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Datasheet for the decision of 21 April 2021

Case Number: T 1964/16 - 3.2.02

Application Number: 10755204.4

Publication Number: 2442725

IPC: A61M5/168

Language of the proceedings: EN

Title of invention:
VASCULAR ACCESS MONITORING DEVICE

Patent Proprietor:
Quanta Fluid Solutions Ltd

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 54(1), 54(2), 56, 100(a), 100(b)

Keyword:
Grounds for opposition - insufficiency of disclosure (no) - lack of novelty (no) - lack of inventive step (no)

Decisions cited:

Catchword:

Europäisches Patentamt
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Case Number: T 1964/16 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 21 April 2021

Appellant: (Patent Proprietor)	Quanta Fluid Solutions Ltd Tything Road Alcester Warwickshire B49 6EU (GB)
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Appellant: (Opponent)	Fresenius Medical Care Deutschland GmbH Else-Kröner-Strasse 1 61352 Bad Homburg (DE)
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Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 27 June 2016 concerning the maintenance of European Patent No. 2442725 in amended form**

Composition of the Board:

Chairman	C. Schmidt
Members:	D. Ceccarelli
	A. Martinez Möller

Summary of Facts and Submissions

I. The proprietor and the opponent have appealed against the Opposition Division's decision, posted on 27 June 2016, that account being taken of the amendments made by the proprietor according to auxiliary request 2, European patent No. 2 442 725 and the invention to which it related met the requirements of the EPC.

II. Oral proceedings took place on 21 April 2021 by videoconference.

The appellant/proprietor ("the proprietor") requested that the decision under appeal be set aside and that the patent be maintained as granted.

The appellant/opponent ("the opponent") requested that the decision under appeal be set aside and that the patent be revoked.

III. The following documents are mentioned in this decision:

D1: US-A-2005/0010118
D2: EP-A-0 121 931
D3: EP-A-0 328 163
D4: US-A-4,534,756
D5: EP-A-0 232 599
D6: US-A-4,648,869
D7: US-A-2008/0195021
D8: WO-A-2009/024333
D9: DE-C-197 34 002
D10: EP-A-0 895 787
D11: US-A-6,077,443
D12: W02009/038834

D13: DE-C-198 48 235
D14: EP-A-0 248 633
D15: EP-A-0 330 761
D16: EP-A-0 332 330
D17: EP-A-0 361 793
D18: EP-A-1 472 973
D19: WO-A-2010/089130
D20: WO-A-97/10013
D22: WO-A-2008/100671
D24: US-A-4,710,163
D25: WO-A-91/00113
D26: DE-A-196 09 698 A1
D27: "Handbook of modern sensors - Physics, Designs, and Applications", Jacob Fraden, Springer, Third Edition 2003

IV. Claim 1 of the patent as granted reads as follows:

"A vascular access monitoring device (1) for monitoring characteristics of a skin piercing vascular access (4) device comprising:

an acoustic sensor (8) operable to detect an acoustic emission created by flow through said vascular access device (4) and produce an electrical signal indicative of said emission; electronics processing means (7) for processing and monitoring said electrical signal, and to determine, by identifying a change of characteristic of said signal, the possibility that the vascular access device (4) has become dislodged from its normal working position, **characterized in that** the electronics processing means comprises an electrical input means (7) for receiving a signal from an extra corporeal blood pump."

Claims 2 to 19 are dependent claims.

V. The opponent's arguments where relevant to the decision may be summarised as follows.

Sufficiency of disclosure

The patent was not sufficiently disclosed over the whole claim scope.

Claim 1 generally mentioned an electrical input means for receiving a signal from an extracorporeal blood pump. However, such a pump was not part of the claim. Moreover, no structural features of the electrical input means were specified. This rendered the claim scope very broad.

The teaching of the patent was not sufficient to enable the person skilled in the art to provide a monitoring device as claimed in which any signal from any possible pump could be received and processed by the electronic processing means.

Novelty over D1

The subject-matter of claim 1 of the patent as granted was not novel over D1.

This document disclosed a vascular access monitoring device comprising an acoustic sensor (pressure sensors 5, 9) operable to detect an acoustic emission created by flow through the vascular access device and produce an electrical signal indicative of the emission.

The term "acoustic sensor" did not imply any limitation with respect to the frequency and amplitude of the

detected signal. Any sensor capable of detecting pressure waves, such as the pressure sensors of D1, had to be considered an acoustic sensor within the meaning of the claim. This was confirmed by D26 (column 1, lines 15 to 20), which disclosed that a pressure sensor was used to detect acoustic emissions, and D27 (page 381), which disclosed that any microphone or hydrophone had the same basic structure as a pressure sensor. It was irrelevant how precise the detection of the pressure waves could be in the absence of any limitation in this regard in the claim.

