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# (54) HUMIDIFIER WITH STRUCTURE TO PREVENT BACKFLOW OF LIQUID THROUGH THE HUMIDIFIER INLET

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claimer.

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#### Related U.S. Patent Documents

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(58) Field of Classification Search

### (56) References Cited

#### U.S. PATENT DOCUMENTS

485,127 A 10/1892 Lynch 933,301 A 9/1909 Hartman (Continued)

#### FOREIGN PATENT DOCUMENTS

AU 200065475 4/2001 DE 275612 1/1913 (Continued)

#### OTHER PUBLICATIONS

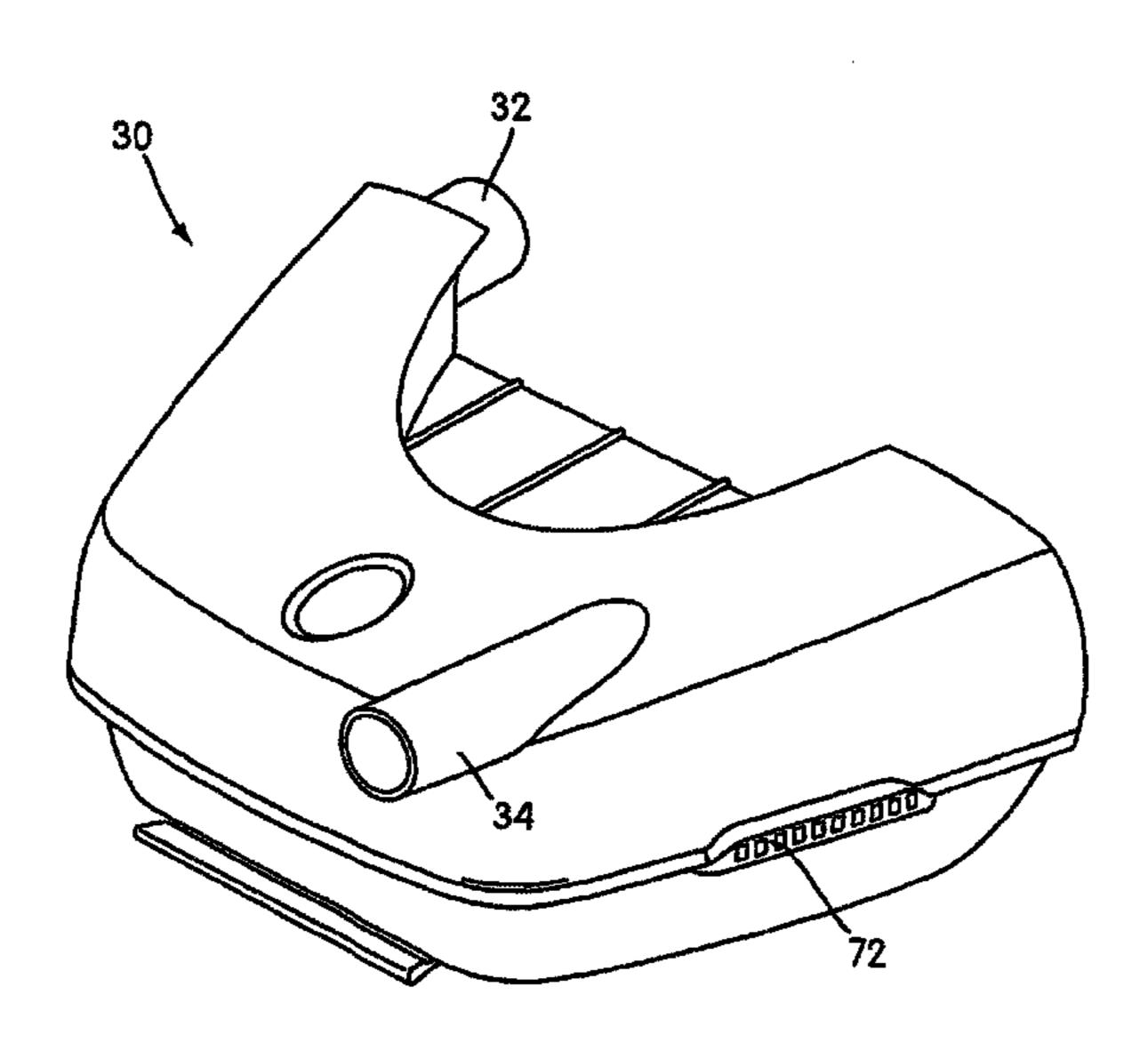
Apex Medical Corporation, Petition Exhibit 1002 in IPR2014-00551, "ResMed's First Amended Complaint for Patent Infringement—Jury Trial Demanded", Case No. SACV-13-00498 CJC (RNBx), USDC, Central District of California, Southern Division, 18 pages. (Continued)

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## (57) ABSTRACT

A humidifier includes a base configured to retain a body of liquid therein, a top cover, and a seal disposed between the top cover and the base. At least a portion of the base is constructed of a heat conducting material. The top cover defines both an inlet and an outlet communicated with an interior of the base. The inlet is configured to receive pressurized breathable gas and the outlet is configured to deliver the pressurized breathable gas with added humidity.

## 26 Claims, 20 Drawing Sheets



## Related U.S. Application Data

No. 15/706,811, filed on Sep. 18, 2017, which is a continuation of application No. 15/182,919, filed on Jun. 15, 2016, now Pat. No. Re. 46,571, which is an application for the reissue of Pat. No. 7,614,398, said application No. 15/182,919 is a continuation of application No. 13/944,960, filed on Aug. 23, 2013, now Pat. No. Re. 46,079, said application No. 13/944,960 is a continuation of application No. 13/100,783, filed on May 4, 2011, now Pat. No. Re. 44,453, said application No. 13/100,783 is a continuation of application No. 10/467,382, filed as application No. PCT/AU02/00155 on Feb. 14, 2002, now Pat. No. 6,935, 337.

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## (56) References Cited

### U.S. PATENT DOCUMENTS

1.005.022		2/1014	TT 7'1
1,085,833 A			Wilson
1,813,959 A			Romanoff
1,974,843 A	*		Blashfield 261/123
RE19,826 E			Aisenstein
2,220,669 A			Allen et al.
2,780,708 A			Glynn et al.
2,945,619 A		7/1960	McLure et al.
3,171,353 A		3/1965	McMahan
3,316,910 A		5/1967	Davis et al.
3,584,401 A		6/1971	Cryer et al.
3,612,710 A		10/1971	
3,620,638 A			Kaye et al.
3,638,926 A			Melville et al.
3,659,604 A			Melville et al.
3,690,317 A		_	Millman
3,806,102 A			Valenta et al
3,864,440 A			Giocoechea
3,954,920 A		5/1976	
4,037,994 A		7/1977	
4,051,205 A			Grant 261/70
, ,		5/1979	_
4,152,379 A			
4,171,190 A		10/1979	
4,222,971 A			Eilert 261/92
4,229,142 A			Le Dall et al.
4,237,080 A			
			Cronenberg 96/311
4,336,798 A		6/1982	
4,383,800 A			Becker et al.
4,523,896 A			Lhenry et al.
4,532,088 A	*	7/1985	Miller 261/142
4,576,616 A		3/1986	Mottram et al.
4,588,425 A		5/1986	Usry et al.
4,621,632 A		11/1986	Bartels et al.
4,657,713 A		4/1987	Miller
4,686,354 A		8/1987	Makin
4,753,758 A		6/1988	Miller
4,799,287 A		1/1989	Belanger et al.
4,802,819 A			Bevington et al.
4,807,616 A			Adahan
4,838,258 A			Dryden et al.
4,906,417 A			Gentry
4,913,140 A			Orec et al.
4,913,140 A 4,921,642 A			LaTorraca
, ,			
4,926,856 A			Cambio, Jr. et al.
4,941,469 A			Adahan
4,946,348 A		8/1990	± ±
4,953,546 A			Blackmer et al 128/203.16
4,973,234 A			Swenson
/[[[]]]] /[[]] /[[]] /[[]]		7 / 1 L IL I I	1 0110337037

4,993,411 A 2/1991 Callaway

5,097,424 A	3/1992	Ginevri et al.
5,127,800 A		Hyll et al.
5,199,009 A	3/1993	•
5,231,979 A *	8/1993	Rose et al 128/204.14
5,237,987 A		Anderson et al.
5,271,391 A	12/1993	
5,329,939 A	7/1994	
5,391,063 A		Hantle et al.
5,443,061 A		Champain et al.
5,445,143 A	8/1995	
5,474,112 A 5,482,031 A	1/1995	Lambert
5,533,506 A	7/1996	
5,537,997 A		Mechlenburg et al.
5,558,084 A *		Daniell et al 128/203.17
5,564,415 A		Dobson et al.
5,577,496 A	11/1996	Blackwood et al.
5,588,423 A	12/1996	Smith
5,598,837 A	2/1997	Sirianne et al.
5,651,775 A	7/1997	Walker et al.
5,655,522 A		Mechlenburg et al.
5,673,687 A	10/1997	Dobson et al.
5,794,219 A	8/1998	Brown
5,822,715 A		Worthington et al.
5,828,943 A	10/1998	Brown
5,832,448 A 5,848,592 A	11/1998 12/1998	Brown Sibley
5,870,283 A	2/1999	
5,879,163 A		Brown et al.
5,887,133 A		Brown et al.
5,888,053 A	3/1999	
5,897,493 A	4/1999	•
5,899,855 A	5/1999	Brown
5,913,310 A	6/1999	Brown
5,916,493 A	6/1999	
5,918,603 A	7/1999	
5,933,136 A		Brown
5,940,801 A	8/1999	
5,943,473 A	8/1999	Levine
5,951,300 A 5,956,501 A	9/1999 9/1999	Brown Brown
5,960,403 A	9/1999	
5,985,559 A	11/1999	Brown
5,997,476 A	12/1999	
D419,658 S	1/2000	
6,012,455 A	1/2000	Goldstein
6,023,686 A	2/2000	Brown
6,032,119 A	2/2000	Brown et al.
6,050,260 A		Daniell et al.
6,101,478 A	8/2000	
6,109,865 A		Ishikawa
6,119,693 A 6,129,524 A	9/2000	Kwok et al. Woollenweber et al.
6,129,324 A 6,131,571 A	10/2000	Lampotang et al.
6,135,432 A	10/2000	1 0
6,144,837 A	11/2000	Quy
6,152,132 A	11/2000	Psaros
6,158,978 A	12/2000	Norbury, Jr.
6,161,095 A	12/2000	
6,185,095 B1	2/2001	Helot et al.
6,189,870 B1	2/2001	Withall
6,202,991 B1	3/2001	Coniglio et al.
6,210,116 B1		3
6,213,119 B1	4/2001	Brydon et al.
6,216,691 B1		Kenyon et al. Rivard
6,257,171 B1 6,279,574 B1		Richardson et al.
6,308,706 B1		Lammers et al.
6,332,462 B1	12/2001	
6,338,473 B1		Hebblewhite et al.
6,340,288 B1		Hulkkonen et al.
6,349,724 B1		Burton et al.
D454,393 S		Lynch et al.
6,374,826 B1		Gunaratnam et al.
6,397,841 B1	6/2002	Kenyon et al.
6,398,197 B1		Dickinson
6,435,180 B1*	8/2002	Hewson et al 128/203.18
6,471,493 B2		Choi et al.
D467,335 S	12/2002	Lithgow et al.

## US RE48,095 E Page 3

(56)	Referei	nces Cited	DE	10016005	12/2001	
	IIS PATENT	DOCUMENTS	DE DE	102005007773 19515739	9/2005 11/2007	
	U.S. IAILIVI	DOCOMENTS	EP	0201985	11/1986	
D468,011	S 12/2002	Lithgow et al.	EP	0274996	7/1988	
D468,017		McCombs	$\mathbf{EP}$	0376584	7/1990	
6,514,053	B2 2/2003	Takura et al.	EP	0 589 429 H		
6,532,961		Kwok et al.	EP EP	0589429 0845277	3/1994 6/1998	
6,543,449		Woodring et al.	EP	0893750	1/1999	
6,554,260 6,591,834		Lipscombe et al 261/142 Colla et al.	EP	0903160	3/1999	
6,604,390		Nooner	EP	1023912	8/2000	
6,615,444		McGill et al.	EP	1 055 431 A		
6,622,724		Truitt et al.	EP	1055431	11/2000	
6,672,300		Grant	EP	1087322	3/2001	
D487,311		Lithgow et al.	EP EP	1318307 1374938	6/2003 1/2004	
6,718,974 D493,520		Moberg 128/204.14 Bertinetti et al.	FR	2323436	4/1977	
D493,320 D493,884		Virr et al.	FR	2714985	7/1995	
6,772,999		Lipscombe et al.	GB	1556492	11/1979	
6,775,882		Murphy et al.	GB	2177006	1/1987	
D498,527		Virr et al.	JР	7-145795	6/1995	
6,827,340		Austin et al.	JP JP	11-398 2000-337670	1/1999 12/2000	
6,837,260			JР	2000-357070	6/2001	
6,874,771 6,896,478		Birdsell et al. Botros et al.	JР	2002-206498	7/2002	
6,910,483		Daly et al.	JP	2002-253672	9/2002	
6,918,389		Seakins et al.	JP	2002-306601	10/2002	
6,935,337	B2 * 8/2005	Virr et al 128/203.16	NZ	503495	3/2001	
7,096,864		Mayer et al.	WO WO	WO 93/05451 WO 95/15778	3/1993 6/1995	
7,111,624		Thudor et al.	WO	WO 93/13778 WO 97/32619	9/1997	
7,137,388		Virr et al 128/203.17 Bowen et al.	WO	WO 98/04311	2/1998	
7,223,309		DiMatteo et al.	WO	WO 98/31937	7/1998	
7,614,398		Virr et al.	WO	WO 98/33433	8/1998	
7,616,871	B2 11/2009	Kramer	WO	WO 98/57691	12/1998	
7,677,246		Kepler et al.	WO	WO 99/13932	3/1999 5/1000	
8,091,547		Thudor et al.	WO WO	WO 99/22794 WO 99/64747	5/1999 12/1999	
RE44,453 8,550,072		Virr et al. Thudor et al.	WO	WO 00/13751	3/2000	
2001/0017134			WO	WO 00/21602	4/2000	
2002/0020930		Austin et al.	WO	WO 00/27457	5/2000	
2002/0022973	A1 2/2002	Sun et al.	WO	WO 00/32261	6/2000	
2002/0056453		Klopp et al.	WO WO	WO 01/10489 WO 01/32069	2/2001 5/2001	
2002/0159897		Kegg et al.	WO	WO 01/32009 WO 01/73653	10/2001	
2003/0062045 2003/0084900		Woodring et al. Leclerc et al.	WO	WO 02/02169	1/2002	
2003/0004900		Satoh	WO	WO 02/066106	8/2002	
2003/0208465		Yurko et al.	WO	WO 02/066107	8/2002	
2003/0230308	A1 12/2003	Linden	WO	WO 2007/019628	2/2007	
2004/0035422		Truitt et al.	WO WO	WO 2009/059359 WO 2009/156921	5/2009 12/2009	
2004/0055597		Virr et al.	WO	WO 2009/130921 WO 2010/092496	8/2010	
2004/0060559 2005/0005937		Virr et al. Farrugia et al.	., 0	0 2010, 052 150	0,2010	
2005/0003337		Daly et al.		OTHED		NTC!
2005/0217673		Daly et al.		OTHER .	PUBLICATIO	NS
2006/0191531		Mayer et al.	Breas	Medical AB "iSleep®	20" Brochure I	Dec. 2007 2 pages
2006/0237005		Virr et al.		unication dated Jul. 1,	·	
2007/0036662 2007/0134085		Pesola et al. Daly et al.		(5 pages).	2010 III Ediope	an rippin. 100. 02 700
2009/0229606		Tang et al.		unication Pursuant to A	Article 94(3) EPC	(examination report)
2010/0229867		Bertinetti et al.		Jun. 12, 2015 in Europ	` ′	`
			pages)	-	P P P P P P P P P P P P P P P P P P P	1,0,00
FO	REIGN PATE	ENT DOCUMENTS		unication Pursuant to A	Article 94(3) EPC	(examination report)
				Jun. 5, 2015 in Europ	` /	` /
DE	3005094	8/1981	pages)	•		
DE	3623162	1/1987	<b>1</b> • /	unication Pursuant to	Article 94(3) EF	PC (European Exami-
DE	3823242	2/1990 2/1001		Report) dated Oct. 7,	` ′	` <u> </u>
DE DE	9014848 4138098	2/1991 5/1993		(4 pages).	, <b> </b>	1
DE	4244493	7/1993		unication Pursuant to	Article 94(3) EP	C dated Feb. 4. 2015
DE	3789221	8/1994		opean Application No.	` /	ŕ
DE	9317450	9/1994		laint for Patent Infring	`	1 0 /
DE	9409231	11/1994	-	United States District	•	
DE DE	19630466 69409024	5/1998 10/1998		No. '13CV1246 MMA	*	,
DE DE	29817685	5/1998 5/1999		ction related to Certa	•	, ,
DE	29909611	9/1999		Systems and Compone	-	•
DE	19936499	2/2001		5, filed on Mar. 28, 20		

### (56) References Cited

#### OTHER PUBLICATIONS

ResMed's First Amended Complaint for Patent Infringement, filed in the United States District Court Central District of California Southern Division, filed on Apr. 8, 2013, 342 pages.

