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**Datasheet for the decision  
of 1 December 2017**

**Case Number:** T 1859/14 - 3.2.03

**Application Number:** 09166059.7

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**IPC:** F25D17/02, A61F7/00

**Language of the proceedings:** EN

**Title of invention:**

Heating-cooling system for medical indwelling heat-exchange catheter

**Applicant:**

ZOLL Circulation, Inc.

**Headword:**

**Relevant legal provisions:**

EPC Art. 56

**Keyword:**

Inventive step - (no)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
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Case Number: T 1859/14 - 3.2.03

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.03**  
**of 1 December 2017**

**Appellant:** ZOLL Circulation, Inc.  
(Applicant) 2000 Ringwood Avenue  
San Jose, CA 95131 (US)

**Representative:** D Young & Co LLP  
120 Holborn  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted on 9 May 2014  
refusing European patent application No.  
09166059.7 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman** G. Ashley  
**Members:** C. Donnelly  
E. Kossonakou

## **Summary of Facts and Submissions**

- I. The appeal lies from the decision of the examining division refusing European patent application No. 09 166 059.7.

In its decision the examining division held that the claim set filed with letter of 10 April 2014 would not be admitted into the procedure under Rule 137(3) EPC, since the proposed amendment to claim 1 made after the issuance of the communication according to Rule 71(3) EPC could not be considered as minor. In particular, the examining division considered that the subject-matter of the amended claim 1 did not *prima facie* meet the requirements of Article 123(2) EPC since it implied the presence of a connector which was not originally disclosed. Furthermore, it came to the conclusion that the subject-matter of the claim would not in any case involve an inventive step in view of US 6 146 411 (D1) in combination with US 3 504 674 (D3).

The applicant (hereinafter: the "appellant") filed an appeal against this decision in due form and time.

- II. The Board set out its provisional opinion in a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA). In particular, it informed the appellant that the subject-matter of claim 1 of all the requests filed with the grounds of appeal did not appear to involve an inventive step in view of D1 in combination with D3.
- III. By letter of 1 November 2017 the appellant filed a new main request and auxiliary requests 1 and 2 to replace all the requests on file.

IV. Oral proceedings were held at the appellant's request on 1 December 2017. At the end of the debate the appellant confirmed its request that the decision under appeal be set aside and that a patent be granted on the basis of any of the main request or first and second auxiliary requests, all filed with letter dated 1 November 2017.

V. *Claim 1 according to the main request reads:*

"1. A working fluid circuit (29, 24, 20, 17,16) for carrying saline working fluid to and from a heat exchange catheter (12) under the influence of a pump (18), the working fluid circuit (29, 24, 20,17, 16) comprising:

a heat exchanger (17) through which working fluid can flow under the influence of the pump,

a working fluid reservoir (22) in fluid communication with the heat exchanger (17), and

a first working fluid tube (20) in the working fluid circuit configured for receiving working fluid from the pump,

characterised in that

the working fluid circuit further comprises a second working fluid tube (24) in the working fluid circuit which is configured to engage with the pump and is disposed so that the working fluid can be pumped from the reservoir to the heat exchanger,

the heat exchanger is a coiled or helical heat exchanger tube (17) being adapted to be disposed within

a bath (14) of a heating/cooling circuit (14, 44, 42) for holding heating/cooling fluid in thermal contact with working fluid; wherein the working fluid circuit (29, 24, 20,17,16) is operable with the heating/cooling circuit (14, 44, 42) such that when the heat exchanger tube is disposed within the bath, the heating/cooling circuit is thermally coupled to the working fluid circuit (29, 24, 20, 17,16);

and in that the working fluid reservoir includes an inlet and an outlet of the working fluid circuit, which are operably coupled with the working fluid reservoir (22) for feeding the working fluid from the working fluid circuit into the working fluid reservoir and for extracting the working fluid from the working fluid reservoir into the working fluid circuit when the pump (18) is energized, the inlet and the outlet being coupled with the working fluid reservoir so that an amount of the working fluid in the working fluid circuit can be detected using a working fluid level detector, the working fluid in the working fluid reservoir being supplied from a working fluid source (26)."