The claim referring to emissions created by flow through the vascular access device did not constitute any limitation to the frequency and amplitude of the pressure waves to be detected by the acoustic sensor. The parameters of such a flow could vary to a very large extent. Hence, any pressure sensor would anticipate the acoustic sensor defined in claim 1 of the patent as granted.

The specific position of the pressure sensors in the device of D1 was not decisive either. Irrespective of their positions, the pressure sensors were per se operable to detect acoustic emissions as claimed. Moreover, D1 explicitly disclosed that the pressure sensors, at their position at respective drip chambers, were capable of detecting the heartbeat propagating through the drip chambers.

Novelty over D7

The subject-matter of claim 1 of the patent as granted was not novel over D7 either.

The patent as granted itself acknowledged that D7

disclosed a vascular access monitoring device according to the preamble of claim 1 (paragraph [0004], last sentence).

D7 disclosed an emitter of ultrasound waves (28, Figure 2) and an acoustic sensor (24, Figure 2). The emitted waves were reflected by red blood cells flowing through a vascular access device, and the reflected waves, with a frequency different from that of the emitted waves, were detected by the acoustic sensor. The difference in frequency depended on the direction of movement and the speed of the red blood cells in the vascular access device. It followed that the acoustic sensor was operable to detect an acoustic emission created by flow through the vascular access device and produce an electrical signal indicative of the emission within the meaning of the claim. The reflected waves were to be considered the claimed acoustic emission. The patent did not distinguish between acoustic emissions created by flow without external influences and acoustic emissions created by the flow reflecting incoming acoustic emissions. Hence, it was of no relevance whether D7 employed an active sensing technique.

D7 also disclosed the characterising portion of claim 1 of the patent as granted, i.e. an electronics processing means comprising an electrical input means for receiving a signal from an extracorporeal blood pump (paragraph [0081]).

Novelty over other documents

The subject-matter of claim 1 of the patent as granted was not novel over each of D2 to D6, D8 to D20, D22, D24 and D25, as also explained in the notice of opposition and in the letter of 8 April 2016, filed

during the first-instance opposition proceedings.

More particularly, each of D2 to D6, D9 to D11, D13 to D17, D20, D24 and D25 disclosed pressure sensors which produced an electrical signal indicative of an emission created by flow through a vascular access device. Such pressure sensors anticipated the acoustic sensor as defined in the claim.

D8 disclosed an electronics processing means which could be included in a dialysis device (page 9, penultimate paragraph). The processor of the dialysis device communicated with an extracorporeal blood pump. It followed that D8 disclosed an electronics processing means comprising an electrical input means for receiving a signal from an extracorporeal blood pump as defined in the claim.

D12 disclosed acoustic sensors (19a, 19b and 19c, Figure 1) operable to detect an acoustic emission created by flow through a vascular access device and produce an electrical signal indicative of the emission. It also disclosed an electronics processing means for processing and monitoring the electrical signal, and to determine, by identifying a change of characteristic of the signal, the possibility that the vascular access device had become dislodged from its normal working position (abstract).

D18 (column 13, lines 6 to 14) and D19 (page 25, line 11) disclosed acoustic sensors operable to detect an acoustic emission created by flow through a vascular access device.

Inventive step starting from D7

The subject-matter of claim 1 of the patent as granted would have been obvious in view of D7 alone or in combination with the common general knowledge and/or D1.

If it was concluded that D7 did not disclose an acoustic sensor operable to detect an acoustic emission created by flow through the vascular access device and produce an electrical signal indicative of the emission as defined in the claim, the skilled person would readily have implemented this distinguishing feature in the vascular access monitoring device of D7.

The implementation was rendered obvious at least by the acknowledgement in the patent that D7 disclosed all the features of the preamble of claim 1, including the acoustic sensor.

Inventive step starting from other documents

The subject-matter of claim 1 of the patent as granted was not inventive when starting from any of D8 to D11, D13 to D20 and D22, as also explained in the notice of opposition and in the letter of 8 April 2016, filed during the first-instance opposition proceedings.

The person skilled in the art would have implemented an electronics processing means comprising an electrical input means for receiving a signal from an extracorporeal blood pump in each of the vascular access monitoring devices disclosed in these documents for effectively controlling the extracorporeal blood pump.

VI. The proprietor's arguments where relevant to the decision may be summarised as follows.

Sufficiency of disclosure

The patent as granted would have provided sufficient information for the person skilled in the art to carry out an electrical input means for receiving a signal from an extracorporeal blood pump as defined in claim 1. It was not the purpose of the claim to teach the skilled person how to carry out the invention. That was the job of the patent as a whole.