Correspondence regarding FDA 510(k) submission, exhibit 1025 in case No. IPR2016-01727 dated Aug. 6, 1997, 5 pages.

De Vilbiss® Healthcare, "DeVilbiss IntelliPAP® Standard CPAP System," Nov. 2007, 2 pages.

Declaration of Joseph Dyro, Petition Exhibit 1007.

Examination Report dated Oct. 10, 2003 in New Zealand Appln. No. 527088 (2 pages).

Extended European Search Report dated Apr. 28, 2011 in European Appln. No. 10189422.8 (5 pages).

Extended European Search Report dated May 4, 2012 in European Appln. No. 12159042.6 (5 pages).

Final Notice of Reasons for Rejection delivered Sep. 24, 2008 in Japanese Appln. No. 2002-565664, with English translation (6 pages).

Fischer & Paykel, "Two Easy Steps to Comfort", 4 pages, Aug. 1995.

Fisher & Paykel Healthcare "SleepStyle™ 200 CPAP Series" Specification Sheet, 1998, 4 pages.

Fisher & Paykel Healthcare "SleepStyle<sup>TM</sup> 200 CPAP Series" Specification Sheet, 2005, 4 pages.

Fisher & Paykel Healthcare "SleepStyle<sup>TM</sup> 600 CPAP Series" Specification Sheet, 2005, 4 pages.

Fisher & Paykel Healthcare Two Easy Steps to Comfort, Humidification and Nasal CPAP Therapy, Aug. 1995, 4 pages.

Fisher & Paykel Healthcare, "HC200 Series Nasal CPAP Blower & Heated Humidifier User's Manual", 1998, 17 pages.

Fisher & Paykel Limited, New Zealand Application No. 503495, filed Mar. 21, 2000, 29 pages.

German Patient Manual for Hoffrichter/Sandmann CPAP Respirator—Perfect CPAP Therapy, 30 pages plus Translation Verification Certificate, Mar. 1998.

HC200 Series Nasal CPAP Blower and Heated Humidifier Fisher & Paykel Healthcare, 17 pages.

Hoffrichter "Vector CP AP—Therapy With Technical Mastery", 4 pages, Oct. 1998.

Hoffrichter GmbH "Vector therapy in perfection" Brochure, 2002, 2 pages.

International Preliminary Examination Report dated Oct. 4, 2002 in International Appln. No. PCT/AU02/00155 (3 pages).

International Search Report dated Mar. 21, 2002 in International Appln. No. PCT/AU02/00155 (2 pages).

J. H. Emerson Co., Cough Assist, "Non-Invasive Removal of Bronchial Secretions," 2 pages.

Madaus Schwarzer Medizintechnik, "New Approaches in Diagnosis and Therapy—Moritz biLevel User Manual", May 1994, 38 pages. Madaus Schwarzer Medizintechnik, "New Approaches in Diagnosis and Therapy—Max nCPAP User Manual", Mar. 1994, 38 pages.

MAP Medizintechnik fuer Arzt and Patient "max II nCP AP moritz II biLevel—The gentle therapy for sleep-related breathing disorders" Brochure, 2000, 4 pages.

MAP Medizintechnik, "minni Max nCPAP®" brochure, 12 pages, Mar. 2005.

MAP Medizintechnik, "Moritz II biLEVEL®—The gentle therapy for sleep-related breathing disorders" brochure, 6 pages, Jan. 2001. MAP Medizin-Technologie GmbH "minni Max nCP AP®, The respiratory therapy device with out an integrated humidifier", Dec. 2003, 17 pages.

MAP Medizin-Technologie GmbH, Moritz® S/Moritz® ST—Sailing toward therapeutic success . . . , Jul. 2004, 4 pages.

Microfilm of Japanese Utility-Model Application No. S54-003858 (Japanese Utility-Model Application Publication No. S55-104925). Motion to Amend the Complaint and Notice of Investigation as filed in the United States International Trade Commission, Investigation No. 337-TA-879, dated May 31, 2013, 18 pages.

Notification of Acceptance of Request for Invalidation and English Translation for corresponding Chinese Patent No. 02804936.5, dated Mar. 20, 2014, 188 pages.

Notification of Acceptance of Request for Invalidation, dated Dec. 24, 2014, in Chinese Patent No. 02804936.5, with English translation, 62 pages.

Notification of Reasons for Rejection dated Feb. 19, 2008 in Japanese Appln. No. 2002-565664, with English translation (5 pages).

Notification of Second Office Action dated Jan. 27, 2006 in Chinese Appln. No. 02804936.5, with English Translation (6 pages).

Notification of the First Office Action dated Jul. 22, 2005 in Chinese Appln. No. 02804936.5, with English translation (8 pages).

Office Action dated Jan. 22, 2008 in Japanese Patent Appln. No. 2002-565665 (w/English translation) (12 pages).

Patent Owner Exhibit No. 2001 in IPR2014-00551, Applicant Transmittal to USPTO re Completion of National Phase Filing of the PCT Application for the Mayer Reference, Aug. 6, 2002, 4 pages.

Patent Owner Exhibit No. 2002 in IPR2014-00551, Re. 44,453 Patent Application Data Sheet, Initial May 4, 2011, 5 pages.

Patent Owner Exhibit No. 2003 in IPR2014-00551, Decision of the Patent Trial and Appeal Board Denying Institution of Inter Partes Review of U.S. Pat. No. 7,614,398, entered Feb. 20, 2014, 5 pages. Patent Owner Exhibit No. 2005 in IPR2014-00551, U.S. National Stage Worksheet of USPTO re National Phase Requirements Completion for the Mayer Reference, 1 page.

Patent Owner Exhibit No. 2010 in IPR2014-00551, Deposition Transcript of Dr. Joseph F. Dyro in Connection with Inter Partes Review Proceedings IPR2013-00511, IPR2013-00512, IPR2013-00514, IPR2013-00515, and IPR2013-00516, Apr. 21, 2014, 46 pages.

Patent Owner Exhibit No. 2011 in IPR2014-00551, Patent Owner ResMed Limited's Preliminary Response to Apex Medical Corp. 's Petition for Inter Partes Review of U.S. Pat. No. 7,614,398, Case No. IPR2013-00513, Nov. 22, 2013, 15 pages.

Petition Exhibit 1003 in IPR2014-01 196, REMStar® Heated Humidifier Manual, Mar. 15, 2001, 8 pages.

Petition Exhibit 1004 in IPR2014-01363, Declaration of Steve Bordewick, Aug. 22, 2014, 90 pages.

Petition Exhibit 1004 in IPR2014-01 196, Declaration of Steve Bordewick, Jul. 22, 2014, 59 pages.

Petition Exhibit 1006 in IPR2014-00551, Patent Owner Amendment mailed Mar. 27, 2009, in U.S. Appl. No. 11/181,807, 10 pages.

Petition Exhibit 1006 in IPR2014-01 196, Patent Owner ResMed Limited's Preliminary Response filed Jul. 10, 2014, in IPR2014-00551, 41 pages.

Petition Exhibit 1007 in IPR2014-00551, Declaration of Joseph Dyro in Support of Inter Partes Review of U.S. Pat. No. Re. 44,453, executed Mar. 26, 2014, 15 pages.

Petition Exhibit 1007 in IPR2014-01 196, ITC Investigation No. 337-TA-890,: Order No. 7: Initial Determination Granting Complainants' Motion to Amend Complaint and Notice of investigation and Granting Respondents' Motion to Terminate the Investigation with Respect to U.S. Pat. No. 7,614,398, served Feb. 4, 2014, 8 pages.

Petition Exhibit 1008 in IPR2014-01 196, Case No. 13-cv-1246-CAB (WMc), Order on Motion to Stay, Motion to Dismiss, and Related Discovery Request, Oct. 15, 2013, 3 pages.

Petition Exhibit 1009 in IPR2014-01 196, Case No. SACV 13-00498: Order Granting Defendants' Motion to Stay Litigation Pending Inter Partes Review, Oct. 4, 2013, 3 pages.

Petition Exhibit 1010 in IPR2014-01 196: Patent Prosecution History of Reissue U.S. Appl. No. 13/944,960, filed Jul. 18, 2013, 228 pages.

Petition Exhibit 1011 in IPR2014-01 196: Patent Prosecution History of U.S. Pat. No. 7,614,398, 174 pages.

Petition Exhibit No. 1012 in IPR2014-01 196: Patent Prosecution History of Reissue U.S. Pat. No. Re. 44,453, 2157 pages.

Petition Exhibit No. 1013 in IPR2014-01 196: Proof of Service of 3B Medical, Inc. In Civil Action No. 13-cv-1246-MMA-WMC, 5 pages.

### (56) References Cited

#### OTHER PUBLICATIONS

Petition Exhibit No. 1014 in IPR2014-01 196: Australian Application No. PR 3117, filed Feb. 16, 2001, 17 pages.

Petition Exhibit No. 1015 in IPR2014-01196: ITC Investigation No. 337-TA-890: Order No. 8: Construing Terms of the Asserted Patents, served Jan. 17, 2014, 51 pages.

Petition Exhibit No. 1016 in IPR2014-01196: ITC Investigation No. 337-TA-890: Order No. 14: Denying Respondents' Motion for Summary Determination of Invalidity of U.S. Pat. No. Re. 44,453, served Mar. 26, 2014, 19 pages.

Petition Exhibit No. 1020 in IPR2014-01 196: Australian Application No. PR 7288, filed Aug. 27, 2001, 23 pages.

Petition Exhibit No. 1022 in IPR2014-01196: ITC Investigation No. 33 7-T A-890: Notice of Commission Determination Not to Review an Initial Determination Granting the Complainants' Motion to Amend the Complaint and Notice of Investigation to Substitute U.S. Pat. No. Re. 44,453 for U.S. Pat. No. 7,614,398 and Granting Respondents' Motion to Terminate the Investigation with Respect to U.S. Pat. No. 7,614,398, Issued: Feb. 10, 2014, 3 pages.

Petition for Inter Partes Review of U.S. Pat. No. 7,614,398, mailed on Aug. 16, 2013.

Petition for Inter Parties Review of U.S. Pat. No. Re. 44,453, *BMC Medical Co. Ltd.*, Petitioner v. *ResMed Limited*, Patent Owner, Case No. IPR2014-01363, Aug. 22, 2014, 66 pages.

Petition for Inter Parties Review of U.S. Pat. No. Re. 44,453 Under To 35 U.S.C. §§ 311 et seq. and 37 C.F.R. §42.100 et seq., *Apex Medical Corp.*, Petitioner v. *ResMed Limited*, Patent Owner, Case No. IPR2014-00551, Mar. 27, 2014, 38 pages.

Petition for Inter Parties Review of U.S. Pat. No. Re. 44,453 Under To 35 U.S.C. §§311-319 and 37 C.F.R. §42.100 et seq., *BMC Medical Co. Ltd.*, Petitioner v, *ResMed Limited*, Patent Owner, Case No. IPR2014-01 196, Jul. 23, 2014, 62 pages.

Photos of HumidAire<sup>TM</sup>, 11 pages.

Photos of MAP Humidifier and Tub, 2 pages and cover sheet, undated.

Photos of tray system available before the critical date, with sample flow generator and humidifier, 5 pages.

ResMed "Sullivan® HumidAire® User's Instructions", 8 pages, 1998.

ResMed, "The Sullivan® HumidAire™", 1997, 1 page.

Respironics "System One Heated Humidifier User Manual", May 2009, 20 pages.

SleepSty1e600 CPAP Series Operating Manual, Thermo Smart, www.Manualslib.com, Fisher & Paykel Healthcare, 11 Pages. Stuff.co.nz, Sleeping beautifully article, exhibit 1024 in case No.

IPR2016-01730 dated Dec. 17, 2013, 4 pages.

Sullivan HumidAire User's Instructions, exhibit 1027 in case No. IPR2016-01727, 8 pages.

Supplementary European Search Report dated Sep. 15, 2009 in European Appln. No. 02700014.0, (3 pages).

U.S. International Trade Commission, Inv. No. 337-TA-890, "Notice of the Commission's Final Determination; Issuance of a Limited Exclusion Order and Cease and Desist Orders; Termination of the Investigation," Issued Dec. 23, 2014, 25 pages.

U.S. International Trade Commission, Inv. No. 337-TA-890, "Office of Unfair Import Investigations' Petition for Review of the Initial Determination," dated Nov. 7, 2014 (Public Version Filed: Dec. 3, 2014), 5 pages.

U.S. International Trade Commission, Inv. No. 337-TA-890, "Office of Unfair Import Investigations' Petition for Review of the Initial Determination," dated Sep. 11, 2014 (Public Version Filed: Oct. 8, 2014), 37 pages.

U.S. International Trade Commission, Inv. No. 337-TA-890, "Office of Unfair Import Investigations' Petition for Review of the Initial Determination," dated Sep. 3, 2014 (Public Version Filed: Oct. 8, 2014), 34 pages.

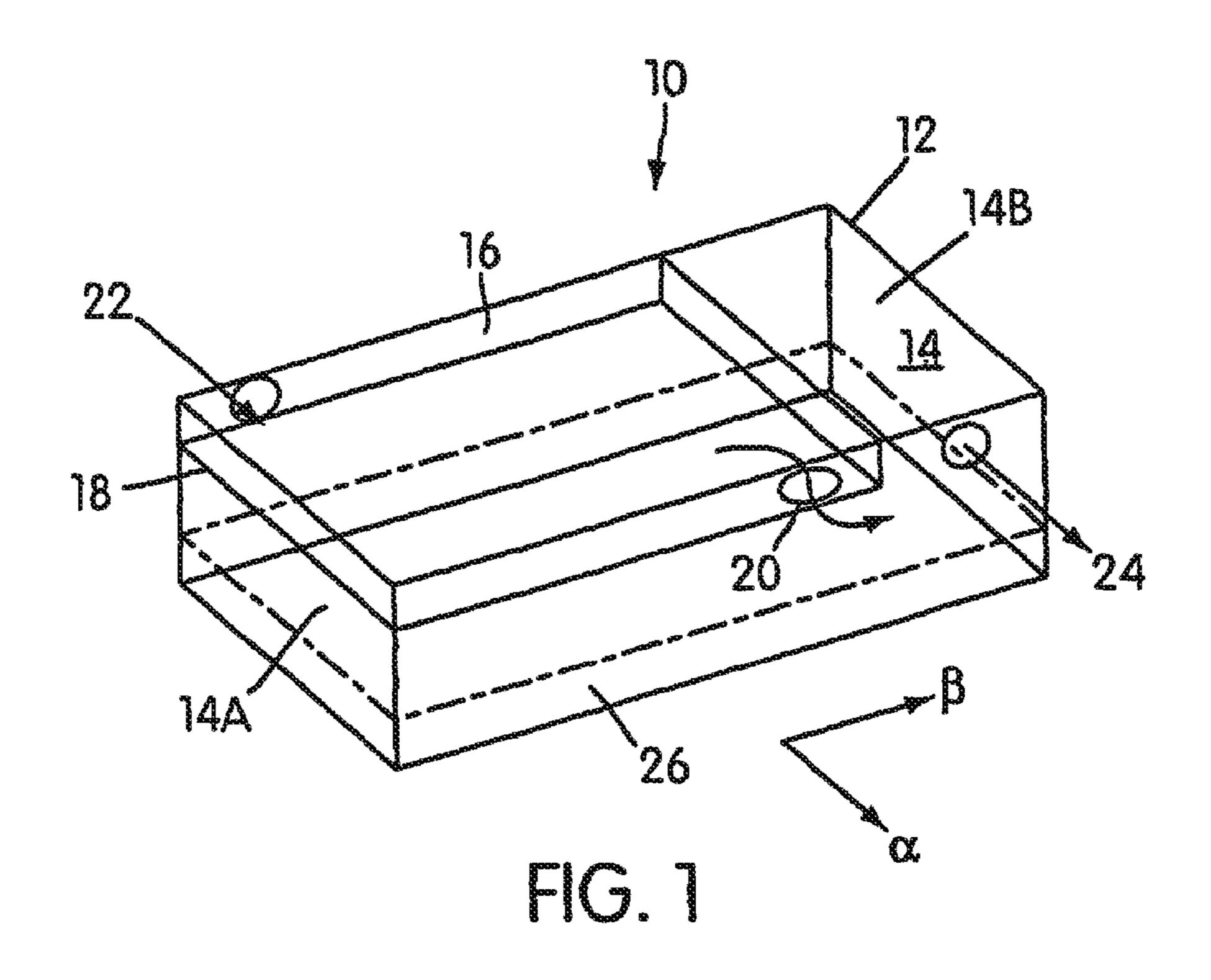
U.S. Patent and Trademark Office, Case IPR2014-01196 and IPR2014-01363, U.S. Pat. No. Re. 44,453 E, "Scheduling Order," Entered: Jan. 21, 2015, 9 pages.

