

SUPPLEMENTARY PARTIAL EUROPEAN SEARCH REPORT

Application Number

under Rule 46, paragraph 1 of the European Patent $\;$ EP $\;03\;$ $71\;$ 0880 Convention

| | DOCUMENTS CONSIDE | ERED TO BE RELEVANT | 1 | |
|---|---|--|---|---|
| Category | Citation of document with in of relevant passa | | Relevant to claim | CLASSIFICATION OF THE APPLICATION (IPC) |
| Y A | WO 02/00101 A (SARN 3 January 2002 (200 | | 1-19, 34-44 45 | INV. A61M31/00 |
| 7 | * page 4, line 3 - * page 5, line 22 - * page 11, line 12 | | 45 | |
| (| WO 01/72220 A (USF SEPARATIONS [US]) 4 October 2001 (200 * page 5, line 9 - * page 7, line 17 - | 1-10-04) page 6, line 31 * | 1-19, 34-44 | |
| A | 1 September 1998 (19 * column 3, line 32 | RT WILSON H [US] ET AL) 998-09-01) - line 43 * - column 5, line 16 * | 1,45 | |
| A | WO 00/74763 A (GEOR 14 December 2000 (2) * abstract * | GIA TECH RES INST [US]) 000-12-14) | 45 | TECHNICAL FIELDS SEARCHED (IPC) |
| The Searc the require namely: | | European patent application does not comply is to several inventions or groups of inventions | | |
| | ent partial European search report has oblication which relate to the invention find the place of search | been drawn up for those parts of the Europea rst mentioned in the claims. Date of completion of the search | un | Examiner |
| | Berlin | 12 October 2007 | Tra | chterna, Morten |
| X : parti Y : parti docu A : tech O : non | ATEGORY OF CITED DOCUMENTS icularly relevant if taken alone cularly relevant if combined with anoth iment of the same category nological background written disclosure mediate document | L : document cited fo | ument, but publice the application or other reasons | shed on, or |



INCOMPLETE SEARCH SHEET C

Application Number EP 03 71 0880

Claim(s) not searched: 47.48

Reason for the limitation of the search (non-patentable invention(s)):

Article 52 (4) EPC - Method for treatment of the human or animal body by surgery

Article 52 (4) EPC - Method for treatment of the human or animal body by therapy

Claims 47, 48 relate to a method for automated analyte monitoring or automated pharmaceutical agent delivery respectively. Both claims comprise the step of extending a microneedle and thereby piercing the skin, it follows that this amounts to a method of surgery. Furthermore, the method of claim 48 is therapeutical as it comprises the step of delivering the pharmaceutical agent.



LACK OF UNITY OF INVENTION SHEET B

Application Number

EP 03 71 0880

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-19, 34-44 (part), 45, 46

An analyte monitoring device according to claims 1 and 45.

2. claims: 20-33, 34-44 (part)

A pharmaceutical agent delivery device operable to deliver a pharmaceutical agent to a subject according to claim 20.

The prior art has been identified as document D1: WO 02/00101 A (SARNOFF CORP [US]) 3 January 2002

The application lacks unity within the meaning of Article 82 EPC for the following reasons:

Invention 1 (claims 1-19, 34-44 (part), 45, 46):

The document D1 discloses (the references in parentheses applying to this document): an analyte monitoring device (see title) operable to draw a fluid sample from a subject, the device comprising: a first plurality of microneedles (p. 4/1. 3-5, (53), a plurality of monitoring microchannels (p. 5/1. 25-27), and wherein each monitoring microchannel is associated with a reagent (p. 5/1. 27-28), at least one actuator (p. 5/1. 22-24) operable to extend each microneedle to draw the fluid sample from the subject, and a controller (p. 4/1. 14-16) operable to initiate analyte testing of the fluid sample. Therefore, the following common feature of claims 1, 45 can be seen to make a contribution over this prior art (special technical features, Rule 30 EPC):

- each of the first plurality of microneedles is at least intermittently in fluid communication with a corresponding monitoring microchannel, From this special technical feature, the common objective problem to be solved can be seen in providing an additional microchannel thereby increasing the flexibility for spatially separated withdrawal and analysis of a fluid.

Invention 2 (claims 20-33, 34-44 (part)):

From the comparison of the subject matter of claim 20 with the apparatus in disclosed in D1, the following features can be seen to make a contribution over this prior art:

- pharmaceutical agent delivery device operable to deliver a pharmaceutical agent to a subject;
- wherein each pharmaceutical agent delivery microchannel is at least partially filled with a pharmaceutical agent

 From this special technical feature, the objective problem to be solved.

From this special technical feature, the objective problem to be solved can be seen in delivering a pharmaceutical agent.

The inventions 1, 2 therefore do not specify special technical features in the meaning of Rule 30(1) EPC, which are in common to the inventions, so that no technical relationship exists between the different subject-matters. Accordingly, the claims contain two groups of separate



LACK OF UNITY OF INVENTION SHEET B

Application Number

EP 03 71 0880 The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely: inventions which are not so linked as to form a single general inventive concept.