Novelty over D1

D1 did not disclose an acoustic sensor operable to detect an acoustic emission created by flow through a vascular access device and produce an electrical signal indicative of the emission.

Acoustic sensors had to be adapted for transduction of pressure oscillations around an underlying pressure level. They were a subset of the more general concept of pressure transducers. For example, while both a microphone and a barometer were pressure sensors, the microphone was also an acoustic sensor, while the barometer was not. Moreover, claim 1 was limited to acoustic sensors which had to be operable to detect a frequency of emission created by flow, not the flow itself. Such an acoustic emission was in an amplitude and frequency range (typically $2x10^{-5}$ to $6x10^{-4}$ Pa and 30 Hz to 8 Khz respectively) not detectable by the pressure sensors of D1, adapted to detect fluctuations of the blood pressure (5 to 10 mmHg in amplitude and 0.5 to 1 Hz in frequency). The acoustic emission created by flow through the vascular access device was, quite literally, the noise on the pressure signal.

In addition, D1 disclosed pressure sensors on arterial and venous drip chambers. However, drip chambers acted as acoustic breaks, as taught by D7, paragraph [0099]. This was a further reason why the sensors of D1 could not be considered acoustic sensors within the meaning of claim 1 of the patent as granted.

Novelty over D7

D7 did not disclose an acoustic sensor operable to detect an acoustic emission created by flow through a vascular access device and produce an electrical signal indicative of the emission.

The acknowledgement in the patent that D7 disclosed an acoustic access disconnection system according to the preamble of claim 1 was wrong. This could be at most a clarity issue.

The embodiment of Figure 2 of D7 employed an active sensing technique with an ultrasound transducer in which ultrasound was emitted into the patient's tissue and the reflected ultrasound signal coming from red blood cells in the patient's blood vessel were detected. Using an analysis of the Doppler effect of the reflected waves, the flow rate and direction of movement of blood cells in the blood vessel was possible. D7 expressly taught that the ultrasound transducer had to be arranged downstream of a vascular access device because the vascular access device itself would interfere with the reflected waves which D7 was seeking to sense. These waves were not acoustic emissions created by flow through the vascular access device but were created by the ultrasound transducer.

Novelty over other documents

The subject-matter of claim 1 of the patent as granted was novel over the cited prior art.

As regards D5, this document disclosed the use of a pressure sensor and not an acoustic sensor within the meaning of claim 1.

The opponent's case in relation to the other documents had correctly been rejected by the Opposition Division.

Inventive step starting from D7

Starting from D7, it would not have been obvious to provide an acoustic sensor operable to detect an acoustic emission created by flow through the vascular access device and produce an electrical signal indicative of the emission as defined in claim 1 of the patent as granted. There was no teaching in the cited prior art as to why such an acoustic sensor should be implemented in the vascular access monitoring device disclosed in D7.

Inventive step starting from other documents

The subject-matter of claim 1 of the patent as granted was also inventive over the other cited prior art.

Reasons for the Decision

1. The invention

The invention relates to a vascular access monitoring device for monitoring characteristics of a skin piercing vascular access device.

Such monitoring devices are typically used to monitor the presence of the skin piercing vascular access device, typically in the form of a needle or cannula, and determine if this becomes dislodged from a patient.

A dislodged needle can cause serious medical consequences. For example, if not noticed, dislodgement of a blood return needle during a dialysis treatment can cause death as during dialysis blood would be withdrawn from the body but not returned to it. Since a dialysis treatment is normally performed for hours, during which time patients may be sleeping, watching TV, reading books, etc., the risk that a needle is dislodged without being noticed is considerable.

A vascular access monitoring device according to claim 1 of the patent as granted is schematically shown in Figure 2, reproduced below.

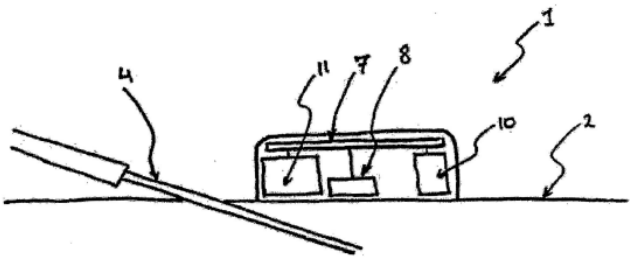


Figure 2.

The vascular access monitoring device (1) for monitoring characteristics of a skin piercing vascular access device (4) comprises an acoustic sensor (8) operable to detect an acoustic emission created by flow through the vascular access device and produce an electrical signal indicative of the emission.