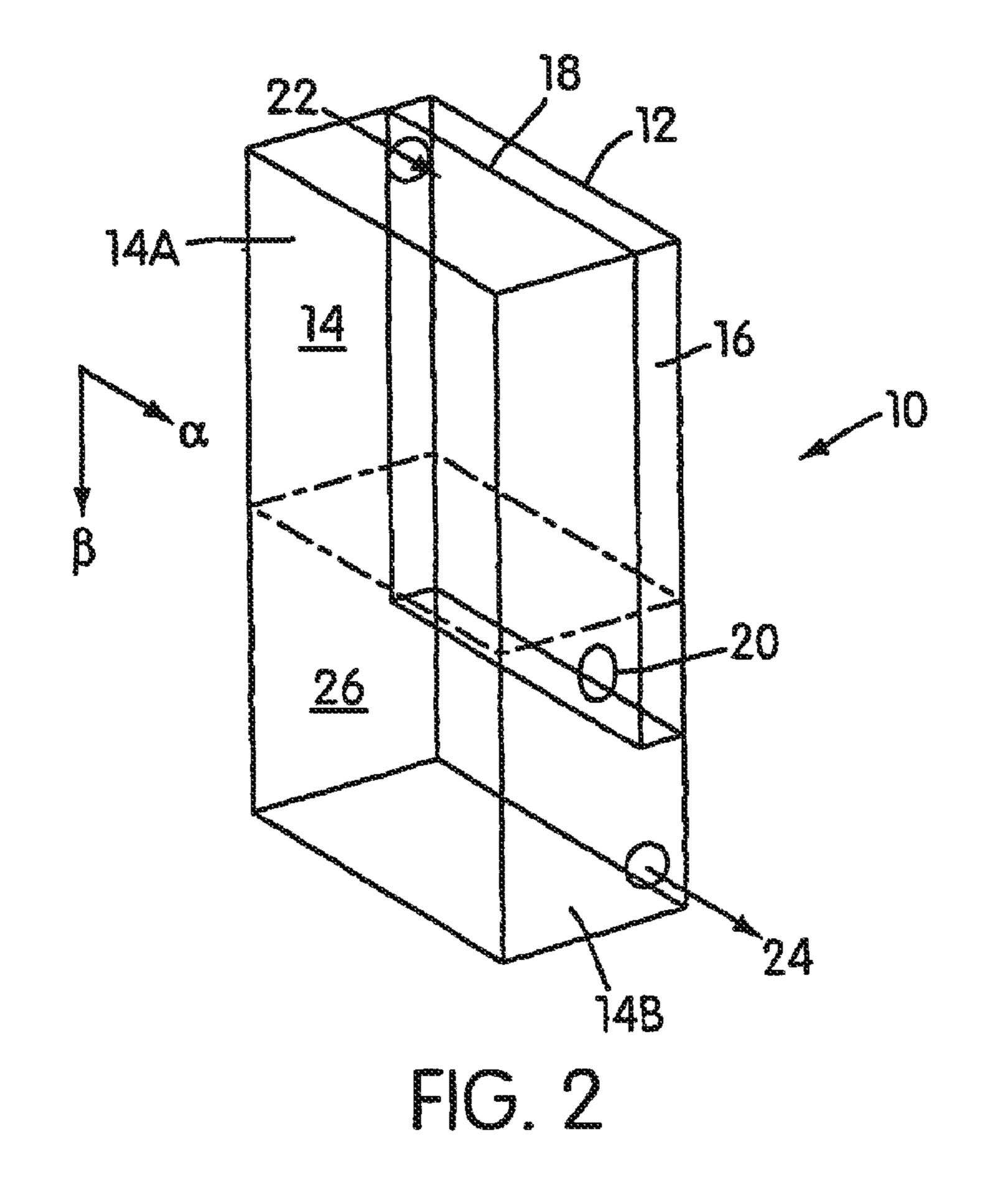
U.S. Patent and Trademark Office, Case IPR2014-01196, U.S. Pat. No. Re. 44,453 E, "Decision Institution of Inter Partes Review 37 C.F.R. §42.108," Paper No. 7, Entered: Dec. 21, 2014, 11 pages. United States Patent and Trademark Office, Before the Patent Trial and Appeal Board, *BMC Medical Co., Ltd., 3B Products, L.L.C. and 3B Medical Inc.* (Petitioner) v. *ResMed Limited* (Patent Owner), Final Written Decision, Paper 25, Entered Jan. 19, 2016 in IPR2014-01196 (14 pages).

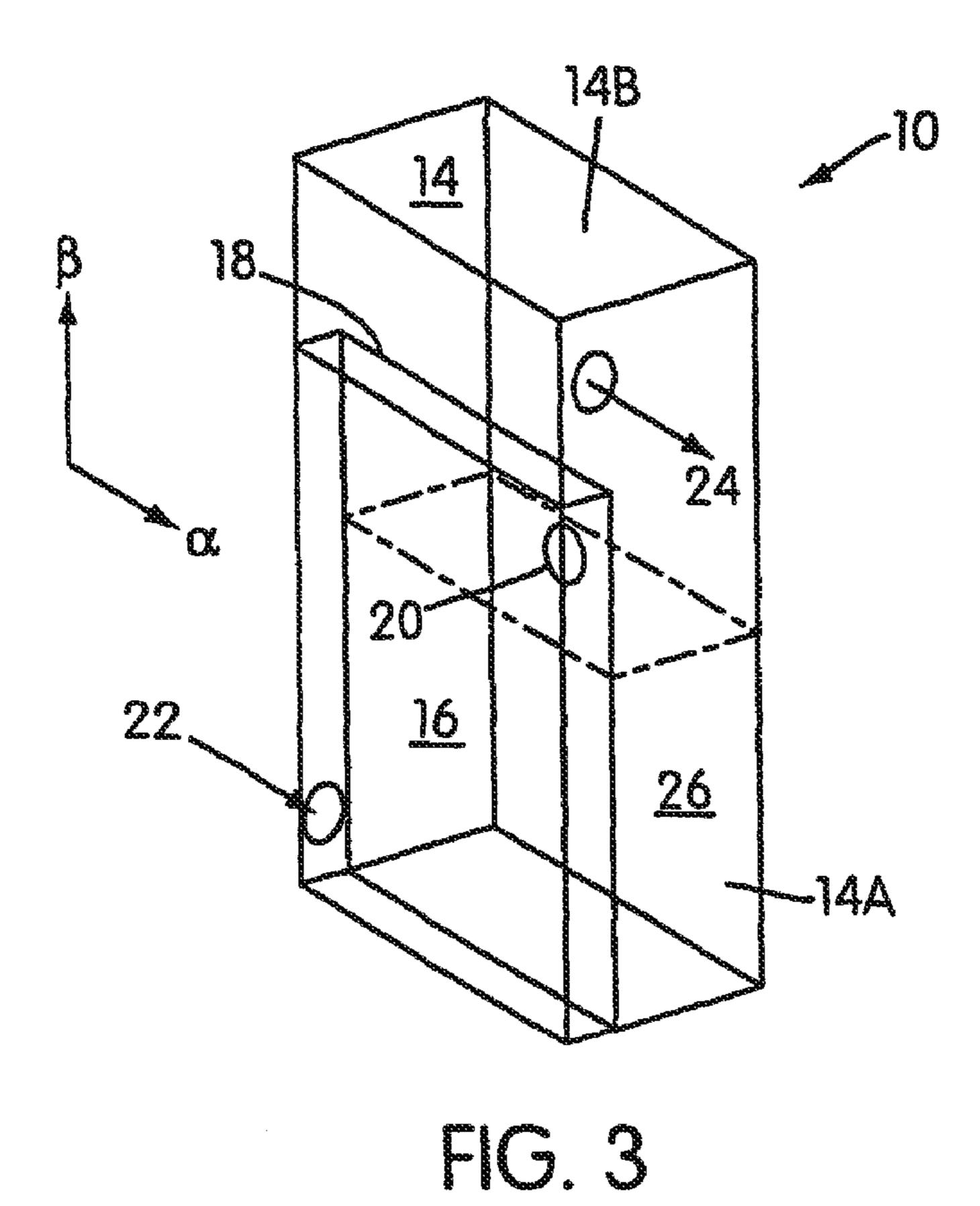
United States Patent and Trademark Office, Before the Patent Trial and Appeal Board, *BMC Medical Co., Ltd., 3B Products, L.L.C. and 3B Medical Inc.* (Petitioner) v. *ResMed Limited* (Patent Owner), Final Written Decision, Paper 25, Entered Jan. 20, 2016 in IPR2014-01363 (39 pages).

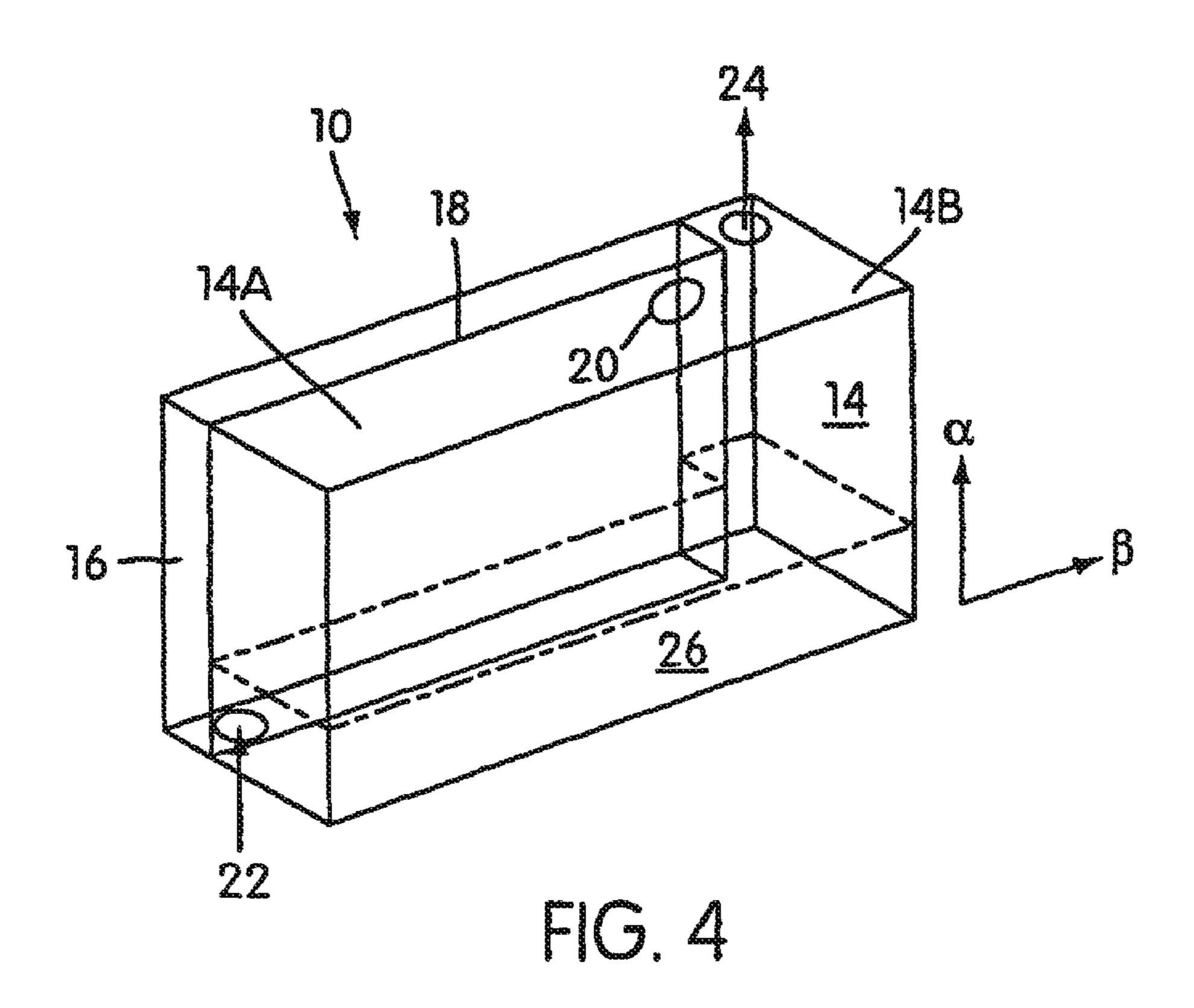
US. Patent and Trademark Office, Case IPR2014-01363, U.S. Pat. No. Re. 44,453 E, Decision Institution of Inter Partes Review 37 C.F.R. §42.108, Paper No. 7, Entered: Jan. 21, 2015, 21 pages.

