



- (51) International Patent Classification:
G01N 21/00 (2006.01)
- (21) International Application Number:
PCT/US2013/074073
- (22) International Filing Date:
10 December 2013 (10.12.2013)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
61/736,389 12 December 2012 (12.12.2012) US
14/100,397 9 December 2013 (09.12.2013) US
- (71) Applicant: **BIO-RAD LABORATORIES, INC.**
[US/US]; 1000 Alfred Nobel Dr., Hercules, California
94547-1803 (US).
- (74) Agents: **BOYD, David W.** et al.; Two Embarcadero Cen-
ter, Eighth Floor, San Francisco, CA 94111 (US).
- (81) Designated States (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR,
KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM,
TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM,
ZW.
- (84) Designated States (*unless otherwise indicated, for every
kind of regional protection available*): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
KM, ML, MR, NE, SN, TD, TG).
- (72) Inventors: **DARMSTADT, Adam**; 1000 Alfred Nobel
Dr., Hercules, California 94547-1803 (US). **WAITE, Mi-
chael**; 1000 Alfred Nobel Dr., Hercules, California 94547-
1803 (US). **FORNI, Theresa**; 1000 Alfred Nobel Dr., Her-
cules, California 94547-1803 (US).

[Continued on next page]

(54) Title: CALIBRATION PROCESS AND SYSTEM

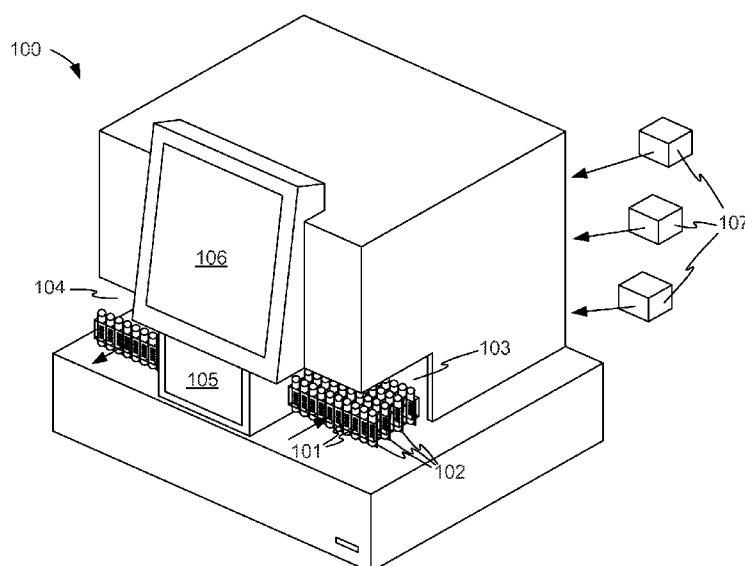


FIG. 1

(57) Abstract: An improved calibration process for a medical testing machine. The machine automatically recognizes that a package of calibration material has been inserted into it, and performs a calibration sequence to ascertain a calibration parameter to be used in performing future tests with the medical testing machine. The calibration package may include machine-readable indicators that the package is to be used for calibration, and of a calibration setpoint of a calibration material in the package. A calibration material may be stored in a lyophilized state in the package, and the medical testing machine may automatically reconstitute the lyophilized material.

**Declarations under Rule 4.17:**

- *as to the identity of the inventor (Rule 4.17(i))*
- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:

7 August 2014

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 13/74073

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - G01N 21/00 (2014.01)

USPC - 73/1.03

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - G01N 21/00 (2014.01)

USPC - 73/1.03

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC 73/1.02, 1.03; 436/11 (Keyword limited, terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase, Google Patents, Google Scholar