The device also comprises an electronics processing means (7) for processing and monitoring the electrical signal, and to determine, by identifying a change of characteristic of the signal, the possibility that the vascular access device has become dislodged.

The electronics processing means comprises an electrical input means for receiving a signal from an extracorporeal blood pump.

According to the patent, the signal from the blood pump enables the electronics processing means to identify the sound pulse associated with the pump. If this sound is lost, the electronics processing means can detect that the vascular access device has become dislodged (as explained in detail in paragraph [0029] of the patent).

2. Sufficiency of disclosure

The opponent argued that the invention as defined in claim 1 of the patent as granted was not sufficiently disclosed over the whole claim scope.

More specifically, it argued that the claim merely referred to an extracorporeal blood pump but that such a pump was not part of the claim. It followed that the person skilled in the art would not have known how to carry out an electrical input means for receiving a signal from any possible extracorporeal blood pump and an electronic processing means for processing every possible signal.

It is a claim requirement that the electrical input means is able to receive - and convey to an electronics

processing means - a signal from an extracorporeal blood pump.

The Board agrees with the opponent that how such an input means and such an electronic processing means are to be carried out may, in part, depend on the nature of the signal. This, in turn, may depend on the specific extracorporeal blood pump.

However, paragraph [0029] of the patent explains that the input signal should provide, in essence, an indication that the pump is pumping. In view of the fact that extracorporeal blood pumps are known per se, the person skilled in the art would have known which signals may be expected from such known pumps for providing the indication disclosed in the patent. Devising an electrical input means and an electronic processing means for processing such signals would have been an everyday task for the person skilled in the art once the nature of the signal was known.

In conclusion, the invention as defined in claim 1 of the patent as granted is sufficiently disclosed. It follows that the ground for opposition under Article 100(b) EPC invoked by the opponent does not prejudice the maintenance of the patent as granted.

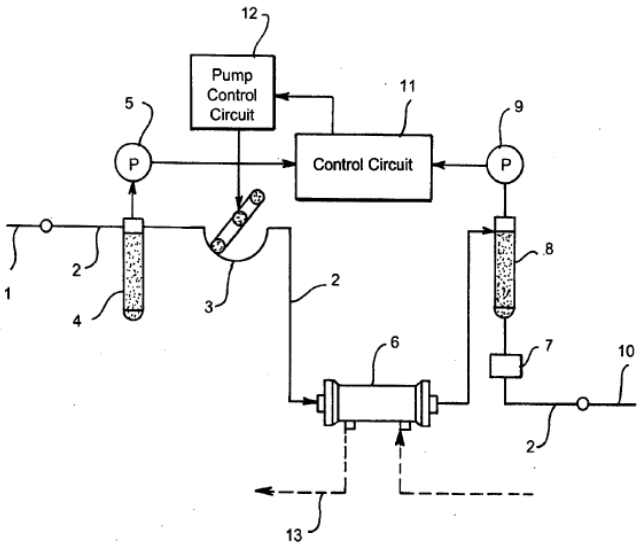
3. Novelty over D1

The opponent argued that the subject-matter of claim 1 of the patent as granted was not novel over D1. This view was shared by the Opposition Division in the impugned decision.

3.1 It is common ground that D1 discloses a vascular access monitoring device with a sensor and an electronics

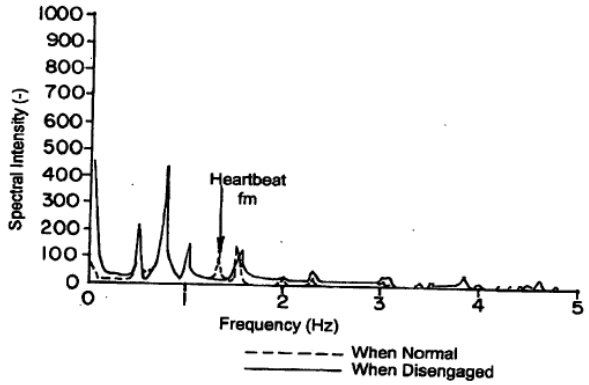
processing means for determining whether the vascular access device has become dislodged from its normal working position (paragraphs [0013], [0023] and [0109]). A schematic arrangement of a dialysis device comprising the vascular access monitoring device is shown in Figure 1 of D1, reproduced below.

FIG. 1



According to D1, frequency analysis is applied to the measurements of pressure sensors (5 and 9) on a venous and an arterial line of the dialysis device to determine a spectrum consisting of various frequency components (paragraph [0018]). If a component dependent on the heartbeat of the patient under treatment cannot be detected, it is concluded that an anomaly exists in the blood vessel access to the patient (paragraph [0100] and Figure 13, reproduced below).

