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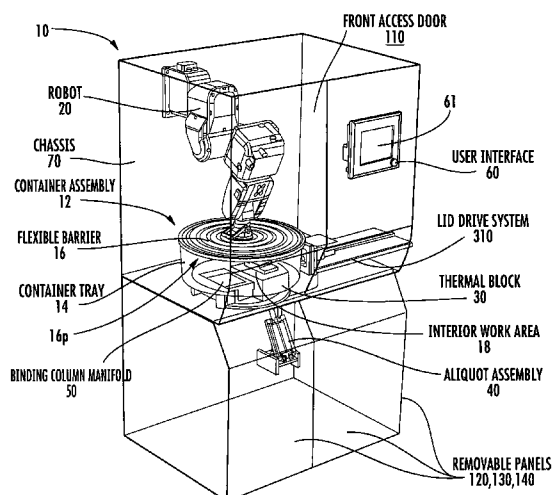
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[Continued on next page]

(54) **Title:** SYSTEMS AND METHODS FOR PROCESSING SAMPLES IN A CLOSED CONTAINER, AND RELATED DEVICES



(57) **Abstract:** A system and method for automated processing of nucleic acids and other samples includes a disposable container comprising a tray and a flexible barrier. The barrier is configured to seal with a top edge of the tray, providing a closed, aseptic work area within the sealed tray. A pipette head and/or other sample manipulation device can be attached to the inside of the barrier, and the barrier can include an interface for a robotic arm or other device. When the barrier is sealed over the tray, the barrier separates the contents of the tray from the robot or other manipulation device. The barrier can be flexible, and allow the robotic arm to move the pipette head throughout the work area of the tray. All samples, reagents, pipette tips and other tools or devices for processing nucleic acid samples may remain within the closed compartment provided by the container during processing.

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RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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PCT/US 07/01 170

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - B25J 3/00; F16K 31/00 (2008.04)

USPC - 414/7; 251/335.2

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): B25J 3/00; F16K 31/00 (2008 04)

USPC. 414/7; 251/335.2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8): B25J 3/00; F16K 31/00 (2008 04)

USPC: 414/7; 251/335.2; 414/1 ; 414/8; 414/2; 414/625; 414/733, 414/277; 414/331 01; 414/217; 901/15; 901/30, 294/1 17, 454/187

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

USPTO WEST (USPT, PGPUB, EPAB, JPAB); barrier, seal\$, pipet\$, robots, arm, 'nucleic acid', sample, resilient, container, cover, robotic, handle, manifold, adsor\$, column, bit\$, move, mov\$, reagent, rack, station, well, seal\$, 'thermal block', base, flexible, wall, aperture, seal, sidewall, lid, moving

Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,232,464 B1 (LANGE) 15 May 2001 (15.05 2001); Abstract], col 1, ln 51 to col 2, ln 1-15; col 3, ln 48-51 and ln 56 to col 4, ln 6; col 5, ln 7-17 and 33-43; col 6, ln 51-55; col 7, ln 49-50, Fig 1	1-4, 8, 21, 27, 28, 31 ----- 5-7, 9-20, 22-26, 29, 30, 32, 33, 43-52, 58-61, 67
Y	US 2004/0029260 A1 (HANSEN, et al.) 12 Feb 2004 (12.02 2004), para [0064]	9, 47, 58-61
Y	US 5,851,492 A (BLATTNER) 22 Dec 1998 (22 12.1998); col 4, ln 42-65	10-12
Y	US 2003/0226796 A1 (BAYER, et al) 11 Dec 2003 (11 12 2003); para [0006], [0094], [0095], [0097], [0103], [0105]	5-7, 13-15,, 22, 29, 30, 58-61
Y	US 5,356,034 A (SCHLUMBERGER) 18 Oct 1994 (18.10 1994), col 3, ln 22-35	16
Y	US 5,693,233 A (SCHEMBRI) 02 Dec 1997 (02 12 1997), col 7, ln 25-29; col 8, ln 3-1 1	17
Y	US 2002/0004994 A1 (RUDD) 17 Jan 2002 (17 01.2002); para [0041]	18, 32, 33, 60, 67
Y	US 5,287,857 A (MANN) 22 Feb 1994 (22 02 1994); col 4, ln 1-3; col 6, ln 41-43	19, 20, 60
Y	US 2005/0042138 A1 (UEDA, et al.) 24 Feb 2005 (24.02 2005); para [0005], [0097], [0099], [0107], [0160], [0161]	11, 12, 23, 26, 46, 48-52, 57-61
Y	WO 2004/1 13052 A2 (BARTOLI, et al) 12 Dec 2004 (12.12.2004); Abstract	43-48
Y	US 2005/0208539 A1 (VANN, et al) 22 Sep 2005 (22 09.2005); para [0073], [01 11]	57

☒ Further documents are listed in the continuation of Box C.