*Claim 1 according to auxiliary request 1 (amendments with respect to claim 1 of the main request in bold) reads:*

"1. A working fluid circuit (29, 24, 20, 17,16) for carrying saline working fluid to and from a heat exchange catheter (12) under the influence of a pump (18), the working fluid circuit (29, 24, 20,17, 16) comprising:

a heat exchanger (17) through which working fluid can flow under the influence of the pump,

a working fluid reservoir (22) in fluid communication with the heat exchanger (17), and

a first working fluid tube (20) in the working fluid circuit configured for receiving working fluid from the pump,

characterised in that

the working fluid circuit further comprises a second working fluid tube (24) in the working fluid circuit which is configured to engage with the pump and is disposed so that the working fluid can be pumped from the reservoir to the heat exchanger,

the heat exchanger is a coiled or helical heat exchanger tube (17) being adapted to be disposed within a bath (14) of a heating/cooling circuit (14, 44, 42) for holding heating/cooling fluid in thermal contact with working fluid; wherein the working fluid circuit (29, 24, 20, 17, 16) is operable with the heating/cooling circuit (14, 44, 42) such that when the heat exchanger tube is disposed within the bath, the heating/cooling circuit is thermally coupled to the working fluid circuit (29, 24, 20, 17, 16);

and in that the working fluid reservoir includes an inlet and an outlet of the working fluid circuit, **the outlet being operably arranged to return the working fluid to the working fluid reservoir (22) from the working fluid circuit and the inlet being operably arranged to extract** the working fluid from the working fluid reservoir **for feeding** into the working fluid circuit **when the pump (18) is energized**, the inlet and the outlet being **arranged with respect to** the working

fluid reservoir so that an amount of the working fluid in the working fluid circuit can be detected using a working fluid level detector, the working fluid in the working fluid reservoir being supplied from a working fluid source (26)."

*Claim 1 according to auxiliary request 2 (amendments with respect to claim 1 of auxiliary request 1 in bold) reads:*

"1. A working fluid circuit (29, 24, 20, 17,16) for carrying saline working fluid to and from a heat exchange catheter (12) under the influence of a pump (18), the working fluid circuit (29, 24, 20,17, 16) comprising:

a heat exchanger (17) through which working fluid can flow under the influence of the pump,

a working fluid reservoir (22) in fluid communication with the heat exchanger (17), and

a first working fluid tube (20) in the working fluid circuit configured for receiving working fluid from the pump,

characterised in that

the working fluid circuit further comprises a second working fluid tube (24) in the working fluid circuit which is configured to engage with the pump and is disposed so that the working fluid can be pumped from the reservoir to the heat exchanger,

the heat exchanger is a coiled or helical heat exchanger tube (17) being adapted to be disposed within



a bath (14) of a heating/cooling circuit (14, 44, 42) for holding heating/cooling fluid in thermal contact with working fluid; wherein the working fluid circuit (29, 24, 20,17,16) is operable with the heating/cooling circuit (14, 44, 42) such that when the heat exchanger tube is disposed within the bath, the heating/cooling circuit is thermally coupled to the working fluid circuit (29, 24, 20, 17,16);

and in that the working fluid reservoir includes an inlet and an outlet of the working fluid circuit, the outlet being operably arranged to return the working fluid to the working fluid reservoir (22) from the working fluid circuit and the inlet being operably arranged to extract the working fluid from the working fluid reservoir for feeding into the working fluid circuit when the pump (18) is energized **and not to extract the working fluid when the pump (18) is de-energized**, the inlet and the outlet being arranged with respect to the working fluid reservoir so that an amount of the working fluid in the working fluid circuit can be detected using a working fluid level detector, the working fluid in the working fluid reservoir being supplied from a working fluid source (26)."