FIG. 13



The working principle of the vascular access monitoring device disclosed in D1 is different from that explained in the patent. According to D1, the heartbeat is monitored, whereas according to the description of the patent, the noise deriving from the cycles of the blood pump is monitored. This explains why the sensors of D1 are applied to lines of the dialysis device, whereas according to the description of the patent, an acoustic sensor is applied to the patient.

3.2 A crucial question to be considered in the analysis of novelty of the subject-matter of claim 1 of the patent as granted over D1 is whether the pressure sensors disclosed in D1 can be considered acoustic sensors within the meaning of the claim.

The Board shares the opponent's view that since an acoustic sensor has to detect pressure waves, it is itself a pressure sensor.

The opponent's arguments based on D26 and D27 that the term "acoustic sensor" can be broad is also accepted. The term as such does not imply any precise definition of the possible lowest and highest amplitude and frequency of the pressure waves to be detected.

3.3 However, claim 1 of the patent as granted requires the acoustic sensor to be operable to detect an acoustic emission created by flow through the vascular access device.

The interaction between the vascular access device and the flow through it, in the per se known intended uses of the vascular access monitoring device, generates acoustic emissions in terms of pressure waves of defined amplitude and frequency ranges. These ranges can be broad, as the opponent submitted. Still, an acoustic sensor as claimed must be operable to detect pressure waves within these ranges.

In this respect, the proprietor argued that the amplitude range would typically be from $2x10^{-5}$ to $6x10^{-4}$ Pa and that the frequency range would be 30 Hz to 8 Khz. The Board is convinced that such ranges, which are indeed broad, provide an appropriate indication of the pressure waves which the acoustic sensors within the meaning of claim 1 of the patent as granted must be operable to detect. It is also noted that the opponent did not provide convincing arguments why such ranges did not reflect all the reasonable conditions of use of a vascular monitoring device of the kind defined in the claim.

As regards the opponent's argument that it was irrelevant how precise the detection of the pressure waves could be, the Board notes that the detection should be precise enough to enable reasonable measurements.

3.4 As a first general consequence, not every pressure sensor can be considered an acoustic sensor as defined in claim 1 of the patent as granted. For example a

barometer, as mentioned by the proprietor, cannot.

Turning to the pressure sensors described in D1, there is no direct and unambiguous disclosure in this document that they may reasonably measure pressure waves with an amplitude and frequency as required by claim 1.

For example, Figure 13 and Figures 3A and 3B do not show that frequency components above 5 Hz can be measured at all.

3.5 A further point to be considered is the location of the pressure sensors in the device of D1. These pressure sensors are typically attached to a respective drip chamber (Figure 1), although D1 discloses other possible locations such as a blood tube (paragraph [0147]). In all the possible locations, the pressure sensors should measure the pressure of the blood circulating through the dialysis device. It is not clearly and unambiguously derivable from D1 that an acoustic emission created by flow through the vascular access device may be measurable at all at the intended locations of the pressure sensors.

The opponent's argument that the pressure sensors of D1 were per se operable to detect acoustic emissions cannot be accepted. Claim 1 of the patent as granted is directed to a vascular access monitoring device comprising an acoustic sensor. Only if the sensor of such a vascular access monitoring device, at its disclosed location, was operable to detect the defined acoustic emissions, could the claimed subject-matter be anticipated by that vascular access monitoring device.

Whether D1 discloses pressure sensors which, at their

position at respective drip chambers, are capable of detecting the heartbeat propagating through the drip chambers is irrelevant. Pressure waves generated by the heartbeat do not have a frequency within the range of the acoustic emissions created by flow through the vascular access device as required by the claim.

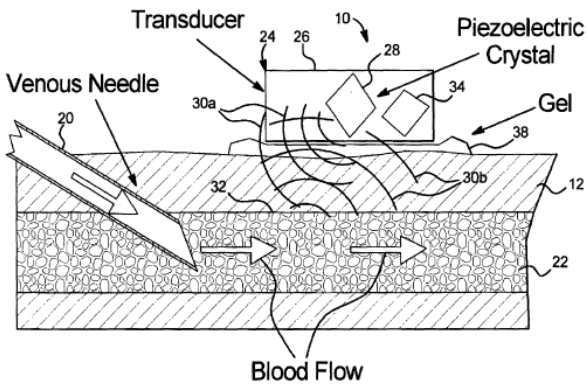
3.6 In conclusion, D1 does not anticipate an acoustic sensor operable to detect an acoustic emission created by flow through a vascular access device and produce an electrical signal indicative of the emission within the meaning of claim 1 of the patent as granted.

It follows that the subject-matter of claim 1 of the patent as granted is novel (Article 54(1) and (2) EPC) over D1.