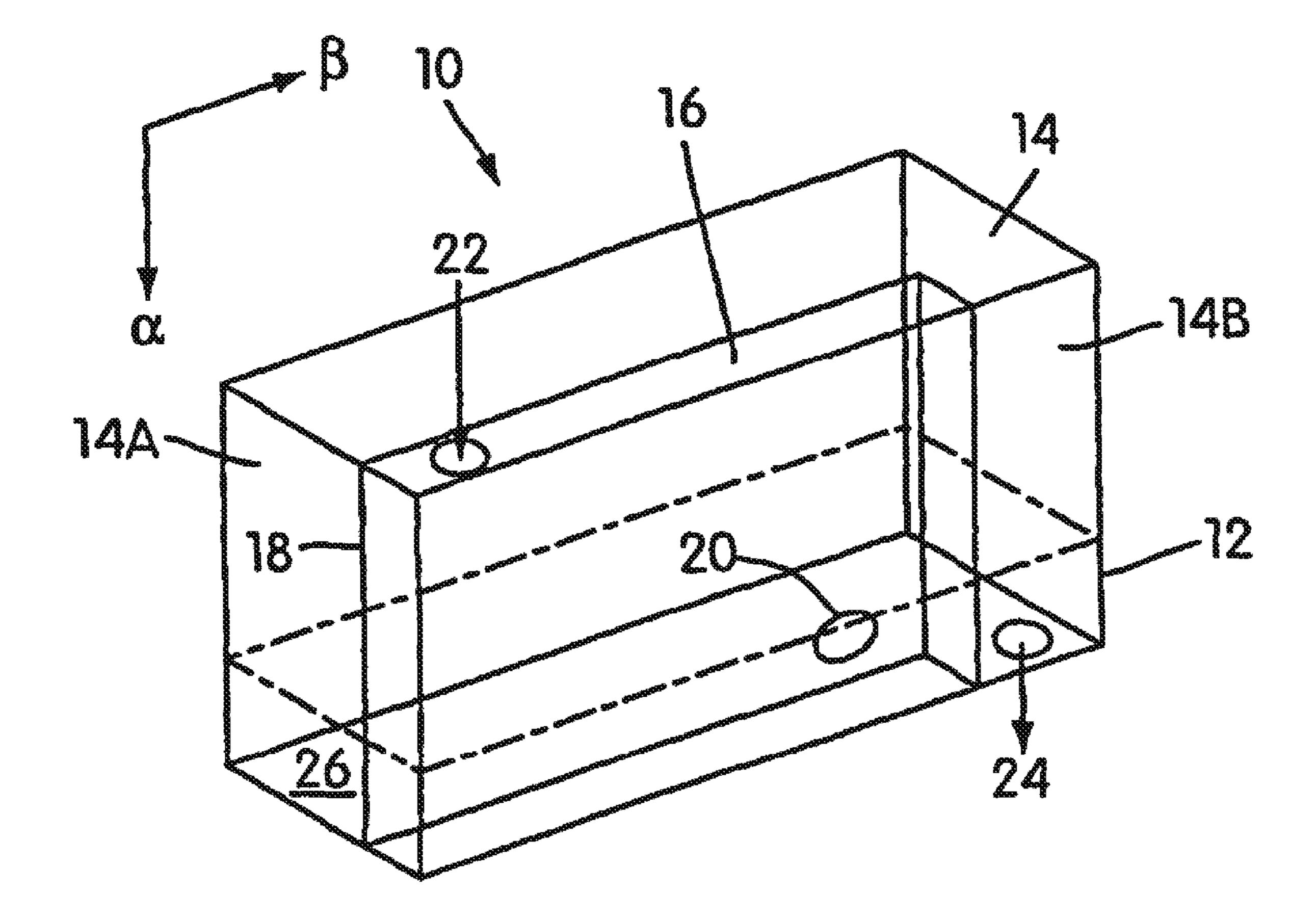
\* cited by examiner











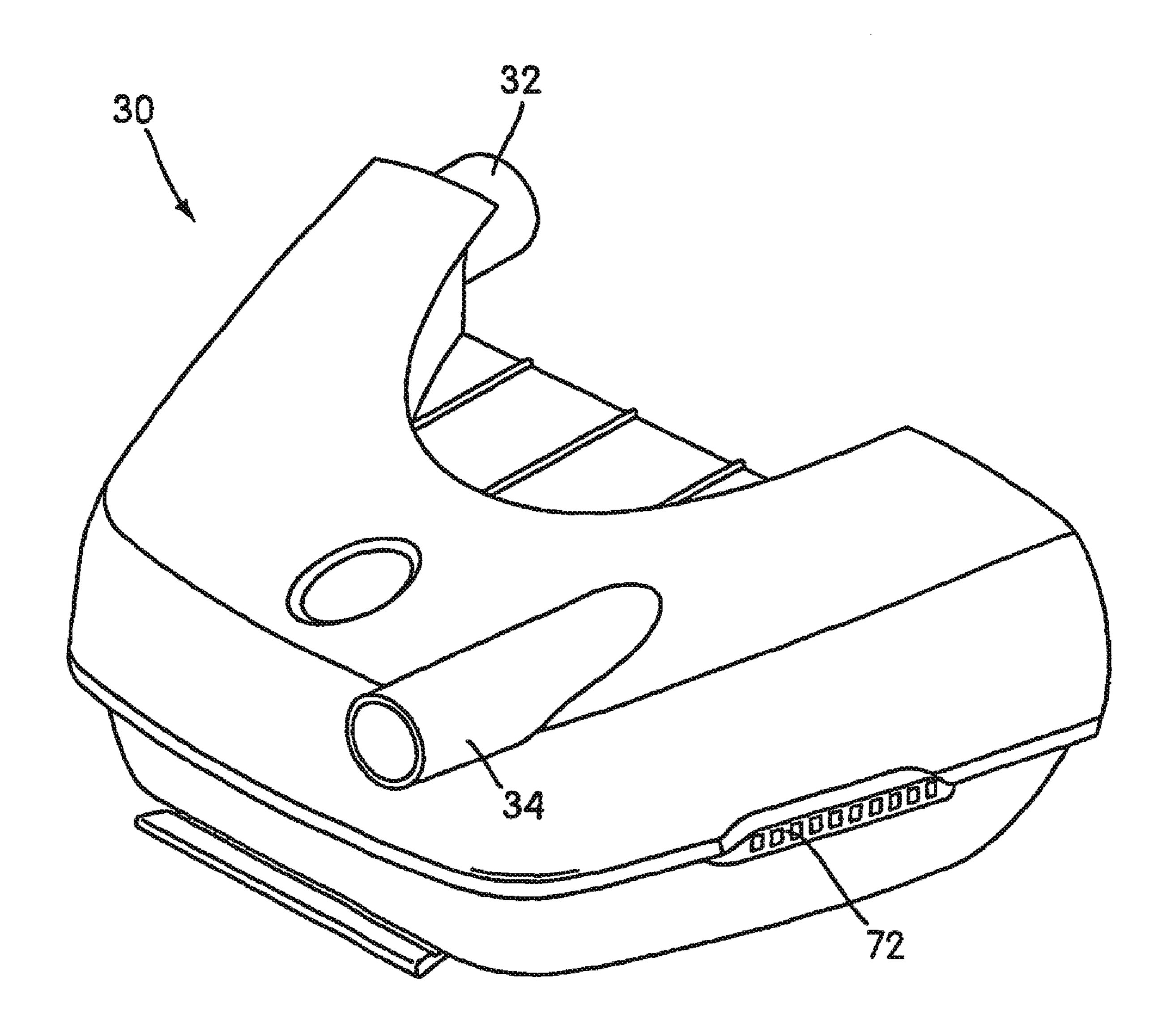
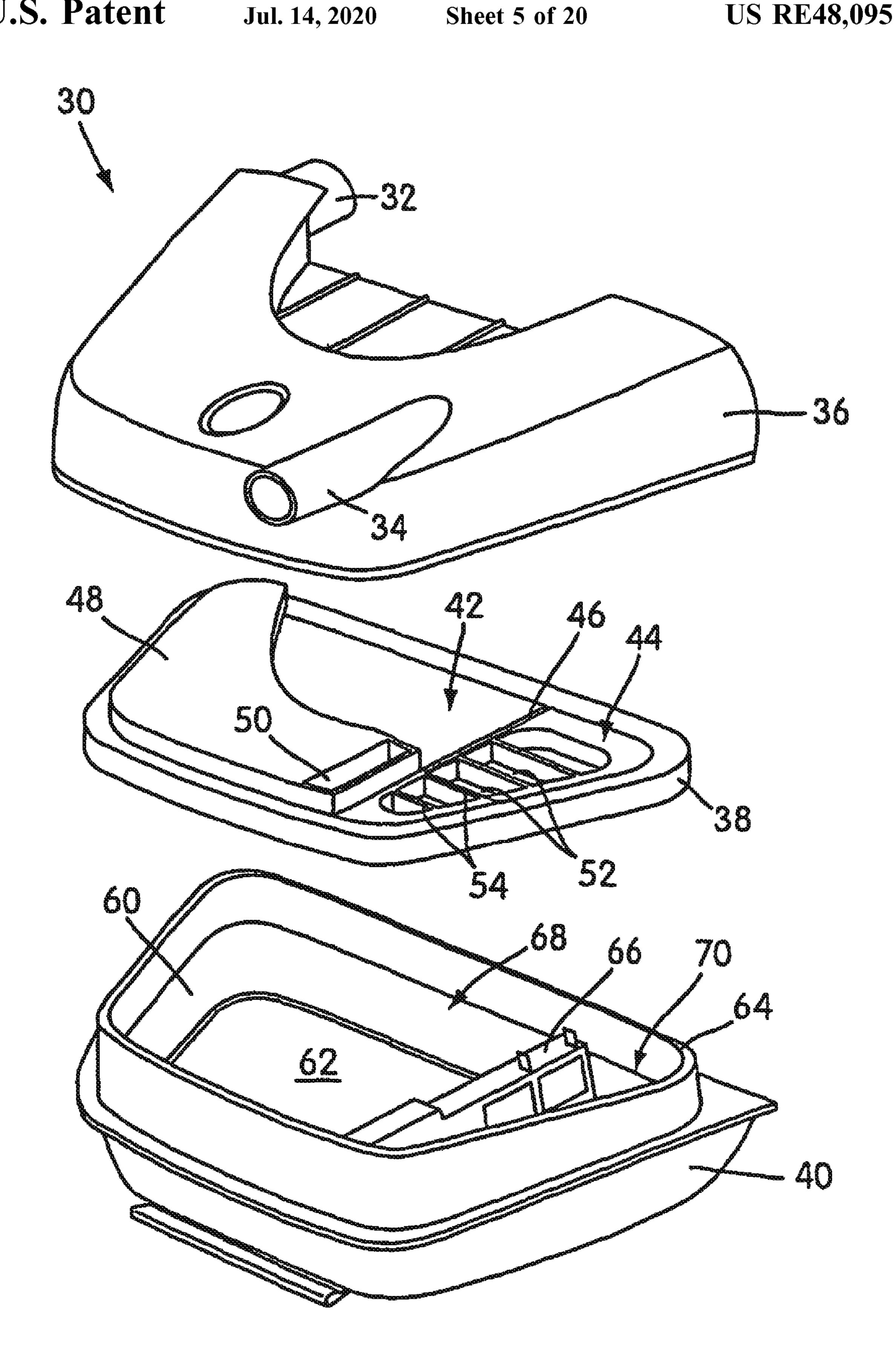
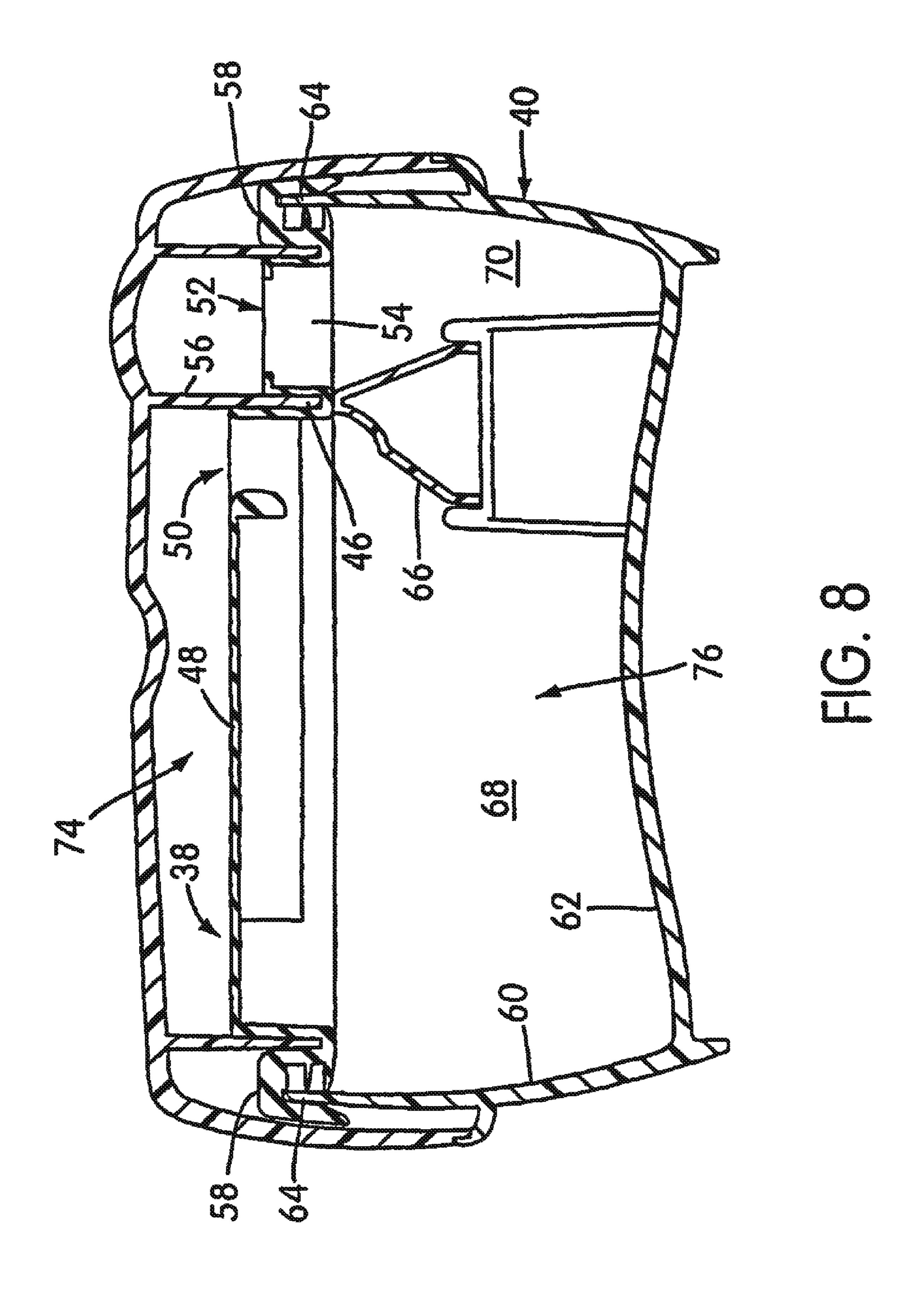