Search terms used: calibration, medical, automatic, storing, memory, later test, electronic, ram, flash, reading, setpoint, lyophilized material, washing, aspirated, chromatography, hemoglobin, blood, HPLC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y --- A	US 3,874,850 A (SORENSEN et al.) 01 April 1975 (01.04.1975), col 1, ln 64-col 2, ln 5; col 4, ln 10-20; col 5, ln 25-30; col 6, ln 19-40; col 7, ln 28-65; col 8, ln 15-60; col 9, ln 5-27; col 10, ln 2-15; col 12, ln 19-33; col 13, ln 1-10; col 14, ln 5-27; col 18, ln 29-50	1, 2, 6-17 ----- 3-5
Y --- A	US 2003/0097229 A1 (HERRMANN et al.) 22 May 2003 (22.05.2003), abstract, para [0019], [0025]	1, 2, 6-17 ----- 3-5
Y	US 2010/0081579 A1 (BUSHWAY et al.) 01 April 2010 (01.04.2010), para [0205], [0206], abstract	2
Y --- A	US 2008/0102525 A1 (RANNIKKO et al.) 01 May 2008 (01.05.2008) para [0005], [0008]-[0010], [0039], [0065]	6, 7, 14, 15 ----- 3-5
Y	US 2009/0127454 A1 (RITCHIE et al.) 21 May 2009 (21.05.2009), para [0215]	8, 9, 11
Y	US 2012/0046203 A1 (WALSH et al.) 23 February 2012 (23.02.2012), para [0542], [0606]	13
Y	US 2012/0245447 A1 (KARAN et al.) 27 September 2012 (27.09.2012), para [0002], [0171]	17
Y	US 2011/0184268 A1 (TAUB) 28 July 2011 (28.07.2011), para [0083]-[0086]	11
A	US 5,229,074 A (HEATH et al.) 20 July 1993 (20.07.1993), abstract; col 2, ln 44-52	3-5
A	US 2012/0234393 A1 (LOWRY) 20 September 2012 (20.09.2012), para [0007]	3-5



Further documents are listed in the continuation of Box C.



* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

17 May 2014 (17.05.2014)

Date of mailing of the international search report

06 JUN 2014

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 13/74073

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: claims 1-17: drawn to an a method and a medical testing machine which performs the steps of automatically detecting/recognizing that a package of calibration material has been inserted into the medical testing machine; performing a calibration sequence using the calibration material to ascertain a calibration parameter for the medical testing machine; and storing the calibration parameter in electronic storage for use in later tests performed by the medical testing machine.

Group II: claim 18-26: drawn to a package of calibration material for calibrating a medical testing machine, which includes two materials at least one of which is a calibration material; and a respective container for each of the materials, the containers maintaining separation between the materials before use of the calibration package, wherein the containers are connected.

-- see extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-17

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 13/74073

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2011/0303671 A1 (MALTEZOS et al.) 15 December 2011 (15.12.2011), para [0101]-[0108]	3-5
A	US 2012/0178091 A1 (GLEZER et al.) 12 July 2012 (12.07.2012), entire document	1-17
A	US 3,885,414 A (REVILLE) 27 May 1975 (27.05.1975), entire document	1-17
A	US 6,684,680 B2 (PIERSKALLA et al.) 03 February 2004 (03.02.2004), entire document	1-17

Continuation of Box No. III -- Observations where unity of invention is lacking

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Special Technical Features:

Group I requires detecting that a package of calibration material has been inserting, performing a calibration sequence and storing the calibration parameter in electronic storage, not found in the other groups.

Group II requires a package comprising two materials one of which is a calibration material, two containers which are connected but maintain separation between the materials before use of the calibration package, not found in the other groups.

Common Technical Features:

The only technical features shared by Groups I and II that would otherwise unify the groups are a medical testing machine and a package of calibration material.

However, these shared technical features do not represent a contribution over prior art, because the shared technical features are disclosed by US 6,684,680 B2 to Pierskalla et al. (hereinafter "Pierskalla") 03 February 2004 (03.02.2004), which discloses a medical testing machine (FIG 1, part 30, col 3, ln 45-48, col 7, ln 8-16) and a package of calibration material (FIG 1, parts 10 & 12, col 7, ln 30 to col 8, ln 37).

Therefore, Groups I and II lack unity under PCT Rule 13.