4. Novelty over D7

The opponent argued that the subject-matter of claim 1 of the patent as granted was not novel over D7, in particular the embodiment shown in Figure 2, reproduced below.

FIG. 2



4.1 D7 was considered by the Opposition Division in the impugned decision, albeit in relation to the then

pending auxiliary request 2. The Opposition Division concluded that D7 did not disclose an acoustic sensor operable to detect an acoustic emission created by flow through a vascular access device and produce an electrical signal indicative of the emission (point 4.2.3 of the Reasons).

The Board comes to the same conclusion.

D7 discloses a vascular access monitoring device comprising a sensor in the form of a piezoelectric transducer (24) operable to generate ultrasound waves (30a) and direct them to blood flowing in a patient proximate to the vascular access (venous needle 20) and detect waves (30b) reflected by blood cells flowing though the vascular access. The speed and direction of movement of the blood cells creates a Doppler effect, i.e. a difference in frequency between the emitted and the reflected waves (paragraph [0074]). The piezoelectric transducer generates an electrical signal fed to an electronics processing means (DSP 44 and CPU 50, Figure 4) for processing and monitoring the electrical signal, and to determine, by identifying a change of characteristic of the signal, the possibility that the vascular access device has become dislodged from its normal working position (paragraphs [0076] and [0077]).

The opponent's argument that the reflected waves corresponded to an acoustic emission created by flow through a vascular access device is not convincing.

The reflected waves are not emitted by flow through the vascular access device but are merely reflected by the flow. They are ultrasound waves with an amplitude and a frequency not disclosed to be within the range of the

acoustic emissions created by flow through the vascular access device as required by claim 1 of the patent as granted.

Hence, D7 does not directly and unambiguously disclose that the piezoelectric transducer may reasonably measure pressure waves with an amplitude and frequency as required by claim 1.

4.2 The opponent argued that the patent as granted itself acknowledged that D7 disclosed a vascular access monitoring device according to the preamble of claim 1 (paragraph [0004], last sentence).

In the Board's view, this is not decisive. The technical assessment of both the patent specification and the prior art has to be conducted in an objective way. In other words, it cannot be excluded that what is written in the patent may be wrong. In the case at hand, the proprietor itself argued so.

4.3 In conclusion, D7 does not anticipate an acoustic sensor operable to detect an acoustic emission created by flow through a vascular access device and produce an electrical signal indicative of the emission within the meaning of claim 1 of the patent as granted.

It follows that the subject-matter of claim 1 of the patent as granted is novel (Article 54(1) and (2) EPC) over D7.

5. Novelty over other documents

The opponent argued that the subject-matter of claim 1 of the patent as granted was not novel over each of D2 to D6, D8 to D20, D22, D24 and D25. In the oral

proceedings, it only referred to previous written submissions.

5.1 D2 to D6, D14, D16, D17, D24 and D25 are all concerned with the detection of needle dislodgement during an infusion therapy (summary of the invention of D2 to D6, and abstracts of D14, D16, D17, D24 and D25). For this purpose they employ pressure sensors for monitoring the pressure along a fluid line of an infusion device. These documents do not directly and unambiguously disclose an acoustic sensor operable to detect an acoustic emission created by flow through a vascular access device and produce an electrical signal indicative of the emission within the meaning of claim 1 of the patent as granted for the same reasons D1 does not.

5.2 D8 discloses a vascular access monitoring device which can be included in a dialysis device (page 9, penultimate paragraph) comprising an acoustic sensor (23, Figure 1) operable to detect an acoustic emission created by flow through a vascular access device. More specifically, if the vascular access device becomes dislodged, air flowing through an opening of the vascular access device (8, Figure 3) generates a sound detected by the acoustic sensor placed upstream, on a blood line (page 12, third paragraph). The output of the acoustic sensor is processed by an electronics processing means (21, Figure 1). When the electronics processing means detects a dislodgement of the vascular access device, it sends a signal to the central control unit (15, Figure 1) of the dialysis device which, in turn, stops an extracorporeal blood pump (page 10, second paragraph). As the opponent submitted, there is thus communication between a processor of the dialysis device and an extracorporeal blood pump. However, this

processor, i.e. central control unit 15, is distinct from electronic processing means 21 for processing and monitoring the electrical signal produced by the acoustic sensor. Hence, D8 does not disclose that the electronics processing means comprises an electrical input means for receiving a signal from the extracorporeal blood pump, as required by claim 1 of the patent as granted.