FIG. 6





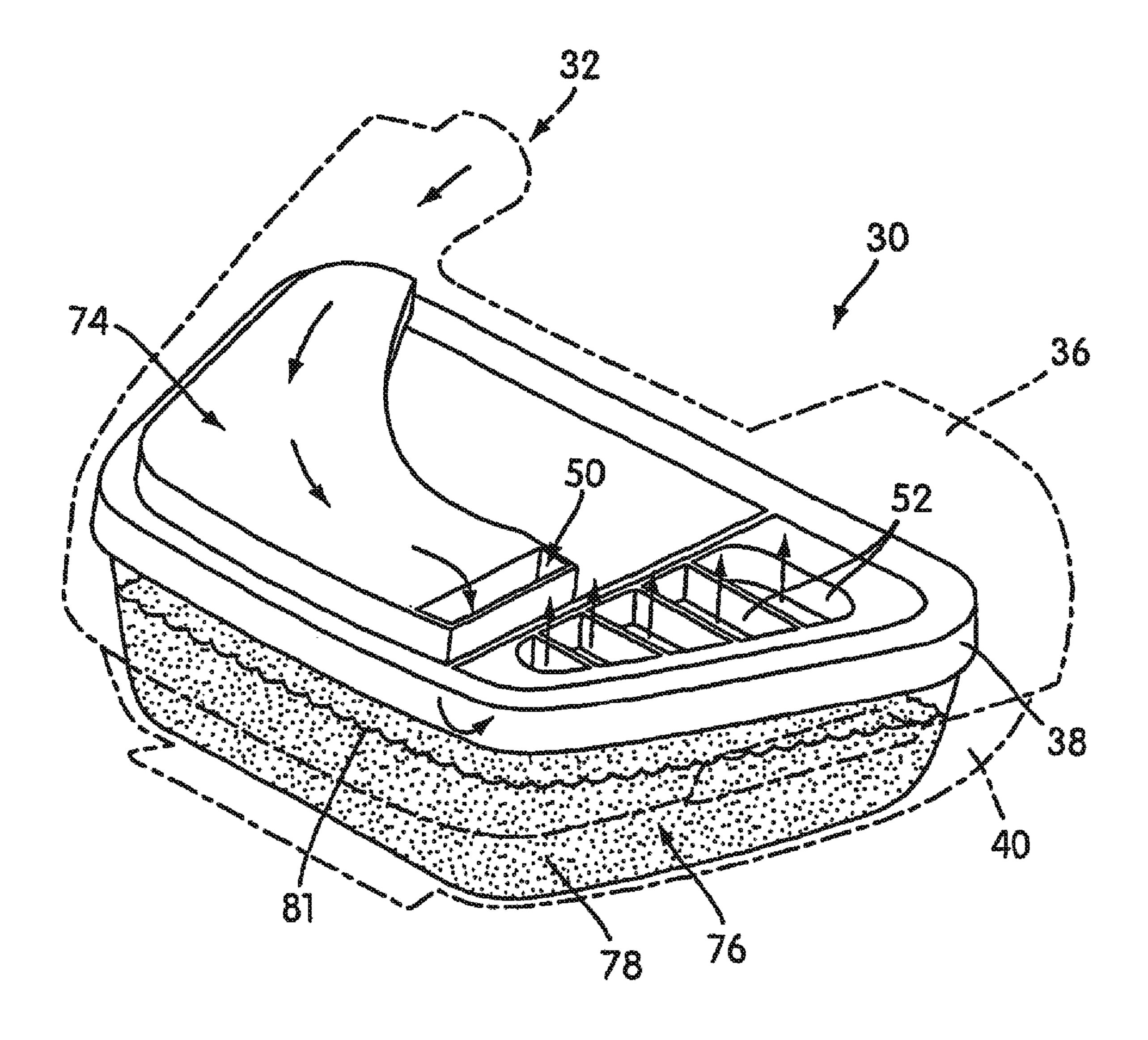
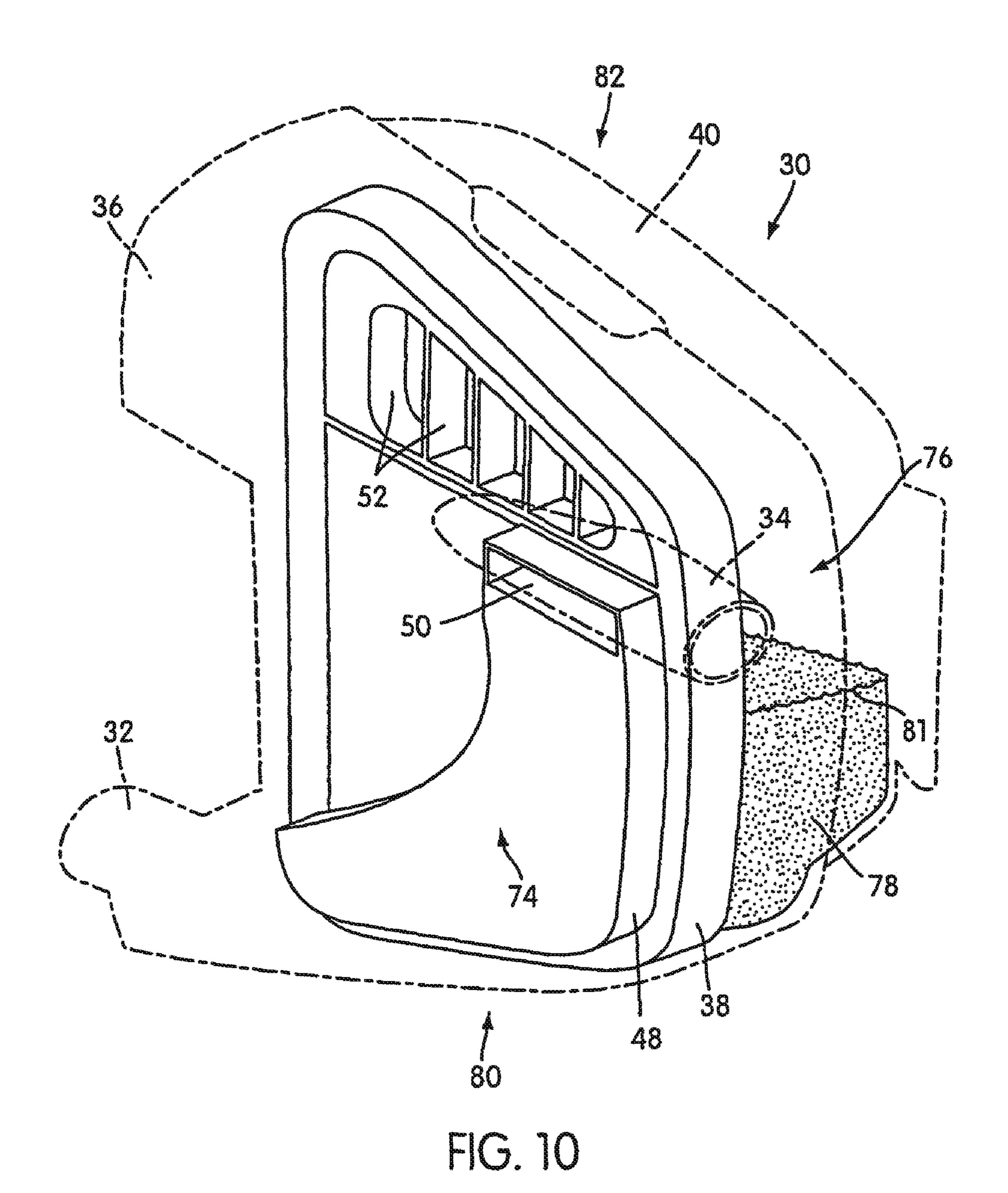
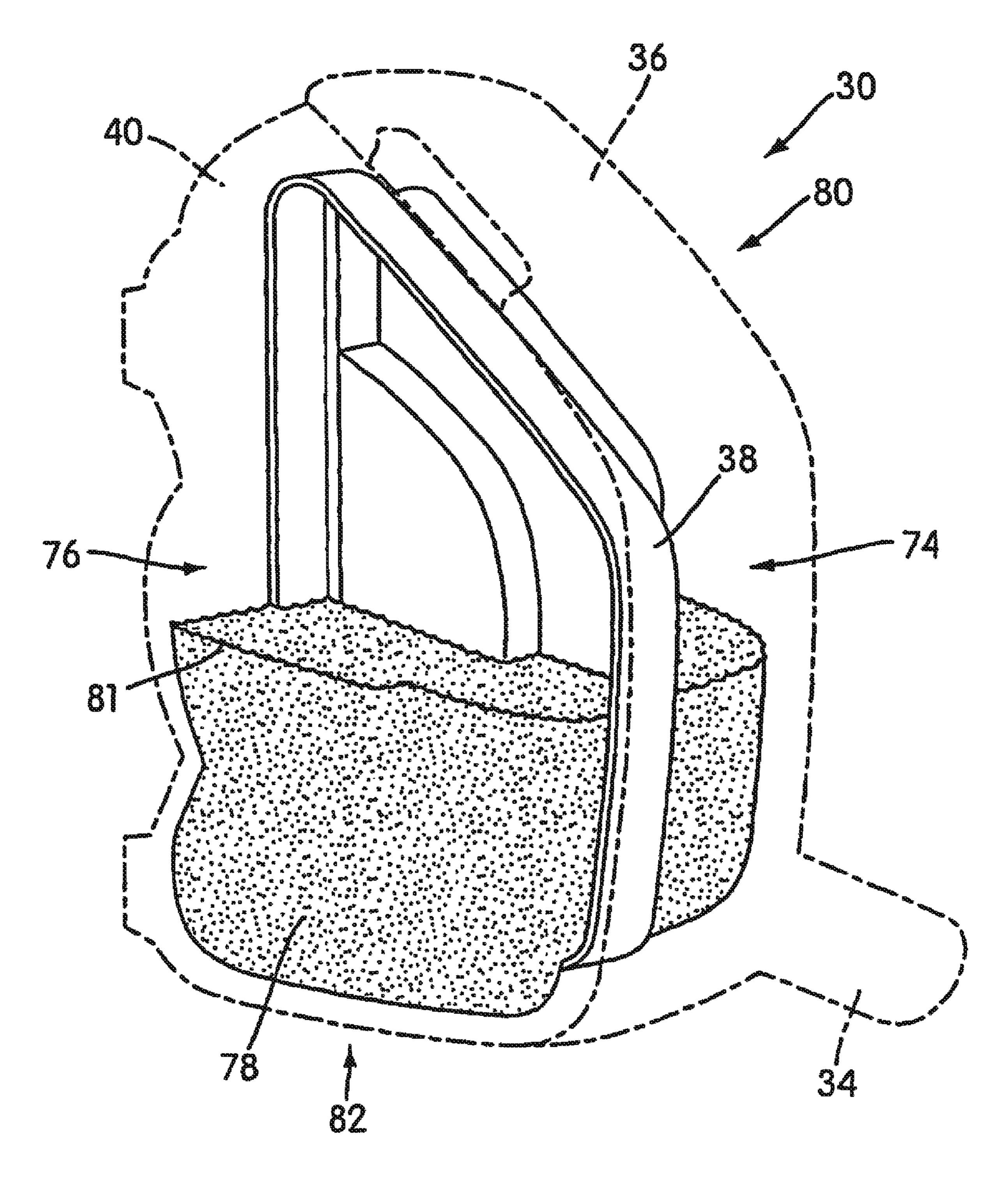
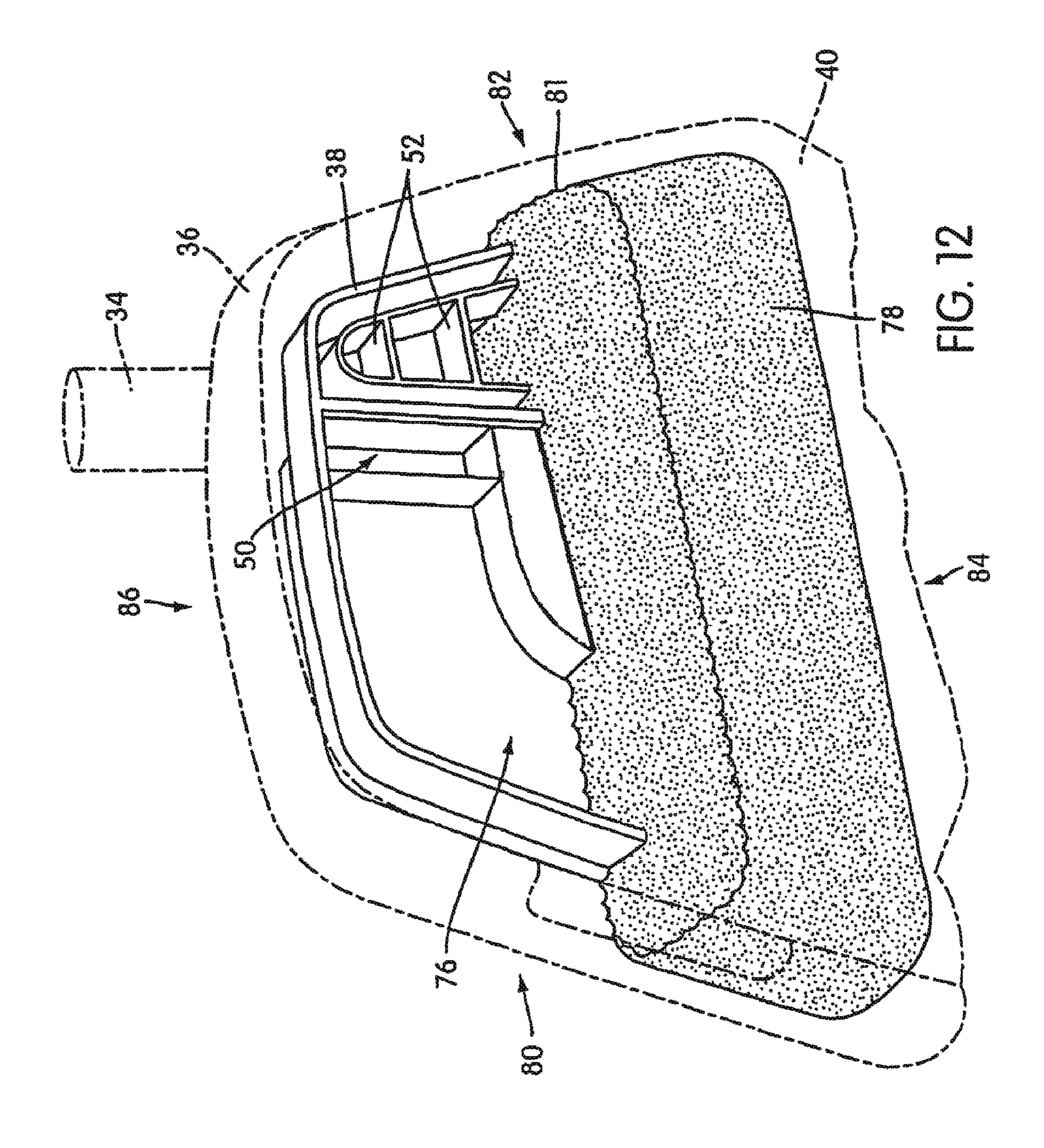
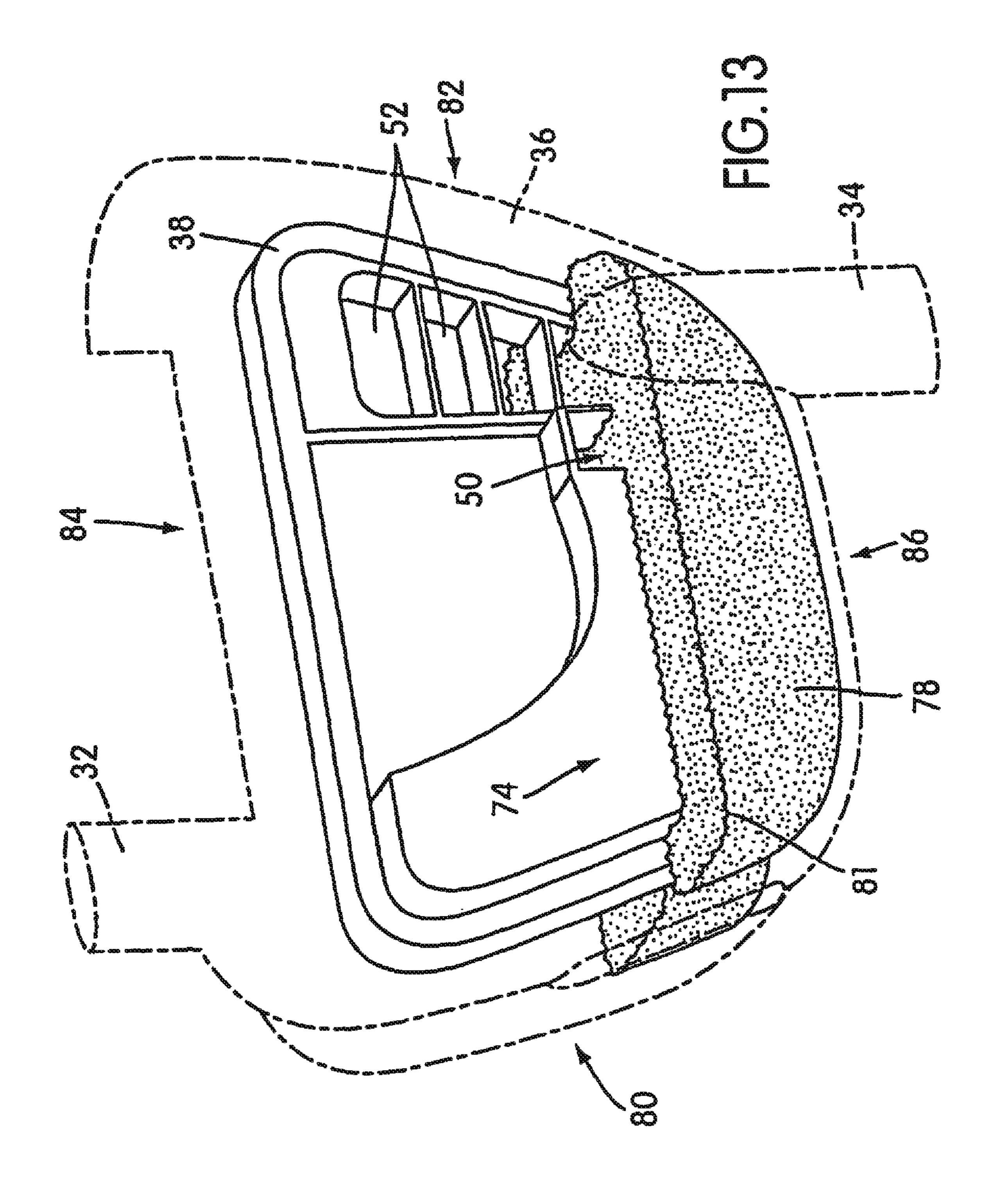