D

* Special categories of cited documents	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search 10 June 2008 (10 06.2008)	Date of mailing of the international search report 24 JUN 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attπ-ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W Young PCT Hlpdesk 571-272-4300 PCT OSP 571-272-7774

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
Y	US 2003/021 1539 A1 (FRANK, et al) 13 Nov 2003 (13 11 2003), Abstract, para [0010], [0035], Fig 6	5-7 , 30 , 61
Y	US 2004/0241713 A1 (MIRZABEKOV, et al) 02 Dec 2004 (02 12 2004), para [0120]	20 , 33
Y	US 5,263,299 A (GALBIERZ, et al) 23 Nov 1993 (23 11 1993), Claim 1	24-26
Y	US 4,815,256 A (BROWN, et al) 28 Mar 1989 (28 03 1989), col 2, ln 64-68, col 13, ln 7-11, col 13, ln 14-18	24-26
Y	US 5,939,582 A (DASSEL, et al) 17 Aug 1999 (17 08 1999), col 21, ln 13-29	45
Y	US 5,556,365 A (DRUMMOND, et al) 17 Sep 1996 (17 09 1996), col 6, ln 53-64	51
Y	US 5,934,312 A (BELLENGER, et al) 10 Aug 1999 (10 08 1999), Abstract	52
Y	US 4,895,280 A (TOURIGNY) 23 Jan 1990 (23 01 1990), col 4, ln 55-68 to col 5, ln 1-6	11 , 12 , 46
Y	US 2005/026641 1 A1 (HOFSTADLER, et al) 01 Dec 2005 (01 12 2005), para [0008], [0081], [0128]	47 , 48 , 58-61
Y	US 2003/0152494 A1 (MORITZ, et al) 14 Aug 2003 (14 08 2003), para[0005]	59

International application No
PCT/US 07/01 170

PCT/US 07/01 170

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 **D** 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)

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

"*****
SEE SUPPLEMENTAL SHEET TO CONTINUE*****"*****"*****"*****"*****"*****

- 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 Group I claims 1-33, 43-52, 57-61, and 67.

<input type="checkbox"/>	The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee
<input checked="" type="checkbox"/>	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
<input type="checkbox"/>	No protest accompanied the payment of additional search fees

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No

PCT/US 07/01170

S U PPLEMENTAL SHEET

BOX III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

Group I claims 1-33, 43-52, 57-61, and 67, directed to an apparatus, comprising

- a container having an interior region configured to hold a plurality of items to be manipulated,
- a flexible barrier configured to sealably attach to the container, and
- a tool integrated with or within the flexible barrier (claims 1-26), a method, comprising
- providing a single-use disposable container,
- loading at least one reagent and at least one sample into the container,
- sealing the container with a flexible barrier,
- attaching the pipette head adapter of the robotic arm to the pipette head, and
- processing at least one sample at one or more of the processing stations (claims 27-33), a processing container (claims 43-48), a flexible barrier (claims 49-52), an elution tray (claim 57) a kit, comprising
- a single-use disposable container comprising a tray and a flexible barrier configured to sealably attach thereto,
- a single-use disposable reagent rack configured to reside in the container at a first workstation,
- a single-use disposable binding column manifold configured to reside in the container, and
- a single-use disposable pipette rack configured to reside in the container (claims 58-61)

Group II claims 34-35, directed to an apparatus, comprising

- a pump for pumping a working fluid,
- a diaphragm in communication with the pump through the working fluid

Group III claims 36-42, directed to an apparatus for measuring volume of a fluid

Group IV claims 53-56 and 62-66, directed to an automated pipette tip disengagement system (claims 53-55) and a system for processing liquids (claim 56), a method of releasing liquids from pipettes (claim 62), and a method of processing a sample (claims 63-66)

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

The common technical feature of the listed groups is a flexible barrier configured to sealably attach to a container and to a robotic arm. However, this is not an improvement over the prior art of US 5,474,303 A (COLES) (12 Dec 95) that teaches an aseptic chamber comprising two first flexible barriers. One of the first flexible barriers is coupled to the mold between the at least one first sterile surface and a respective molding machine to substantially prevent the passage of contaminants from the molding machine therethrough. The other first flexible barrier is coupled to the mold between the at least one second sterile surface and a respective molding machine to substantially prevent the passage of contaminants from the molding machine therethrough (para [0009]). COLES further teaches that the assembly device 24 may take the form of a robot including, for example, a base that extends upwardly from a mounting flange, a first robotic arm that is pivotally driven on the base, and a second robotic arm that is pivotally driven on top of the first robotic arm (para [0040]). Thus, the shared technical feature cannot function as a novel (special) technical feature to maintain unity of invention. Groups I - IV therefore lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.