## Reasons for the Decision

### 1. *Main request, Inventive step*

1.1 D1 is considered to be the closest prior art since it concerns a similar type of apparatus intended for the same purpose. This document discloses:

a working fluid circuit (30) for carrying saline working fluid to and from a heat exchange catheter (20) under the influence of a pump (34), the working fluid circuit (30) comprising:

a heat exchanger (50) through which working fluid can flow under the influence of the pump (34),

a working fluid reservoir (38) in fluid communication with the heat exchanger (50), and

a first working fluid tube (32A) in the working fluid circuit (32) configured for receiving working fluid from the pump (34),

and wherein

the working fluid circuit further comprises a second working fluid tube (32C) in the working fluid circuit which is disposed so that the working fluid can be pumped from the reservoir to the heat exchanger,

and in that the working fluid reservoir (38) includes an inlet and an outlet of the working fluid circuit, which are operably coupled with the working fluid reservoir (38) for feeding the working fluid from the working fluid circuit into the working fluid reservoir

and for extracting the working fluid from the working fluid reservoir into the working fluid circuit when the pump (18) is energized, the inlet and the outlet being coupled with the working fluid reservoir so that an amount of the working fluid in the working fluid circuit can be detected using a working fluid level detector (44).

1.2 The subject-matter of claim 1 differs therefrom in that:

(i) the heat exchanger is a coiled or helical heat exchanger tube being adapted to be disposed within a bath of a heating/cooling circuit for holding heating/cooling fluid in thermal contact with working fluid; wherein the working fluid circuit is operable with the heating/cooling circuit such that when the heat exchanger tube is disposed within the bath, the heating/cooling circuit is thermally coupled to the working fluid circuit;

(ii) the working fluid in the working fluid reservoir is supplied from a working fluid source.

(iii) the second working fluid tube is configured to engage with the pump.

1.3 The appellant confirmed at the oral proceedings that it essentially agreed with this analysis, but was also of the view that D1 does not disclose a working fluid reservoir with an inlet and an outlet which are operably coupled to the reservoir so that an amount of working fluid within the reservoir can be detected by a working fluid level detector.

- 1.4 The Board disagrees with the appellant's submission since D1 discloses two different kinds of working fluid level detectors in detail (see figures 2 to 7 and corresponding description). The claim under examination does not specify any interaction between the inlet/outlet and the working fluid level detector other than that the inlet and outlet act conventionally to allow liquid in and out of the reservoir which may result in a change of the liquid level. However, this does not amount to the same thing as actually participating in the action of liquid level detection.
- 1.5 Furthermore, the appellant considered that in D1 the working fluid cannot be said to be circulated when the pump is energised since gravity plays a role. However, the Board is of the view that there will certainly be circulation of the working fluid in D1 when the pump is energised since this is the very purpose of the pump.
- 1.6 As regards distinguishing feature (i), the Board considers that it can be handled separately since there is no synergy between this feature and the other distinguishing features. The appellant does not contest this.
- 1.7 D1 does not disclose the details of the heat exchanger 50, merely stating at column 6, lines 1 to 4, that "exchanger 50 interfaces between the two fluid circuits and serves to facilitate heat transfer there between in a well known manner whose details will be omitted herein for purposes of clarity".
- 1.8 However, the skilled person seeking the details of a suitable heat-exchanger design would have consulted D3 since it relates to a similar apparatus. D3 discloses a heat exchanger according to distinguishing feature (i)

intended for the same purpose as the exchanger of D1. Therefore, D3 gives the skilled person a direct teaching that a heat exchanger according to distinguishing feature (i) would be suitable for use in the apparatus of D1.

- 1.9 During the oral proceedings the appellant submitted that there is synergy between distinguishing features (ii) and (iii) since both contribute to maintaining an adequate level of fluid in the reservoir. However, the Board does not accept this view since it has not been demonstrated how the position of the pump affects the detection of the working liquid level in the reservoir. Indeed, no apparent technical effect is obtained by placing the pump in any particular part of the working fluid circuit, especially since a peristaltic pump is used both in D1 and the application. This type of pump works by squeezing flexible tubing and is used in medical applications since the working fluid does not come into contact with the pump. This type of pump is easy to position anywhere in a fluid circuit where flexible tubing is easily accessible. Thus, the Board considers that the position of the pump would be dictated by practical considerations of equipment arrangement around the patient.
- 1.10 Accordingly, when applying the problem-solution approach, these features can also be handled separately since there is no technical synergy between them.
- 1.11 As regards feature (ii), the applicant argues that there is no separate working fluid source in D1 since the IV bag forms the working fluid reservoir. However, the separate working fluid source of the application is also not a part of the apparatus claimed.