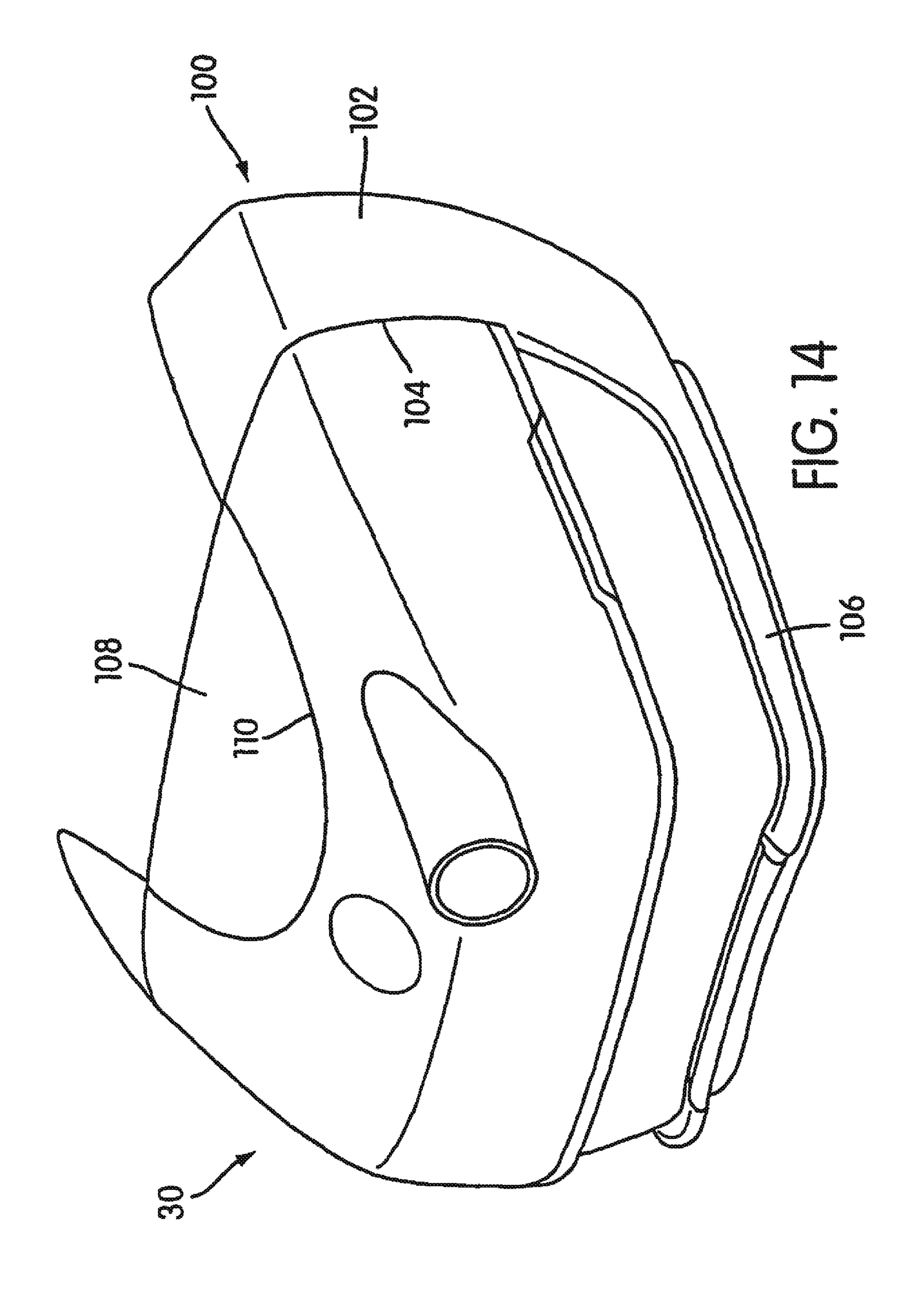
FIG. 9

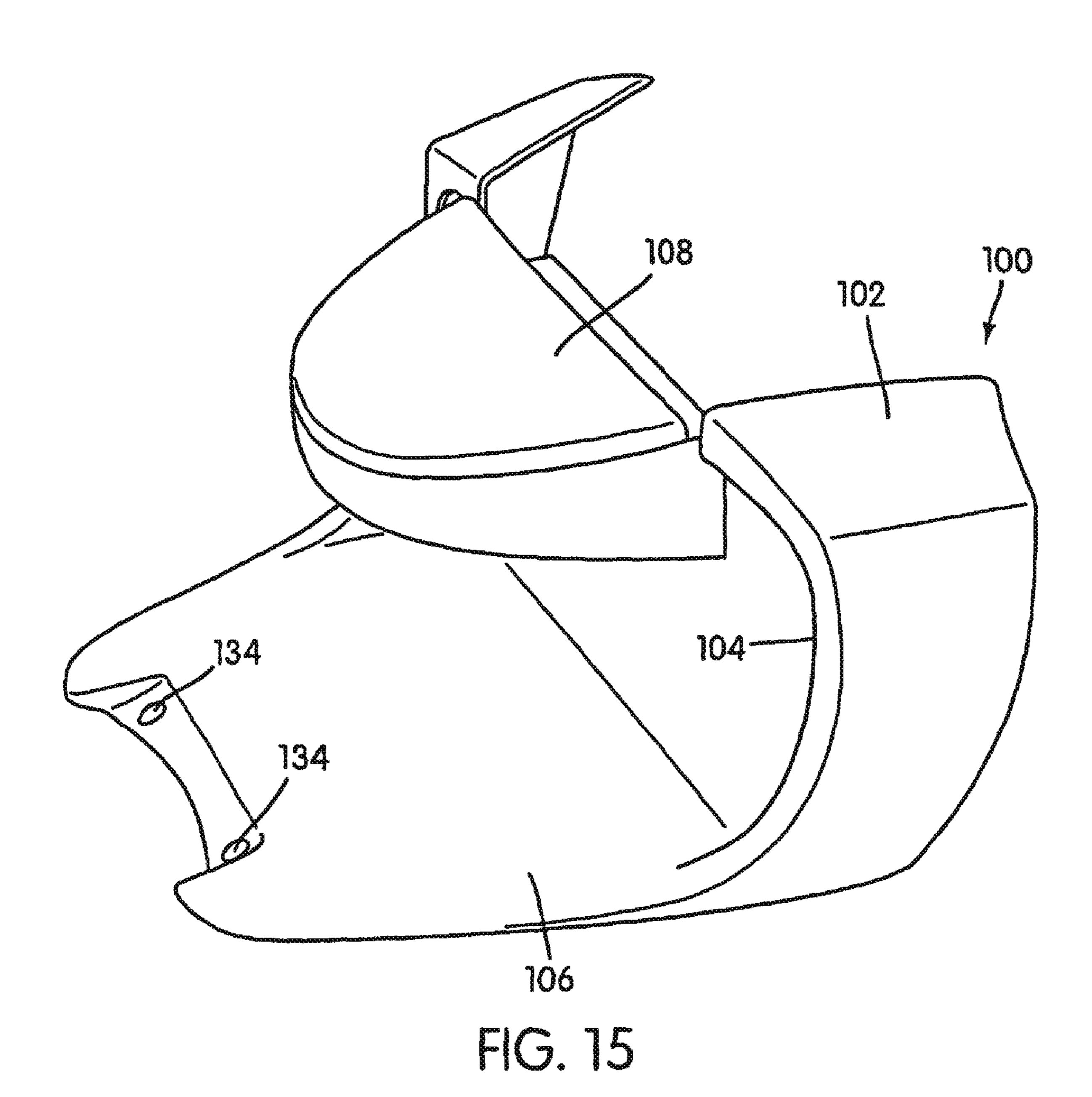


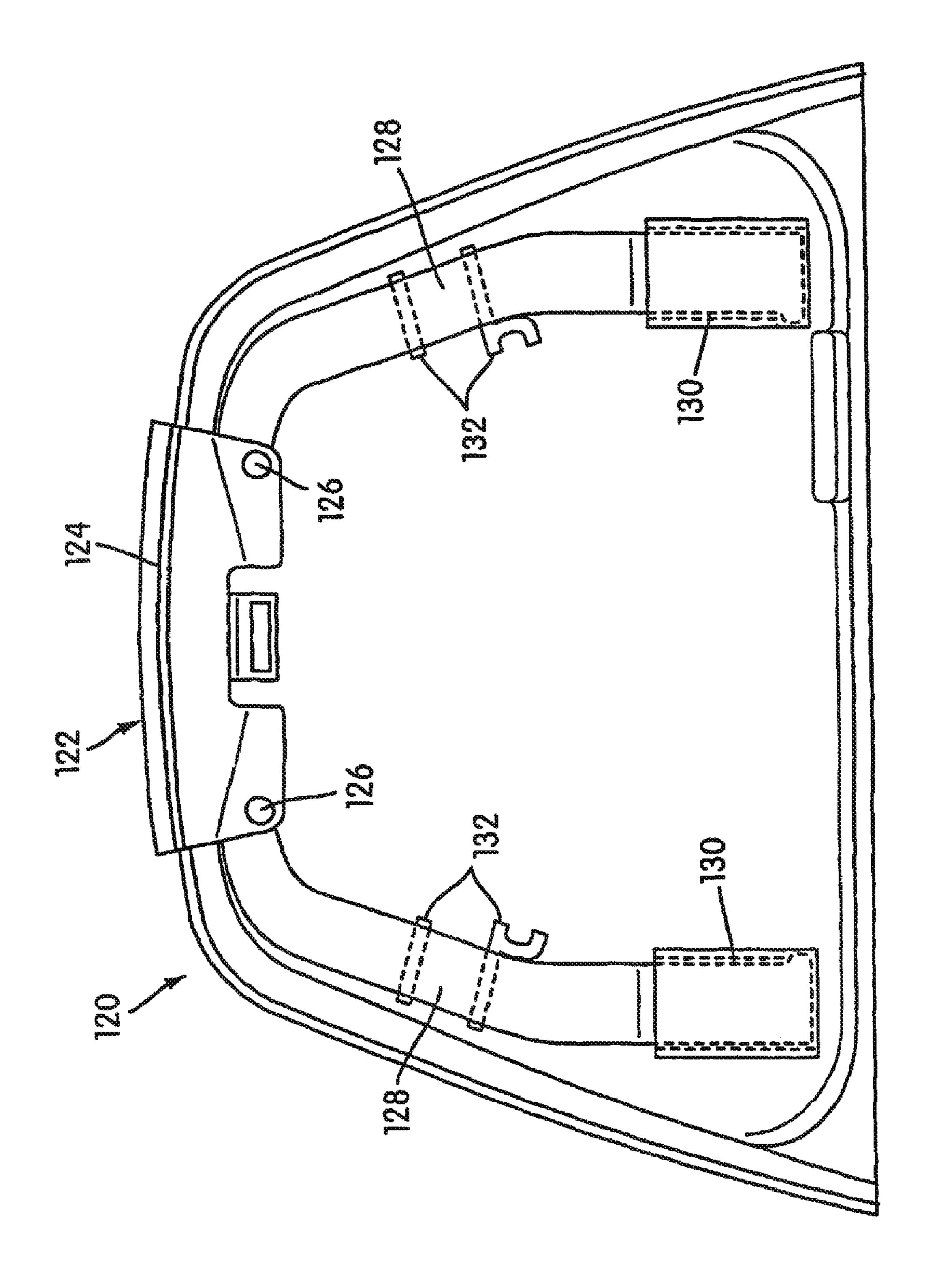


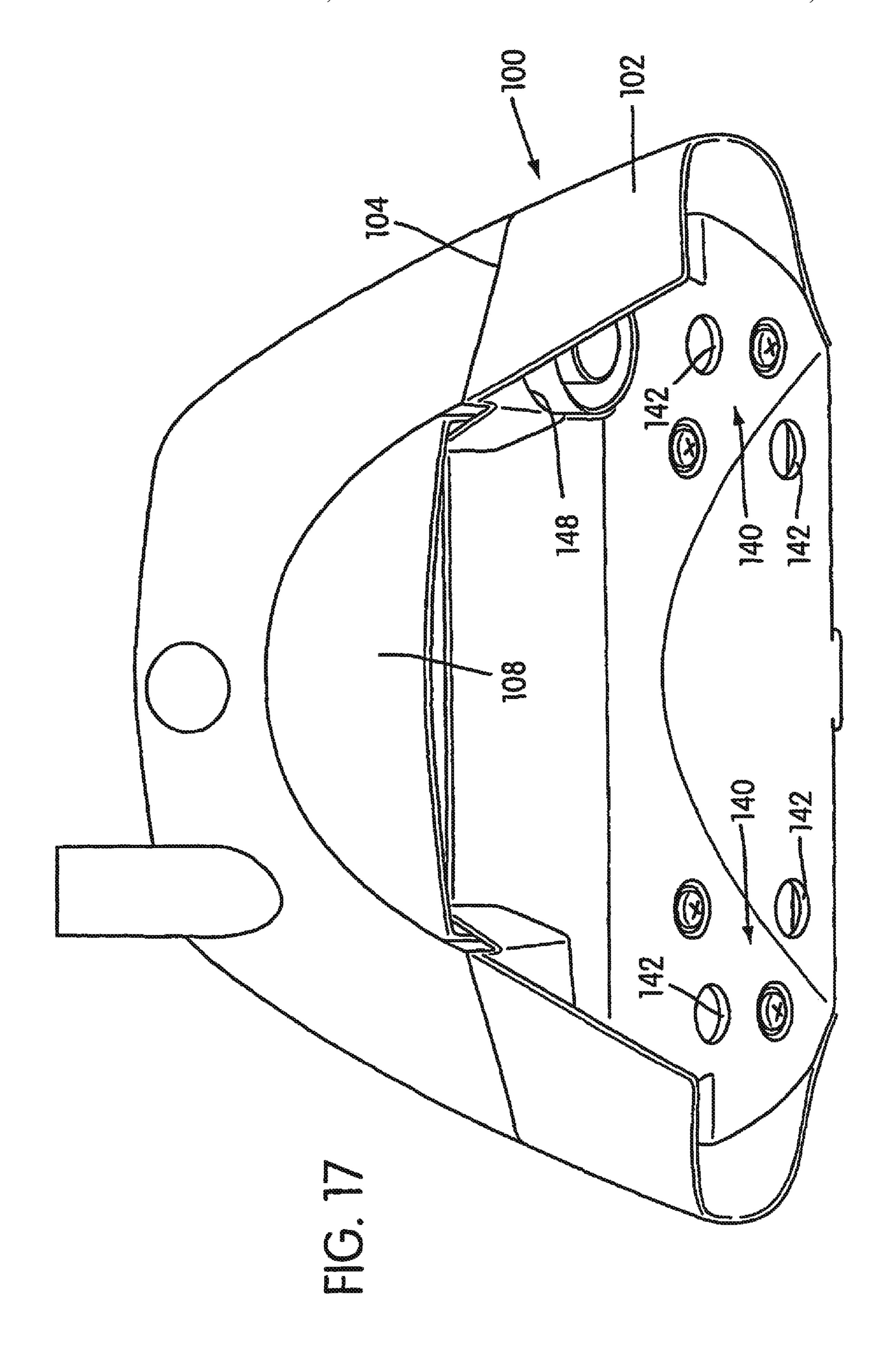












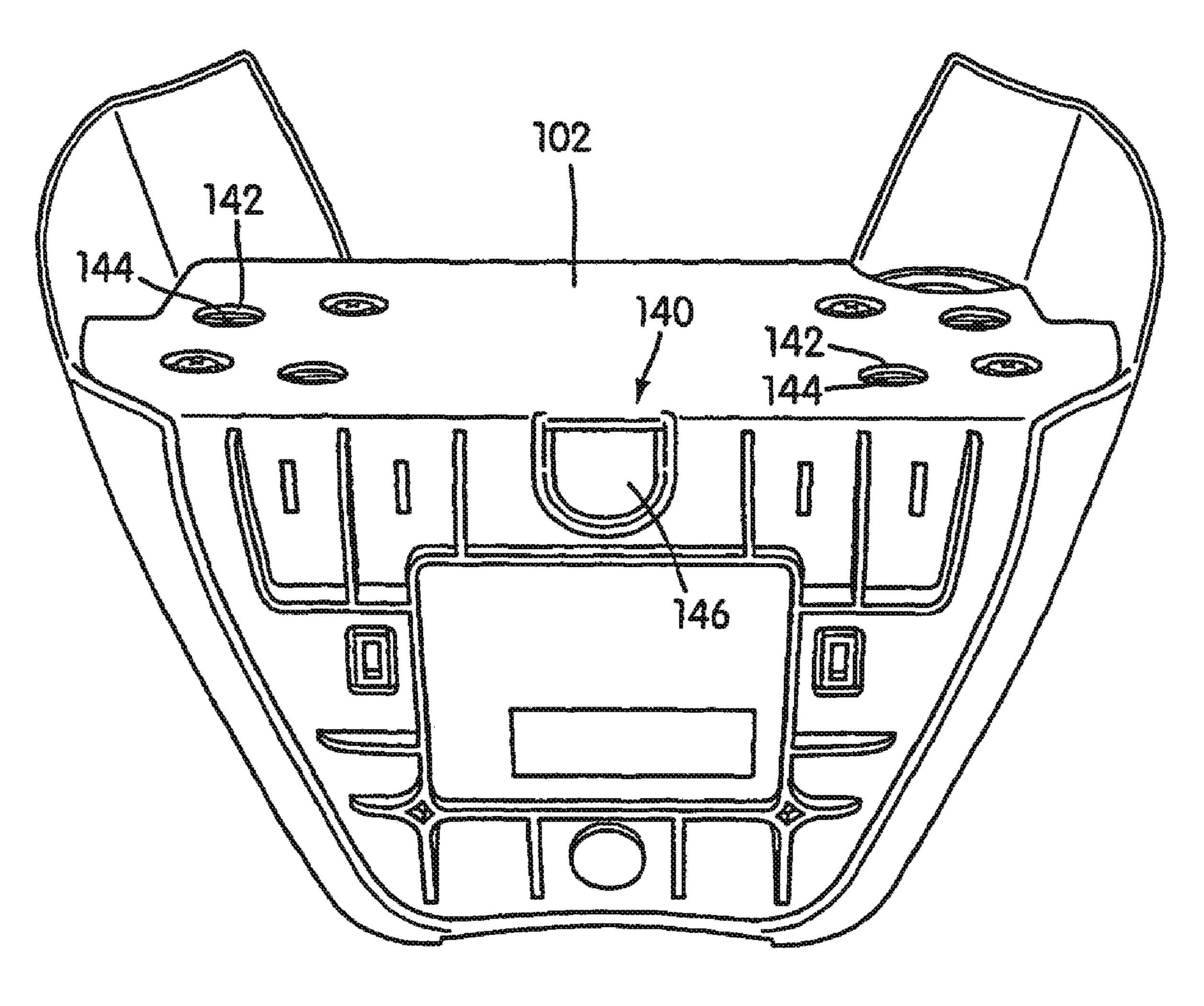
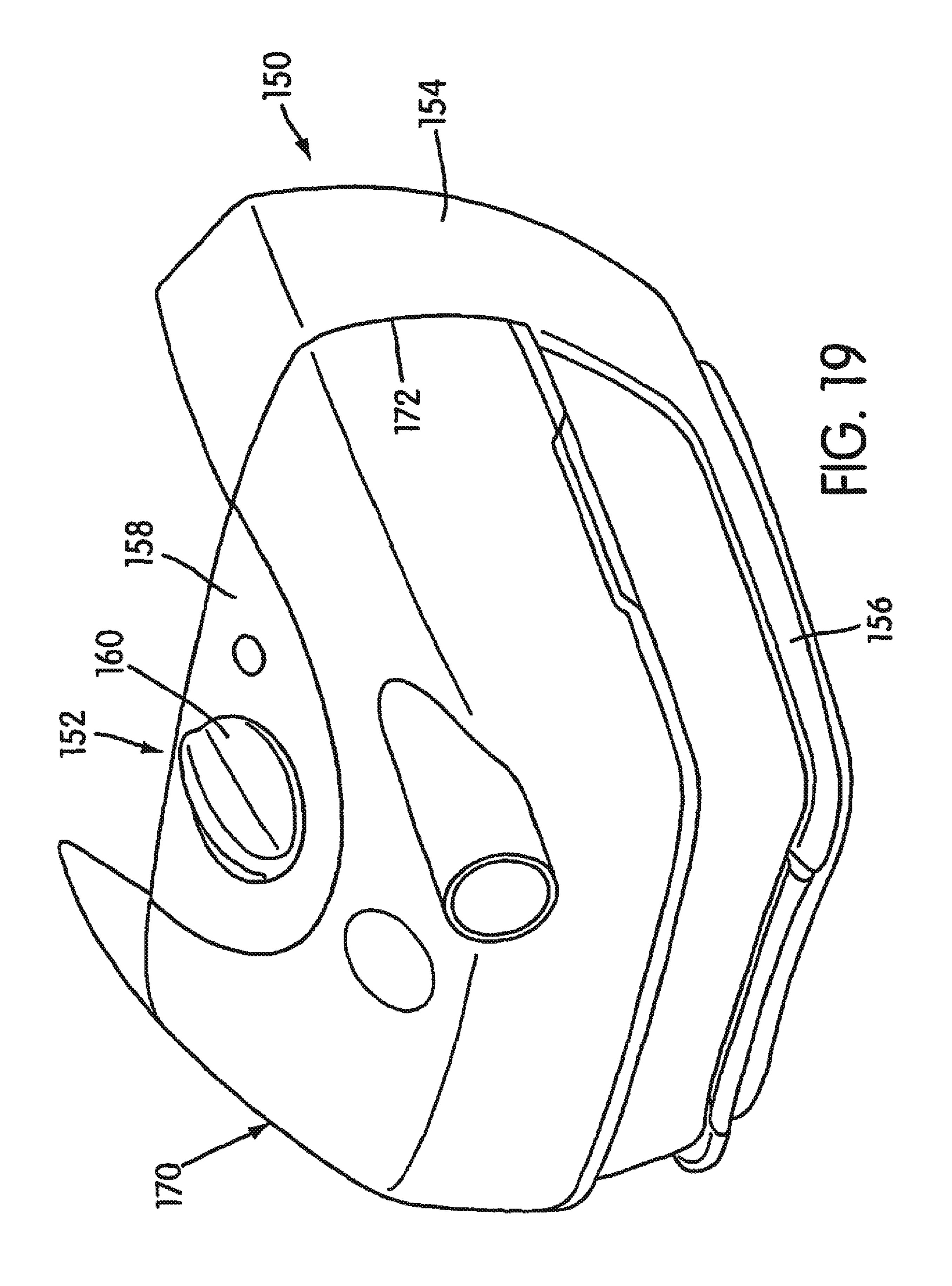
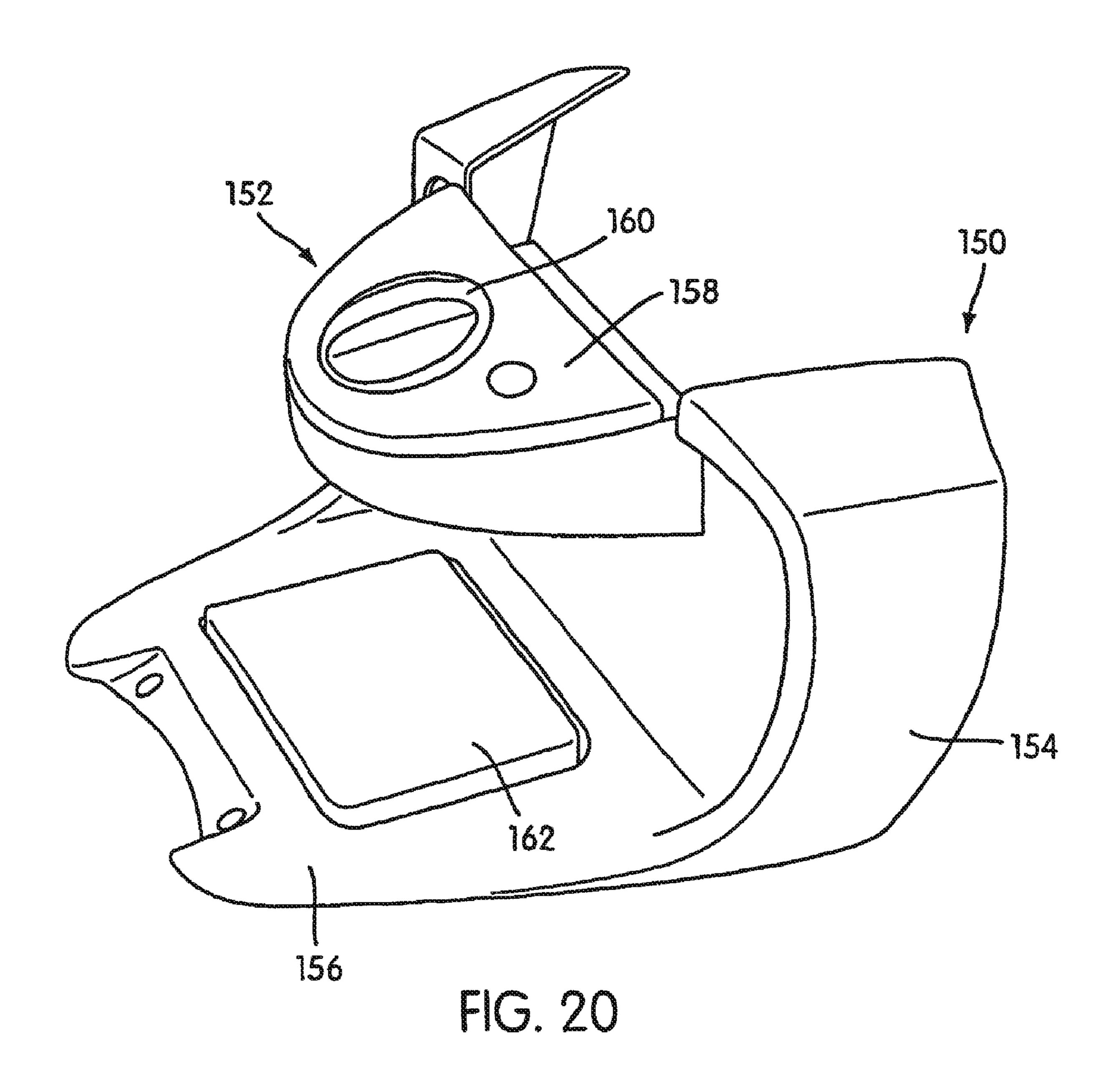
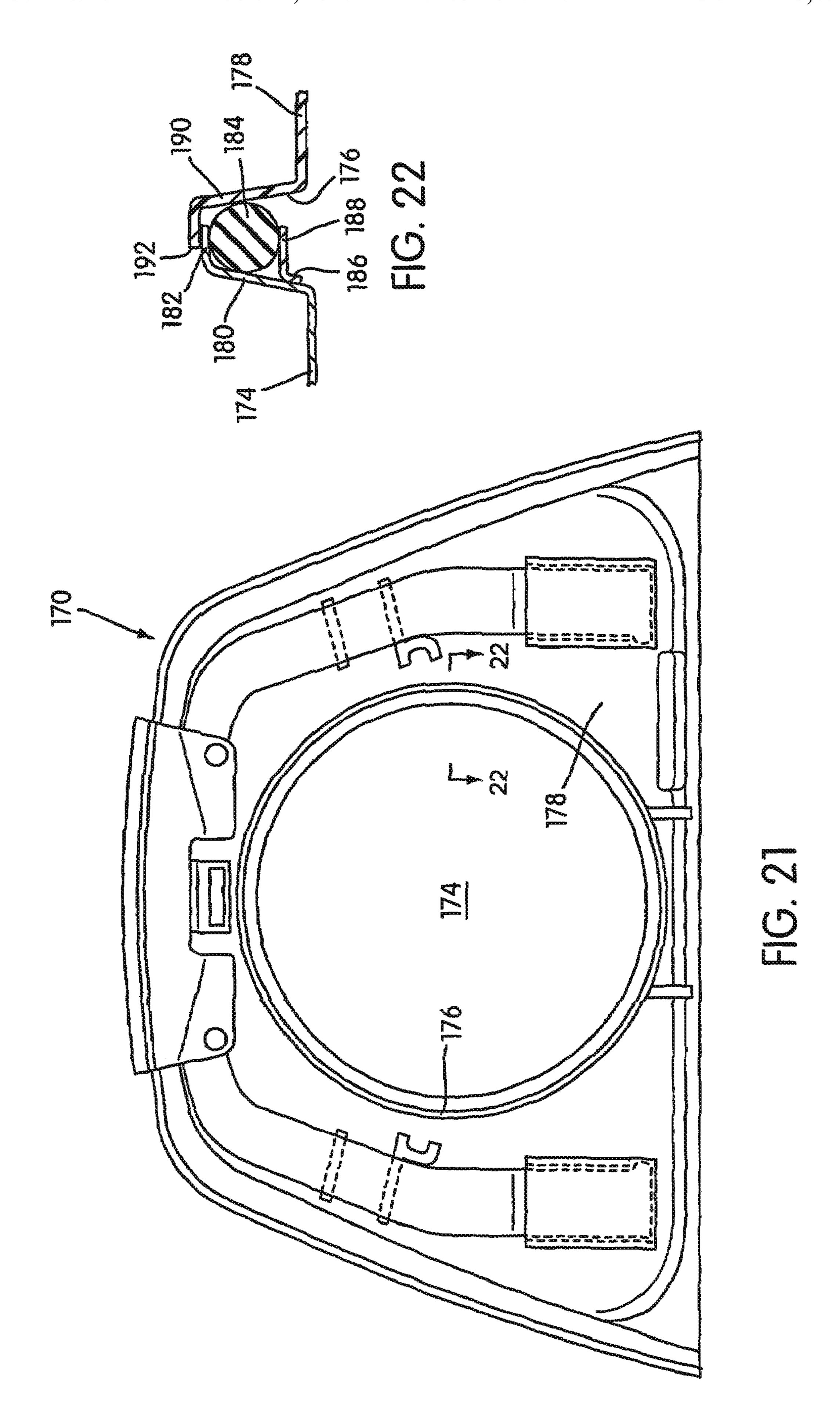
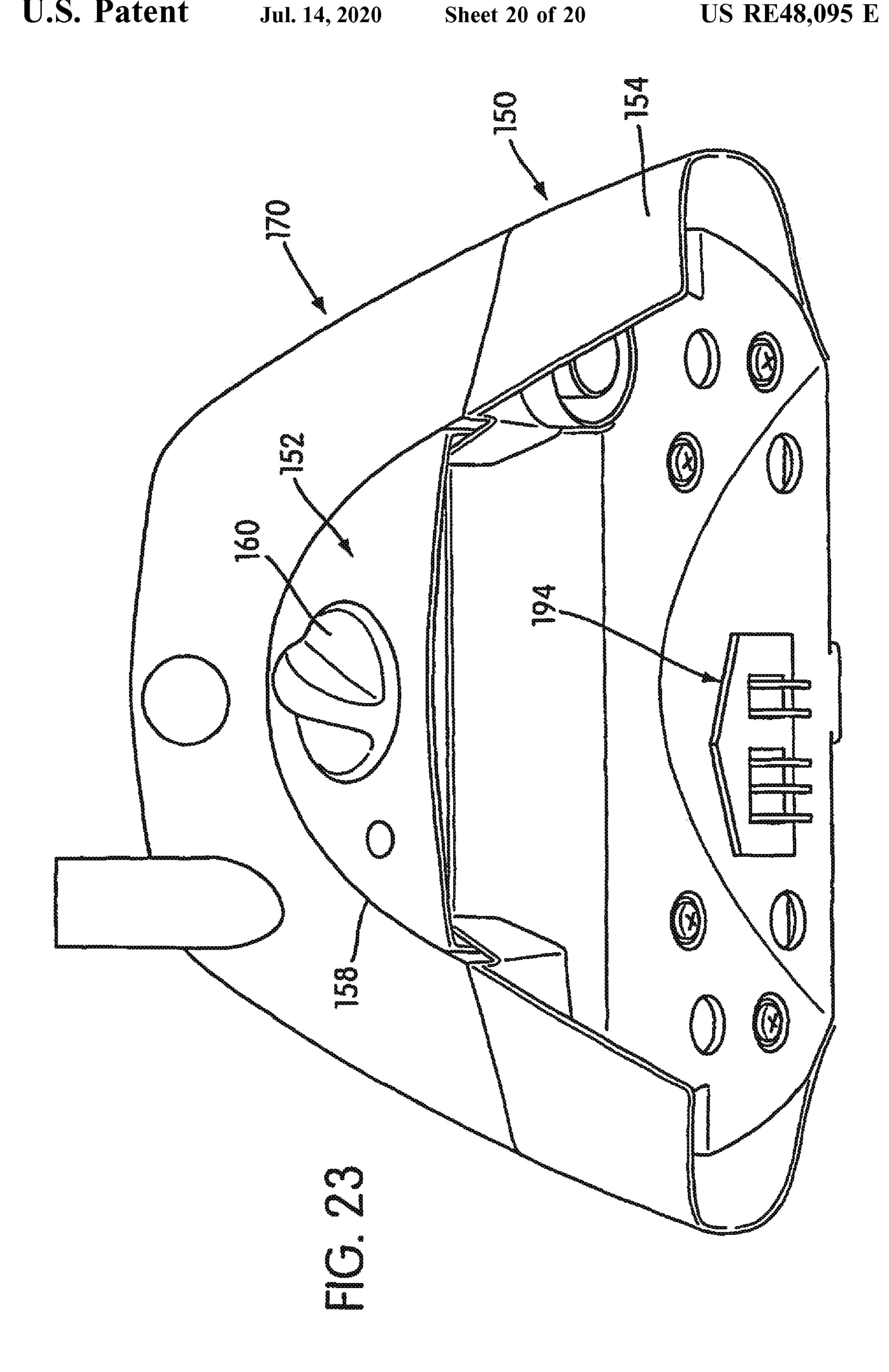


FIG. 18









# HUMIDIFIER WITH STRUCTURE TO PREVENT BACKFLOW OF LIQUID THROUGH THE HUMIDIFIER INLET

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held 10 invalid by a prior post-patent action or proceeding.

## CROSS REFERENCE TO RELATED APPLICATIONS

This application is a *continuation of Ser. No. 16/231,286*, filed Dec. 21, 2018, which is a continuation reissue of Ser. No. 15/706,811 filed Sep. 18, 2017, which is a continuation reissue of Ser. No. 15/182,919 filed Jun. 15, 2016 which is a continuation reissue of Ser. No. 13/944,960 filed Aug. 23, 2013 now RE 46,079 which is a continuation reissue of Ser. No. 13/100,783, now RE 44,453, which is an application for reissue of U.S. Pat. No. 7,614,398 filed as Ser. No. 11/181, 807 filed Jul. 15, 2005 which is a continuation of Ser. No. 25 blower. 10/467,382, filed 7 Aug. 2003, now U.S. Pat. No. 6,935,337, which is the [US] U.S. national phase of international application PCT/AU02/00155 filed 14 Feb. 2002, which designated the United States, and claims the benefit of Australia Application Nos. PR3117, filed Feb. 16, 2001, and 30 PR 7288, filed Aug. 27, 2001, each of which is incorporated herein by reference in its entirety.

The present application claims priority to Australian Provisional Applications PR3117, filed on Feb. 16, 2001 and PR7288, filed on Aug. 27, 2001, the specifications and drawings of which are incorporated by reference in their entireties.

The present invention relates to a humidifier for use with an apparatus for supplying breathable gas such as those used for Non-invasive Positive Pressure Ventilation (NIPPV) or Continuous Positive Airway Pressure (CPAP).

An apparatus for NIPPV or CPAP typically comprises a blower whose output is connected to a patient interface, such as a mask, via an air delivery conduit. Some patients find NIPPV or CPAP more comfortable when provided with humidified air. To this end, manufacturers often supply humidifiers which may be attached in the air circuit between the blower outlet and the patient interface. Humidifiers typically include a water reservoir and are configured such 50 that ambient air from the blower entering the humidifier collects moisture through contact with the water, before continuing on to the patient interface.

Typically, the blower and humidifier are separate components connected via a flexible conduit. An air delivery 55 conduit connects the humidifier outlet to a patient interface mask. Alternatively, the blower and humidifier may be rigidly-connected together. Air from the blower outlet passes into the humidifier inlet where it is humidified and then passes to the air delivery conduit. A potential problem with 60 either arrangement is that if the humidifier is tilted relative to its normal orientation, water may run or spill from the humidifier into the blower outlet which may damage the electrical circuits of the blower and potentially cause infection control problems.

It is one aspect of the present invention to substantially overcome or at least ameliorate the prior art disadvantages.

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It is another aspect to provide a humidifier for a CPAP apparatus that is adapted to substantially prevent liquid contained thereto from undesirably exiting an inlet of the humidifier.

It is another aspect to provide a humidifier that is capable of directly connecting to a CPAP apparatus.

It is another aspect to provide a humidifier that has an inlet that is directly connectable with a CPAP apparatus to effectively eliminate a supply tube.

It is another aspect to provide a humidifier that is capable of heating the liquid contained therein.

One embodiment of the present invention includes an apparatus for humidifying breathable gas including a humidifier body configured to retain a body of liquid therein, an inlet communicated with an interior of the humidifier body and connectable to a blower outlet, and an outlet communicated with the interior of the humidifier body and connectable to a patient supply conduit. The interior of the humidifier is arranged such that liquid from the body of liquid is prevented from exiting the humidifier body through the inlet thereof when the humidifier body is rotated from a working, upright orientation.

In this manner, the liquid is substantially prevented from entering the blower outlet and possibly damaging the blower.