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

12-10-2007

| | atent document d in search report | | Publication date | | Patent family member(s) | | Publication date |
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| WO | 0200101 | A | 03-01-2002 | EP JP US US | 1296587 2004500948 2003135333 2002087056 | T A1 | 02-04-20 15-01-20 17-07-20 04-07-20 |
| WO | 0172220 | A | 04-10-2001 | AT AU CA CC DE EP ES HCP TUS US | 314001 4946701 2005202586 2403759 1431884 20023521 60116281 1276412 1639938 2256225 1054310 2003527917 PA02009563 358181 592665 2002177788 6612111 | A A1 A3 T2 T3 A1 T A A1 B A1 | 15-01-200 08-10-200 07-07-200 04-10-200 17-09-200 17-08-200 22-05-200 22-01-200 29-03-200 16-07-200 04-08-200 24-09-200 14-05-200 09-08-200 28-11-200 02-09-200 |
| US | 5801057 | А | 01-09-1998 | NONE | | | |
| WO | 0074763 | А | 14-12-2000 | AU CA EP | 5461300 2376128 1187653 | A1 | 28-12-20 14-12-20 20-03-20 |



| 专利名称(译) | 自主,动态分析物监测器或药物输 | 送设备 | |
|----------------|--|--|---|
| 公开(公告)号 | EP1480710A4 | 公开(公告)日 | 2008-06-25 |
| 申请号 | EP2003710880 | 申请日 | 2003-02-07 |
| [标]申请(专利权)人(译) | 珀丽医疗 | | |
| 申请(专利权)人(译) | 珀丽MEDICAL, INC. | | |
| 当前申请(专利权)人(译) | 珀丽MEDICAL , INC. | | |
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| 发明人 | ACETI, JOHN, GREGORY MCBRIDE, STERLING, EDUARD MORONEY, RICHARD, MORGAN GREGORY, CHRISTOPHER, CAR ZANZUCCHI, PETER, JOHN | | |
| IPC分类号 | A61B5/15 A61B5/00 A61B5/145 A | 61B5/155 A61B5/157 A61M5/20 | 0 A61M5/32 A61M37/00 G01N33/49 |
| CPC分类号 | | 1B5/150389 A61B5/150503 A61 09 A61B5/15119 A61B5/15123 1B5/681 A61B5/6833 A61B2560 | B5/150526 A61B5/150755 A61B5 A61B5/15146 A61B5/15153 A61B5 0/0412 A61B2560/0443 A61M37/0015 |
| 代理机构(译) | 法思博事务所 | | |
| 优先权 | 10/131268 2002-04-23 US 60/355195 2002-02-08 US | | |
| 其他公开文献 | EP1480710A2 EP1480710B1 | | |
| 外部链接 | Espacenet | | |

摘要(译)

分析物监测装置,可操作以从受试者抽取流体样品。该装置包括第一多个微针,多个监测微通道,其中第一多个微针中的每一个至少间歇地与相应的监测微通道流体连通,并且其中每个监测微通道与试剂相关联,至少一个致动器可操作以延伸每个微针以从受试者抽取流体样品,并且控制器可操作以启动流体样品的分析物测试。

| | DOCUMENTS CONSID | ERED TO BE RELEVANT | | | |
|-----------|---|---|----------------------|--|--|
| Category | Oitation of document with it of relevant pass | ndication, where appropriate, | Relevant to claim | CLASSIFICATION OF THE APPLICATION (IPC) | |
| Y A | WO 02/00101 A (SAR) 3 January 2002 (200 * page 4, line 3 - | | 1-19, 34-44 45 | INV. A61M31/00 | |
| | * page 5, line 22 - * page 11, line 12 | - page 6, line 2 * - page 16, line 13 * | | | |
| Y | WO 01/72220 A (USF SEPARATIONS [US]) 4 October 2001 (200 * page 5, line 9 - * page 7, line 17 - | 01-10-04) | 1-19. 34-44 | | |
| А | 1 September 1998 (1 | ART WILSON H [US] ET AL) 1998-09-01) 2 - line 43 * 5 - column 5, line 16 * | 1,45 | | |
| A | WO 00/74763 A (GEO) 14 December 2000 (2 * abstract * | RGIA TECH RES INST [US]) 2000-12-14) | 45 | TECHNICAL FIELDS | |
| | " abstract " | | | SEARCHED (IPC) | |
| | | | | A61B | |
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| LACK | OF UNITY OF INVENT | TION | | 1 | |
| The Sean | ch Division considers that the present | European patent application does not comply | with | 1 | |
| namely: | ements of unity of invention and relate | es to several inventions or groups of inventions | | | |
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| | sheet B | | | | |
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| The prese | ent partial European search report has | s been drawn up for those parts of the Europe | *** | | |
| patent ap | plication which relate to the invention Place of search | first mentioned in the claims. Date of completion of the search | | Examiner | |
| Berlin | | 12 October 2007 | Tre | achterna, Morten | |
| C. | ATEGORY OF CITED DOCUMENTS | T : theory or principle | underlying the | invention | |
| ⊗ : part | icularly relevant if taken alone icularly relevant if combined with anot | E : earlier patent dos after the filling dat ther D : document cited is | | snea on, or | |
| - : pare | | L : document cited for | or other reasons | | |
| A · tent | mological background | | | | |