5.3 D9 to D11, D13, D15 and D20 are concerned with the detection of needle dislodgement during an extracorporeal blood treatment (abstracts of D9 to D11, D13 and D20, and page 1, lines 1 to 14, of D15). For this purpose they employ pressure sensors disposed along a blood line of a dialysis device. These documents do not directly and unambiguously disclose an acoustic sensor operable to detect an acoustic emission created by flow through a vascular access device and produce an electrical signal indicative of the emission within the meaning of claim 1 of the patent as granted for the same reasons D1 to D6, D14, D16, D17, D24 and D25 do not.

5.4 D12 is concerned with the detection of needle dislodgement during an extracorporeal blood treatment (abstract). More specifically, it discloses an extracorporeal blood treatment machine with a venous and an arterial access site (Figure 1). The machine comprises an acoustic transmitter (18), acoustic sensors (19a and 19b) positioned on a venous line (17) and an acoustic sensor (19c) positioned on an arterial line (16). The transmitter, which is proximate to the acoustic sensors on the venous line, generates an acoustic emission detected by the acoustic sensors on the venous line and by the acoustic sensor on the arterial line. The sensor on the arterial line detects

the emission after it has travelled down the venous line, through the patient and back up the arterial line (paragraphs [0037] and [0038]). If there is a disconnection of an access site, the acoustic path of the emission towards the acoustic sensor on the arterial line is interrupted. Thus, this sensor does not detect the acoustic emission generated by the transmitter any longer in an appreciable amount (paragraph [0038] and Figure 4). Under this condition, an electronics processing means of the machine (controller 20) indicates dislodgement. Similar to D7, the acoustic emission detected by the sensor on the arterial line is not created by flow through the vascular access device. D12 does not directly and unambiguously disclose that an acoustic emission created by flow through the vascular access device could reasonably be measured by the acoustic sensors of the extracorporeal blood treatment machine. Even assuming that the acoustic sensors could be operable to detect an acoustic emission created by flow through the vascular access device, there is no disclosure in D12 that the electronics processing means may determine the possibility that the vascular access device has become dislodged by identifying a change of characteristic of the signal indicative of this acoustic emission, as required by claim 1 of the patent as granted. Upon dislodgement, it is even less likely that an acoustic emission created by flow through the vascular access device could reasonably be measured by the acoustic sensors of the extracorporeal blood treatment machine.

5.5 D18 is concerned with the detection of leaks during an infusion therapy (abstract). For this purpose it may employ an ultrasound pulse generator for transmitting ultrasound pulses through an infusion line and an ultrasonic detector for detecting the pulses reflected

back from the patient (paragraph [0077]). If the time lapsed between the generation and detection changes beyond an acceptable range between successive measures, an anomaly is detected (paragraph [0030]). D18 does not directly and unambiguously disclose an acoustic sensor operable to detect an acoustic emission created by flow through a vascular access device and produce an electrical signal indicative of the emission within the meaning of claim 1 of the patent as granted for the same reasons D7 does not.

5.6 D19 is concerned with the detection of dislodgement of a vascular access device (abstract). For this purpose a generator and a detector of vibrations on the vascular access device is employed. The response to the generated vibrations changes if the device is dislodged (Figure 4 and page 24, lines 14 to 24). D19 does not directly and unambiguously disclose an acoustic sensor operable to detect an acoustic emission created by flow through a vascular access device and produce an electrical signal indicative of the emission within the meaning of claim 1 of the patent as granted for the same reasons D7 and D18 do not.

5.7 The disclosure of D22 is similar to that of D12. It is concerned with the detection of needle dislodgement at a venous or an arterial access site of an extracorporeal blood treatment machine (abstract). The machine comprises an acoustic transmitter (62) and an acoustic sensor (64) positioned on different blood lines of the machine (abstract and Figure 7). The transmitter generates an acoustic emission on the venous or arterial line detected by the acoustic sensor on the arterial or venous line respectively. The sensor detects the emission after it has travelled down one line, through the patient and back up the other line

(paragraph [0093]). If there is a disconnection of an access site, the acoustic path of the emission towards the acoustic sensor is interrupted. Under this condition, an electronics processing means of the machine indicates dislodgement. D22 does not anticipate an electronics processing means which may determine the possibility that a vascular access device has become dislodged by identifying a change of characteristic of a signal indicative of an acoustic emission created by flow through the vascular access device as required by claim 1 of the patent as granted for the same reasons D12 does not.

5.8 In conclusion, the subject-matter of claim 1 of the patent as granted is novel (Article 54(1) and (2) EPC) over each of D2 to D6, D8 to D20, D22, D24 and D25.

5.9 It follows that the ground for opposition of lack of novelty under Article 100(a) EPC invoked by the opponent does not prejudice the maintenance of the patent as granted.