It is contemplated that the apparatus may also include a first chamber having an inlet and an outlet, the first chamber inlet preferably being connectable to a blower outlet, a second chamber having an inlet preferably connected to the first chamber outlet, and an outlet preferably connectable to the patient supply conduit, the second chamber preferably having the carrying capacity for the body of liquid. The first chamber inlet and outlet and volumes of the first and second chambers may be adapted such that, when the humidifier is disposed in the working upright orientation, the body of liquid is contained in the second chamber and, in other relative positions of the humidifier, the body of liquid is retained in at least one of the second chamber and the first and second chambers at a level therewithin below a level of the first chamber inlet.

A volume of the second chamber may be larger than a volume of the first chamber.

The first chamber may be located substantially above the second chamber in the working upright orientation of the apparatus.

The first chamber inlet and outlet may be located adjacent opposing sections of the first chamber.

The second chamber outlet may be located closer to the first chamber outlet than the first chamber inlet.

At least a portion of a base of the second chamber may be made of a heat conducting material.

The heat conductive portion may be in the form of a metallic cap which covers an opening of the base.

The apparatus may also include a top cover, a base, and a divider disposed between the top cover and base, wherein the base defines a receptacle formed therewithin, which preferably retains the body of liquid in the working orientation of the apparatus.

The top cover and the divider together may define the first chamber and the receptacle and the divider together form the second chamber.

The first chamber inlet and the second chamber outlet may be formed in the top cover and is the first chamber outlet and the second chamber inlet may be formed in the divider, the first chamber outlet and the second chamber inlet may be defined by a single aperture in the divider which communicates the first and second chambers.

The divider may define first and second sections, the first section together with the top cover preferably defining the first chamber.

The divider may include a plurality of apertures, separated by ribs, which may provide fluid communication from the second chamber to the second chamber outlet formed in the top cover.

The top cover and the base may be formed from a relatively rigid polymer material and the divider may be formed from a relatively resilient material.

The first chamber inlet may be connected to a blower outlet, the first chamber outlet may be connected to the second chamber inlet, the second chamber outlet may be connected to the patient supply conduit, and a portion of the second chamber below and behind the second chamber inlet 15 may define a volume thereof greater than a volume of the body of liquid.

A portion of the second chamber between the first chamber inlet and the second chamber inlet and below the second chamber inlet may define a volume thereof greater than the volume of the body of liquid.

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Portions of the first chamber and second chamber between the first chamber inlet and the second chamber outlet may define a volume thereof greater than the volume of the body of liquid.

Another embodiment of the present invention includes a CPAP apparatus including an apparatus for humidifying breathable gas as described above.

Another embodiment of the present invention includes a humidifier for a CPAP apparatus having a humidifier body 30 defining a fluid reservoir and a fluid passage therein. The humidifier body has first and second chambers with a dividing member therebetween. The dividing member includes an orifice therethrough to communicate the first and second chambers with one another. Air from a blower (not 35) shown) arrives in the first chamber via a first chamber inlet and departs from the second chamber via a second chamber outlet. The fluid passage includes the inlet, outlet, the orifice, and, at least, portions of the first and second chambers. The humidifier is designed to carry a body of liquid having a 40 19; maximum volume,  $V_{max}$ . In a working orientation of the humidifier, the liquid body lies in a bottom portion of the second chamber. With respect to the working orientation of the humidifier the orifice lies forward of and to the side of the inlet. The first and second chambers are configured such 45 that a volume of a first portion of the second chamber, which lies directly beneath the fist chamber, is greater than  $V_{max}$ . Additionally, the volume of a second portion of the second chamber, which is disposed to the side of the first chamber, is greater than  $V_{max}$ . Furthermore, the volume of a portion 50 of the second chamber forward of the inlet plus a portion of the first chamber forward of the inlet is greater than  $V_{max}$ . Additionally, the volume of a portion of the second chamber to the side of the inlet plus a portion of the first chamber to the side of the inlet is greater than  $V_{max}$ .