- 1.12 Nevertheless, the Board agrees that, when a low fluid level is detected in the apparatus of D1, the IV bag would most likely just be changed out, entailing an interruption of operations. Thus, distinguishing feature (ii) indicates that the working fluid reservoir can be refilled rather than changed out.
- 1.13 Thus, the objective technical problem to be solved can be seen as one of how to ensure continuous operation.
- 1.14 The skilled person tackling this problem would have consulted D3 which relates to a like apparatus for a similar purpose. In particular D3 discloses that the reservoir 17 allows for topping up from a separate source during operation should the operator notice that the liquid level is getting low (see D3, column 2, lines 64 to 66). Thus, D3 offers the skilled person a direct suggestion as to how to solve the problem of ensuring continuous operation by providing a suitable inlet to the reservoir through which the working fluid may be added from time to time.
- 1.15 It is accepted that D3 does not teach an automatic level detecting device as described in the application or in D1. However, D3 does teach that working liquid level monitoring is essential. The Board considers that it lies within the skilled person's general knowledge and would come within the realm of obvious modifications offered by advances in technology and/or imposed by safety regulations to integrate an automatic fluid level detection device into the reservoir of D3.
- 1.16 Distinguishing feature (iii) effectively relates to the position of the pump within the circuit. In the exemplary embodiment shown in figure 1 of D1, the pump is placed between the heat exchanger and the patient.

In the application, the pump is placed between the reservoir and the heat exchanger. However, D1 also states at column 4, lines 65 to 67 that "Pump 34 is preferably coupled to segment 32A of primary circuit 30, although other segments can be used for this purpose." Therefore, D1 itself suggests that the pump could equally well have been placed in segment 32C of figure 1 in the same manner as the apparatus of the application. As already stated in paragraph 1.9, the position of the pump would be dictated by practical considerations of equipment placement around the patient.

- 1.17 The applicant further argued that in D1, due to the opposite orientation of the working fluid reservoir compared to the invention and the associated coupling of the outlet to the underside of the reservoir, coupling the outlet to the reservoir in the manner disclosed in the present application would actually increase the risk of air being circulated in the working fluid circuit and therefore would not be considered by the skilled person.
- 1.18 This is essentially an argument that the reservoir outlet is at the top of the receptacle. However, this is not defined in the claim, which does not specify the relative positions of the inlet and outlet.
- 1.19 In conclusion, the subject-matter of claim 1 according to the main request does not meet the requirements of Article 56 EPC since it does not involve an inventive step.

2. *Auxiliary requests*

2.1 *Auxiliary request 1*

The amendments made to claim 1 merely define further the conventional function of an inlet and an outlet. The level of the working fluid in the reservoir can always be detected, whatever the arrangement of the inlet and outlet. Accordingly, since the subject-matter of claim 1 according to auxiliary request 1 also differs from the device known in D1 by the same distinguishing features identified when analysing claim 1 of the main request, it also does not involve an inventive step.

2.2 *Auxiliary request 2*

During the oral proceedings, the appellant submitted that the working fluid in the device of D1 would continue to circulate under the influence of gravity when the pump was de-energised. The Board disagrees with this interpretation of D1 since a closed circuit using a sealed IV bag is under consideration in which the hydrostatic pressure at the inlet and outlet of the IV bag reservoir is the same. As a consequence, when the pump in the device of D1 is de-energized, the working fluid would cease to circulate and would not be extracted from the IV bag reservoir.

Thus, the subject-matter of claim 1 according to auxiliary request 2 differs from the device known from D1 by the same distinguishing features identified for the main request and the same reasoning as for the main request applies.



**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



C. Spira

G. Ashley

Decision electronically authenticated