6. Inventive step starting from D7

The opponent argued that the subject-matter of claim 1 of the patent as granted lacked an inventive step when starting from D7 alone or in combination with the common general knowledge and/or D1.

6.1 As explained under points 4.1 to 4.3 above, D7 does not disclose an acoustic sensor operable to detect an acoustic emission created by flow through a vascular access device and produce an electrical signal indicative of the emission within the meaning of claim 1 of the patent as granted.

Instead, D7 discloses an ultrasonic piezoelectric transducer operable to emit and detect ultrasonic waves.

6.2 With a sensor as defined in the claim, it is possible to detect dislodgement of the vascular access device by monitoring the noise normally occurring during a dialysis treatment, without the need of an active measuring technique in which a dedicated signal has to be generated for the measure.

This addresses the objective technical problem of simplifying the detection of the dislodgement of the vascular access device.

6.3 There is no teaching derivable from D7, the common general knowledge or D1 that an acoustic sensor as claimed should be implemented in the vascular access monitoring device according to D7 for solving the objective technical problem. In particular, D1, as explained under points 3.1 to 3.6 above, does not teach such a sensor at all.

As regards the opponent's argument based on the acknowledgement of D7 in the patent in suit, the patent itself does not belong to the state of the art for the assessment of inventive step.

6.4 In conclusion, the subject-matter of claim 1 of the patent as granted is inventive (Article 56 EPC) when starting from D7.

7. Inventive step starting from other documents

The opponent argued that the subject-matter of claim 1 of the patent as granted was not inventive when

starting from any of D8 to D11, D13 to D20 and D22. In the oral proceedings, it only referred to previous written submissions.

7.1 The objections starting from any of D9 to D11 and D13 to D20 assume that the only distinguishing feature of the subject-matter of claim 1 of the patent as granted over each of these documents is an electrical input means of an electronics processing means for receiving a signal from an extracorporeal blood pump.

However, as explained under points 4.1 to 4.3, 5.1, 5.3, 5.5 and 5.6 above, none of these documents disclose an acoustic sensor operable to detect an acoustic emission created by flow through a vascular access device and produce an electrical signal indicative of the emission within the meaning of claim 1 of the patent as granted.

The implementation of this feature in the devices of these documents would not have been obvious for the same reasons as when starting from D7.

7.2 Starting from D8, the distinguishing feature of the subject-matter of claim 1 of the patent as granted over this document is an electronics processing means that comprises an electrical input means for receiving a signal from an extracorporeal blood pump, as explained under point 5.2 above.

According to the patent, such an input enables the electronics processing means to identify an acoustic emission for which the pump is responsible. If this emission is not detected by the acoustic sensor as claimed, the electronics processing means establish that the vascular access device has become dislodged.

Hence, the distinguishing feature addresses the objective technical problem of simply and reliably detecting dislodgement of a vascular access device.

D8 works according to a different principle based on the processing and monitoring of an electrical signal produced by an acoustic sensor in response to the detection of a sound generated by air flowing through an opening of a vascular access device when the vascular access device is dislodged. There is no need to detect or monitor any acoustic emission for which an extracorporeal blood pump may be responsible.

Hence, the person skilled in the art would have had no motivation to provide any input from such a pump to the electronics processing means for processing and monitoring the electrical signal produced by the acoustic sensor.

It follows that the subject-matter of claim 1 of the patent as granted would not have been obvious when starting from D8.

7.3 Starting from D22, the distinguishing feature of the subject-matter of claim 1 of the patent as granted over this document is an electronics processing means which may determine the possibility that a vascular access device has become dislodged by identifying a change of characteristic of a signal indicative of an acoustic emission created by flow through the vascular access device, as explained under point 5.7 above.

According to D22, dislodgement is detected via an active measuring technique in which a dedicated signal has to be generated for the measure.

Hence, the distinguishing feature addresses the objective technical problem of simply and reliably detecting dislodgement of a vascular access device.

With the device of D22, there is no need to consider the acoustic emission created by flow through the vascular access device. Hence, the person skilled in the art would have had no motivation to implement the distinguishing feature.

As a result, the subject-matter of claim 1 of the patent as granted would not have been obvious when starting from D22.

7.4 In conclusion, the subject-matter of claim 1 of the patent as granted is inventive (Article 56 EPC) when starting from any of D8 to D11, D13 to D20 and D22.

7.5 It follows that the ground for opposition of lack of inventive step under Article 100(a) EPC invoked by the opponent does not prejudice the maintenance of the patent as granted.

8. It has been explained that none of the grounds for opposition relied on by the opponent prejudices the maintenance of the patent as granted.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar: The Chairman:

D. Hampe C. Schmidt

Decision electronically authenticated