, and that claim 1, which is based on this embodiment, is not clear, accordingly.

The applicant's representative argued plausibly at the oral proceedings before the Board, that it was found in practice that only the first few samples (20 to 30) of the waveform were found to saturate the amplifier chain and the remainder of the waveform of about 513 samples did not to saturate the amplifier chain. A meaningful signal could be extracted from the waveform so this short term saturation did not render the apparatus useless and the apparatus of Figure 6 did indeed work. The Board accepts this explanation and considers claim 1 to be based on a workable embodiment, and does not lack clarity, accordingly.

Claims 1 and 2, although cast as apparatus claims, contain use features (for example, "said reference waveform being derived from ultrasonic waves collected when the probe is in said first area and said electric signals representing said echo waveform being derived from ultrasonic waves collected when the probe is in said second area"), but these do not detract from the clarity of the claims since the construction of the apparatus is clear in each case. The use features may be regarded as non-technical features for the purpose of the apparatus claim, which explain how the apparatus is used, and a mixture of technical and non-technical features in a claim is permissible if the overall construction is clear, which is so in the present case.

5. *Novelty*

This was not an issue during the examination procedure, a finding with which the Board concurs.

6. *Inventive step*

6.1. The technical problem

The opening parts of the description describe the prior art with reference to D1, and the technical problems this prior art addresses, one of these being the occurrence of a blind spot or corona in the image of a vessel, caused by the ringing of a transducer excited by an electrical pulse. This problem is approached in D1 using circuit techniques.

This problem was solved in another (unreported) attempt by the applicant by the subtraction method described on the first part of page 4, which involved obtaining a reference waveform in a relatively large vessel such as a water tank. This led to the following disadvantages:

(i) it is difficult to match the acoustic impedance of the water with that of the blood in the vascular system, so that the amplitude and phase of the ringdown signal generated and recorded in the environment of the water-filled tank may be somewhat different than the ringdown signal generated in the blood,

(ii) drifting of the ringdown signal is caused by variations in temperature between the water in the tank and the blood in the vascular system,

(iii) sterility of the catheter may be compromised by placing the sterile catheter in a tank of water

or saline solution prior to insertion into a patient.

6.2. The solution

The present solution is based on the realisation that data for a reference waveform may be collected for only a portion of the sampling time period usually dedicated to detecting an entire echo waveform. Since the reference data are collected for only a portion of the total sampling time period instead of the entire sampling period, they can, therefore, be collected in a smaller echo-free environment than previously possible, such as in one of the larger areas of the vascular system, rather than in a vessel outside the body. This is described on page 6, line 19 to page 8, line 15.

The solution is embodied in the claimed apparatus in the form of a second buffer, referred to as the reference data buffer, provided with means for storing M, for example, 513 bytes of the reference waveform, as compared with, for example, 2048 bytes for the echo waveform stored in the imaging data buffer.

Claim 1 defines this extra feature in the following terms: "a second buffer (70) provided with means for storing M bytes of the electrical signals as a reference waveform; comprising M bytes of non-zero data, wherein N > M". Thus, two buffers are provided, one for storing a complete waveform of N (for example 2048) sample bytes and the other for storing fewer, M (for example 513) sample bytes.

A similar construction is defined in claim 2. In this embodiment, although the reference signal in the

buffer 92 is subtracted directly from the probe signal, in the subtracter 95, the subtracted signal is then stored in the buffer 84 for storing a complete waveform of N bytes, and the *in-vivo* calibration is possible only by virtue of the two buffers having means for storing a different number of bytes, respectively.

6.3. Inventive step

The technical problem discussed above is not disclosed in the prior art and is of itself indicative of an inventive step. Moreover, starting from document D1 as the closest prior art, the remaining prior art also does not give any reason for adding an additional buffer having a different storage capability and a subtracter for solving the problem. Nor is there any suggestion of sampling only a part of the reference waveform and providing means for writing a different number of bytes to the two buffers, respectively. These features make it possible to calibrate the reference waveform entirely *in-vivo* and overcome the technical problems set out above.

Since these modifications, for solving the stated technical problem, are not suggested in the prior art, the apparatus of each of claims 1 and 2 involves an inventive step.

6.4 Document D2 deals with an ultrasound system for inspecting mechanical bodies for near surface flaws. It works by removing the front surface echo from a test piece so that a flaw close to the surface can be detected, since the strong surface reflection would otherwise mask a weaker reflection from the flaw. A reflected waveform is stored when the ultrasonic probe

is positioned over a defect-free surface to provide a reference waveform, and the probe is then positioned over the test object and the stored waveform subtracted to remove the surface reflection signal.

This cancellation system always involves the return of echoes from the body, there is no suggestion of using it in an echo-free environment, which is an important part of the present application, since the reference waveform must be obtained in an effectively echo-free environment (large diameter area). D2 refers, in column 3, lines 26 to 30, to removing transducer artefacts, but no details are given. However, it must be assumed that echoes are involved, in keeping with the remainder of D2, and contrary to what the application requires.

Moreover, D2 describes apparatus for inspecting materials for flaws within the material, by detecting return echo signals and essentially involves times of flight of echoes. There is no suggestion of imaging the surface of the material. Moreover, the apparatus does not operate in an environment such as blood, nor does it operate within the confines of a narrow vessel, it operates by direct contact with a test piece, and therefore does not encounter the problems set out in point 6.1 above. For these reasons the person skilled in the art would not consult this document for a solution to the above problems.

7. As noted above, claims 1 and 2 are based on the embodiments of Figures 6 and 7, respectively. The embodiment of Figure 6 is the basic one that solves the stated technical problem, and in which the subtraction step occurs after amplification. The embodiment of

Figure 7 also solves the stated problem but the subtraction step occurs before amplification, and this embodiment contains the further refinement that remnants of the ringdown signal may also be removed, as described in the paragraph linking pages 27 and 28. Therefore, the apparatus of Figures 6 and 7 are inter-related and claims 1 and 2 comply with Rule 29(2) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to grant a patent on the basis of the following documents:

   - claims 1 to 3

   - description pages 1, 1A and 2 to 29

   - figures pages 1/7 to 7/7

   as submitted at the oral proceedings.

The Registrar: The Chairman:

V. Commare W. D. Weiß