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**Datasheet for the decision  
of 12 October 2011**

**Case Number:** T 0570/09 - 3.2.02

**Application Number:** 03761226.4

**Publication Number:** 1515773

**IPC:** A61M 25/06

**Language of the proceedings:** EN

**Title of invention:**

Method of and apparatus for controlling flashback in an  
introducer needle and catheter assembly

**Applicant:**

Becton Dickinson and Company

**Opponent:**

-

**Headword:**

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**Relevant legal provisions:**

EPC Art. 123(2), 56

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"Added subject-matter (no)"

"Inventive step (yes, after amendments)"

**Decisions cited:**

-

**Catchword:**

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Case Number: T 0570/09 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 12 October 2011

**Appellant:** Becton Dickinson and Company  
One Becton Drive  
Franklin Lakes  
New Jersey 07417-1880 (US)

**Representative:** von Kreisler Selting Werner  
Deichmannhaus am Dom  
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D-50667 Köln (DE)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 9 October 2008  
refusing European patent application  
No. 03761226.4 pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** M. Noël  
**Members:** D. Valle  
M. J. Vogel

## Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal by notice received on 10 December 2008 against the decision of the Examining Division to refuse the application for lack of inventive step of its subject-matter. The fee for the appeal was paid on the same day. A statement setting out the grounds for appeal was received on 7 February 2009.
- II. The following documents are relevant for the present decision:
- D1: EP-A-0 806 221  
D2: US-A-4 193 399  
D3: US-A-4 894 052.
- III. Following a communication of the Board dated 18 July 2011, the appellant submitted with letters of 8 and 13 September 2011 an amended set of claims and amended pages of the description, respectively. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:
- description: pages 1, 1a, 2 to 17 as filed with letter of 13 September 2011;
  - claims: 1 to 3 as filed with letter of 8 September 2011;
  - drawings: Figures 1 to 6 as published.

IV. Claim 1 reads as follows:

"An introducer needle assembly for accessing a patient's vein comprising:  
a translucent catheter (20) having a central bore (120), a distal end and a proximal end; a needle (40) disposed in the central bore of the catheter, the needle having a tip and a notch (42) disposed near the tip, wherein the needle tip extends in an insertion position out beyond the distal end of the catheter (20) and the notch (42) is disposed within the catheter;  
an annular space (60) defined between the needle (40) and the catheter (20) such that blood flowing through the notch passes into the annular space (60) to provide visual confirmation to a caregiver that the needle tip has accessed the vein;  
a translucent extension tube (50) having an interior chamber (54) with a cross section, which chamber is in fluid communication with the annular space (60),  
Characterized in that  
the size of the notch (42), the annular space (60) and the internal diameter of the extension tube (50) are selected to cause blood to fill the extension tube at a flow rate of at least 25.4 mm (1 inch) per minute when the blood is at 45 mmHg and has a viscosity of about 1.8 times that of water at 37°C (98.6 degrees F)."

V. The appellant argued essentially that the amendments made were supported by the original disclosure and that the claimed subject-matter involved an inventive step with respect to the prior art documents.

## Reasons for the Decision

1. The appeal is admissible.

2. Amendments - Article 123(2) EPC

Claim 1 is based on the original claim 18 and on the description, page 13, lines 18 to 23 of the application as filed. Claim 2 is based on original claims 21 and 22. Claim 3 is based on page 5, line 10, to page 6, line 2 of the application as filed.

The description has been adapted to the newly filed claims and contains an evaluation of the relevant state of the art. All units have been converted into the metric system, in accordance with Rule 49(10) EPC.

Accordingly, the provisions of Article 123(2) EPC are complied with.

3. Inventive step - Article 56 EPC

Using the words of claim 1 at issue, D1 discloses (see Figure 1 and text referred to) an introducer needle assembly for accessing a patient's vein comprising a translucent catheter 20 (see column 5, line 13) having a central bore; a distal end and a proximal end; a needle 40 disposed in the central bore of the catheter, the needle having a tip and a notch 42 disposed near the tip, wherein the needle tip extends in an insertion position out beyond the distal end of the catheter 20 and the notch 42 is disposed within the catheter (see Figure 1 and column 5, lines 14 to 15); an annular space defined between the needle 40 and the catheter 20

such that blood flowing through the notch 42 passes into the annular space to provide visual confirmation to a caregiver that the needle tip has accessed the vein (see column 5, lines 6 to 13); a translucent extension tube 50 having an interior chamber with a cross section, which chamber is in fluid communication with the annular space.

The subject-matter of claim 1 is distinguished therefrom by the features forming the characterizing portion of the claim, i.e. in that the size of the notch, the annular space and the internal diameter of the extension tube are selected to cause blood to fill the extension tube at a flow rate of at least 25.4 mm (1 inch) per minute when the blood is at 45 mmHg and has a viscosity of about 1.8 times that of water at 37°C (98.6 degrees F).

The objective technical problem underlying the solution given by the above distinguishing features is to provide an introducer needle assembly which permits a distinct confirmation flashback of the blood at a controlled rate when the needle assembly is located within the patient (see page 3, lines 3 to 6). More specifically, as the blood continues to flow, it passes through the extension tube used as a visual flow front rate (page 4, lines 7 to 10 and 13 to 14), and this continuous, active confirmation flashback occurs for a relatively long period of time, irrespective of the manipulation of the needle in the catheter, i.e. whether the needle is in place or not (page 13, lines 3 to 7 and 15 to 18).

The solution to this problem is given by the characterizing features of claim 1, in particular by the functional feature according to which the blood has to fill the extension tube at a flow rate of at least 25.4 mm (1 inch) per minute, in order that the flashback becomes visible during a sufficient time period (up to 4 minutes) (see page 4, lines 20 to 22; page 7, lines 5 to 6; page 14, lines 1 to 4).

This minimum flow rate is obtained by appropriately selecting the geometry and size of the various elements of the needle assembly, i.e. notch, annular space, internal diameter of the extension tube, and having regard to the physical characteristics of the fluid (blood), in order to throttle the flow of blood and thereby control its flow rate (see page 4, lines 22 to page 5, line 6; page 6, lines 9 to 13; page 13, lines 18 to 20; page 17, lines 13 to 17).

D1 discloses an extension tube 50 mounted within a support 25 having a window 27 for observing the flow of blood when it passes from the annular space through the extension tube. However, D1 does not disclose the concept upon which the invention is based, of a controlled flow rate sufficient to be visible for a long period of time, nor it contains any hints pointing to the solution as claimed of selecting the dimension of the elements of the needle assembly in order to provide a throttle operating at the minimum flow rate required.

Documents D2 and D3 cannot lead to the claimed invention either, since there is no disclosure at all

of an extension tube allowing a control of the flow rate and a confirmation flashback.

Accordingly, the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC.

## **Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the department of the first instance with the order to grant a patent based on the following documents:
  - description: pages 1, 1a, 2 to 17 as filed with letter of 13 September 2011;
  - claims: 1 to 3 as filed with letter of 8 September 2011;
  - drawings: Figures 1 to 6 as published.

The Registrar:

The Chairman:

D. Hampe

M. Noël