Yet another embodiment of the present invention includes a humidifier for a CPAP apparatus having first and second chambers, wherein an inlet to the humidifier is communicated with the first chamber, an outlet from the humidifier is communicated with the second chamber, and the first and second chambers are intercommunicated via an orifice extending therebetween. The inlet and orifice are arranged relative to one another such that a level of a volume of liquid present within the humidifier is below at least one of the inlet and orifice for any orientation of the humidifier.

Although certain embodiments of the invention are illustrated and described herein as having certain features, one

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skilled in the art would recognize that alternative embodiments of the invention could be provided based on at least one or more features, either individually or in combination, of the illustrated and described embodiments.

The benefits of the present invention will be readily appreciated and understood from consideration of the following detailed description of embodiments of this invention, when taken with the accompanying drawings, wherein:

FIG. 1 is a schematic view of a humidifier according to one embodiment of the present invention in a working, upright orientation;

FIGS. 2-5 are schematic views of the humidifier shown in FIG. 1 in corresponding non-working, upright orientations;

FIG. **6** is a perspective view of a humidifier according to another embodiment of the present invention in a working, upright orientation;

FIG. 7. Is an exploded perspective view of the humidifier shown in FIG. 6;

FIG. 8 is a partial sectional view of the humidifier shown in FIG. 6.

FIG. 9 is schematic view of the humidifier shown in FIG. 6 showing an air flow path through the humidifier;

FIGS. 10-13 are schematic views of the humidifier shown in FIG. 6 in corresponding non-working, upright orientations;

FIG. 14 is a perspective view of a humidifier and connecting structure according to another embodiment of the present invention;

FIG. 15 is a perspective view of the connecting structure shown in FIG. 14;

FIG. 16 is a bottom plan view of the humidifier shown in FIG. 14;

FIG. 17 is a rear perspective view of the humidifier and connecting structure shown in FIG. 14;

FIG. 18 is a bottom perspective view of the connecting structure shown in FIG. 14;

FIG. 19 is a perspective view of a humidifier and heater according to another embodiment of the present invention; FIG. 20 is a perspective view of the heater shown in FIG.

FIG. **21** is a bottom view of the humidifier shown in FIG. **19**;

FIG. 22 is a cross-sectional view taken along line 22-22 in FIG. 21; and

FIG. 23 is a rear perspective view of the humidifier and heater shown in FIG. 19.

FIG. 1 schematically illustrates one embodiment of the humidifier of the present invention, indicated at 10. The humidifier 10 includes a humidifier body 12 defining a fluid reservoir and fluid passage therein. Additionally, there are two chambers 14, 16 defined by the humidifier body 12 and a dividing member 18. The dividing member 18 includes an orifice 20 therethrough to communicate the chambers 14, 16 to one another. Air from a blower (not shown) arrives in the first chamber 16 via a first chamber inlet 22. Air departs from the second chamber 14 via a second chamber outlet 24. The fluid passage includes the inlet 22, outlet 24, the orifice 20, and, at least, portions of the chambers 14, 16. The humidifier 10 is designed to carry a body of liquid 26 having a maximum volume, V<sub>max</sub>.

In a working orientation represented in FIG. 1, the liquid body 26 lies in a bottom portion of the second chamber 14. With respect to the orientation of the humidifier 10 depicted in FIG. 1, e.g., the orifice 20 lies forward of and to the side of the first chamber inlet 22 (e.g., at a diagonally opposite end of the chamber 16). As shown, the volume of a first portion 14A of the second chamber 14, which lies directly

beneath the first chamber 16, is greater than  $V_{max}$  due to its relatively increased height. Additionally, the volume of a second portion 14B of the second chamber 14, which is disposed to the side of the first chamber 16, is greater than  $V_{max}$ . Furthermore, the volume of a portion of the second <sup>5</sup> chamber 14 forward of the inlet 22 plus a portion of the first chamber 16 forward of the inlet 22 is greater than  $V_{max}$ . Additionally, the volume of a portion of the second chamber 14 to the side of the inlet 22 plus a portion of the first chamber 16 to the side of the inlet 22 is greater than  $V_{max}$ . Hence, in order to minimize the volume of the humidifier 10, the first chamber inlet 22 is positioned as far to one side of the humidifier body 12 and as far rearward of the humidifier body 12 as possible.

The embodiment of the humidifier 10 shown in FIGS. 1-5 is configured to prevent liquid from the liquid body 26 from exiting through the inlet 22 thereof, such as when inadvertently rotated from an upright, normal working position (generally illustrated in FIG. 1). For this reason, it is 20 sponding to the position of the blower outlet. preferable for the humidifier 10 to be capable of being rotated from the upright, working position by about 120° without allowing liquid to exit from the inlet 22. It is more preferable for the humidifier 10 to be capable of being rotated from the upright, working position by about 80°- 25 110° without allowing liquid to exit from the inlet 22. It is contemplated that for the embodiment of the humidifier 10 shown in FIG. 1, it may be especially preferable for the humidifier 10 to be capable of being rotated from the upright, working position by about 90° without allowing 30° liquid to exit from the inlet 22, since the humidifier 10 is readily able to be placed on one side thereof due to the substantially fiat, normal sides thereof. However, of course, it may be desirable for the humidifier 10 to be capable of being rotated more or less than 90°, depending on the 35 particular configuration of the humidifier 10. It is noted that while the humidifier 10 is designed to prevent liquid from exiting the inlet thereof when inadvertently oriented in other than the upright working position, it may be possible to purposefully enable liquid to exit from the inlet, such as by 40 jostling or rapidly and/or repeatedly rotating the humidifier 10. In situations wherein it is highly undesirable for liquid to exit the inlet of the humidifier, the configuration (e.g., volume) of the chambers, size and placement of the inlet and outlet, and size and placement of the aperture intercommu- 45 nicating the chambers may be altered from the illustrated embodiment to decrease the possibility of liquid exiting the inlet of the humidifier.

As shown in FIG. 2, the arrangement of the chambers 14, 16, inlet 22, and outlet 24 means that, if the humidifier 10 is 50 rotated in a clockwise direction by up to 90° about axis  $\alpha$ , then the liquid body 26 will accumulate in the second portion 14B of the second chamber 14 and a portion of the first chamber 16 adjacent the outlet 24. In this situation, liquid of the liquid body 26 may run out of the outlet 24, but 55 will not run out of the inlet 22 back into the blower.

Similarly, as shown in FIG. 3, if the humidifier 10 is rotated in a counter-clockwise direction (relative to the position illustrated in FIG. 1) by up to 90° about axis  $\alpha$ , then the liquid body 26 will accumulate in the first portion 14A 60 of the second chamber 14, but will not spill over orifice 20 into the first chamber 16.

As shown in FIG. 4, if the humidifier 10 is rotated in a clockwise direction (relative to the position illustrated in FIG. 1) up to 90° about axis  $\beta$ , then the liquid body 26 will 65 accumulate in a rearward portion of the second chamber 14 but will not spill over orifice 20 into the first chamber 16.

As shown in FIG. 5, if the humidifier 10 is rotated in a counter-clockwise direction (relative to the position illustrated in FIG. 1) up to 90° about axis β, then the liquid body 26 will accumulate in forward portions of the first and second chambers 14, 16 and will not spill back through first chamber inlet 22. Furthermore, liquid of the liquid body 26 will drain out of the humidifier 10 through second chamber outlet 24.

In the embodiment illustrated in FIGS. 1-5, the humidifier 10 10 has an exterior shape that is generally rectangular and the humidifier 10. As illustrated, the inlet 22 is positioned to correspond to a blower outlet being on the upper left-hand side when viewed from the front in an upright position. Therefore the humidifier inlet 22 is positioned at the back of 15 the humidifier 10 on the upper left-hand side, when viewed from the front in an upright position. The humidifier outlet 24 lies on the front upper right-hand side, when viewed from the front in an upright position. However, it is, of course, possible for the inlet and outlet to be repositioned corre-

For each of the orientations of the humidifier 10 shown in FIGS. 1-5, the level of the liquid body 26 is always below the level of at least one of the inlet 22 and orifice 20 intercommunicating the first and second chambers 16, 14. In this manner, in a case wherein the inlet 22 is disposed below the level of the liquid body 26 (such as in orientations illustrated in FIGS. 3 and 4), the orifice 20 is disposed above the level of the liquid body 26, which prevents liquid from flowing therethrough and exiting the inlet 22. Conversely, in a case wherein the orifice 20 is disposed-below the level of the liquid body 26 (such as in orientations illustrated in FIGS. 2 and 5), the inlet 22 is disposed above the level of the liquid body 26. Accordingly, liquid may flow through the orifice 20, but is prevented from exiting through the inlet 22.

FIG. 6 shows another embodiment of a humidifier 30 according to the present invention. The humidifier 30 includes an inlet 32 and an outlet 34, both of which are communicated with an interior of the humidifier 30. The interior of the humidifier 30 defines a reservoir for a body of liquid and a fluid passage. The fluid passage is communicated to each of the inlet 32 and outlet 34 and is configured such that fluid (e.g., breathable gas at an elevated pressure) flowing therethrough is exposed to the body of liquid. Additionally, the humidifier 30 is adapted for detachable connection to an NIPPV or CPAP apparatus (not shown) which includes a blower. When connected, the output of the blower is attached to the inlet 32. Air from the blower enters the inlet 32, flows through the fluid passage, and collects moisture through contact with the liquid body, before continuing on to the outlet 34 and then to the patient.

It is also contemplated that the humidifier 30 may include an additional internal passage to allow monitoring of the CPAP pressure without degrading signal strength or necessitating relatively large correction factors due to signal attenuation within the humidifier, such as described in co-pending Applications incorporated above, as well as co-pending Application No. WO 02/066107, entitled "Air Pressure Signal Monitoring in Apparatus for Treating Sleep Disordered Breathing", filed on even date herewith and hereby incorporated by reference in its entirety.

As shown in FIG. 7, the humidifier 30 includes a top cover 36, a gasket 38, and a base 40. The gasket 38 is disposed between the top cover 36 and base 40, which are secured together via sliding clips 72. (See FIG. 6.) Of course, other suitable fastening arrangements and constructions are possible. For example, the top cover 36 and base 40 may be formed with snap-fit or other cooperating constructions.

Alternatively, other types of mechanical fasteners may be utilized. It is contemplated that the top cover 36 may be formed from a relatively rigid polymer material, such as polysulfone (for example, grade UDEL P1700, manufactured by BP Amoco Polymers), and includes the inlet 32 and 5 the outlet **34**. The gasket **38** may be formed from a relatively resilient material, such as silicone rubber (for example, SILASTIC 94595-IIC, manufactured by Dow Corning) and is divided into first and second sections 42 and 44 by a channel structure 46. The first section 42 includes a raised 10 portion 48 having a first aperture 50 extending vertically therethrough. The second section 44 includes a plurality of second apertures 52 extending vertically therethrough and being separated from one another by ribs 54. The top cover which corresponds to and is received within the channel structure 46 of the gasket 38. The gasket 38 includes a sealing flange **58** formed about a periphery thereof. The base 40 may be formed from the same or similar rigid polymer material as the top cover **36** and may include a receptable **60** 20 formed therewithin, a bottom portion 62, and side walls 64 extending upwardly from the bottom portion **62**. The base **40** may also include a removable bridge structure 66, which divides the receptacle 60 into two sections 68 and 70, which correspond to the sections [22] 42 and [24] 44 of the gasket 25 **38**.

As shown in FIG. 8, to assemble the humidifier 30, the gasket 38 is attached the base 40. The flange 58 of the gasket **38** forms a sealing engagement with an upper edge portion of the side walls **64** of the base **40**. The top cover **36** is then 30 attached to the base 40 via sliding clips 72 (FIG. 6) on opposite sides of the humidifier 30, such that the top cover 36 covers and seals with the gasket 38. The removable bridge structure 66 vertically supports an intermediate portion of the gasket 38. As shown, a downwardly facing 35 surface of the channel structure 46 of the gasket 38 engages an upwardly facing surface of the bridge structure 66. When assembled, the gasket first section 42, the top cover 36, and the divider wall structure of the top cover 36 together form a first chamber 74. The receptacle 60 of the base 40 together 40 with the gasket 38 form a second chamber 76. The first chamber 74 is thus located above the second chamber 76 and the volume of the second chamber 76 is larger than the volume of the first chamber 74. The first and second chambers 74, 76 are in communication with one another via 45 the first aperture 50 within the gasket 38. The second chamber 76 is in communication with the outlet 34 via the second apertures 52 within the gasket 38.

In use, a predetermined maximum volume of liquid is poured into the receptacle 60 of the base 40 after removing 50 the top cover **36** and the sealing gasket **38** from the base **40**. The top cover 36 and the sealing gasket 38 are then reattached to the base 40. As shown in FIG. 9, a body of liquid 78 is held in the second chamber 76 when the humidifier 10 is in the upright working orientation of the 55 humidifier 30. Breathable gas from the blower enters the inlet 32 and travels through the first chamber 74 and into the first aperture 50. The gas passes through the aperture 50 and enters the second chamber 76 where it is humidified by contact with the body of liquid 78, before exiting through 60 apertures 52 in the gasket 38, and then out through outlet 34 (FIG. **6**).

In the working upright orientation of the humidifier 30, as shown in FIG. 9, a liquid level, indicated at 81, of the body of liquid 78 is below the aperture 50. Thus, liquid from the 65 body of liquid 78 cannot exit via the inlet 32 and there is no risk of damaging the electronic components of the NIPPV or

CPAP apparatus. The body of liquid 78, however, will be displaced in the humidifier 30 according to the orientation of the humidifier 30. Accordingly, the humidifier 30 is configured to substantially prevent liquid of the body of liquid 78 from exiting through the inlet 32 in non-upright orientations to avoid damage to the NIPPV or CPAP apparatus connected to the humidifier 30.

Similarly as with the embodiment illustrated in FIGS. 1-5, the embodiment of the humidifier 30 shown in FIGS. 6-13 is configured to prevent liquid from the liquid body 78 from exiting through the inlet 32 thereof, such as when inadvertently rotated from an upright normal working position (generally illustrated in FIG. 6). For this reason, it is preferable for the humidifier 30 to be capable of being 36 may also include a divider wall structure 56 (FIG. 8) 15 rotated from the upright, working position by about 120° without allowing liquid to exit from the inlet 32. It is more preferable for the humidifier 30 to be capable of being rotated from the upright, working position by about 80°-110° without allowing liquid to exit from the inlet 32. It may be especially preferable for the humidifier 30 to be capable of being rotated from the upright, working position by about 90° without allowing liquid to exit from the inlet 32. However, of course, it may be desirable for the humidifier 30 to be capable of being rotated more or less than 90°. It is noted that while the humidifier 30 is designed to prevent liquid from exiting the inlet thereof when inadvertently oriented in other than the upright working position, it may be possible to purposefully enable liquid to exit from the inlet, such as by jostling or rapidly and/or repeatedly rotating the humidifier 30. In situations wherein it is highly undesirable for liquid to exit the inlet of the humidifier, the configuration (e.g., volume) of the chambers, size and placement of the inlet and outlet, and size and placement of the aperture intercommunicating the chambers may be altered from the illustrated embodiment to decrease the possibility of liquid exiting the inlet of the humidifier.

> For each of the orientations of the humidifier 30 shown in FIGS. 10-13, the level of the liquid body 78 is always below the level of at least one of the inlet 32 and aperture 50 intercommunicating the first and second chambers 74, 76. In this manner, in a case wherein the inlet **32** is disposed below the level of the liquid body 78 (such as in orientations illustrated in FIGS. 10 and 12), the aperture 50 is disposed above the level of the liquid body 78, which prevents liquid from flowing therethrough and exiting the inlet 32. Conversely, in a case wherein the aperture **50** is disposed below the level of the liquid body 78 (such as in orientations illustrated in FIGS. 11 and 13), the inlet 32 is disposed above the level of the liquid body 78. Accordingly, liquid may flow through the aperture 50, but is prevented from exiting through the inlet 32.

> In FIG. 10, the humidifier 30 is rotated to an angle about 90° from the working upright orientation, such that a side 80 thereof corresponding to the side of the humidifier 30 adjacent the inlet 32, is oriented below a side 82 thereof corresponding to the side of the humidifier 30 adjacent the outlet 34. Because the raised portion 48 of the gasket 38 increases the volume of the second chamber 76, the body of liquid 78 remains only in the second chamber 76 and the level 81 of the liquid body 78 remains below the first aperture 50. Thus, the liquid will not exit through the inlet **32**.

> In FIG. 11, the humidifier 30 is rotated to an angle about 90° from the working upright orientation, such that the side 82 is below the side 80 (i.e., flipped 180° from the orientation illustrated in FIG. 11). As the level 81 of the body of liquid 78 is above (at least initially) the apertures 52, liquid

will pass therethrough and exit the outlet **34**. However, since the level 81 of the liquid body 78 is below the inlet 32, liquid will not exit through the inlet 32. Liquid exiting through the outlet 34 is generally acceptable as there is not generally a risk in damaging the NIPPV or CPAP apparatus.

In FIG. 12, the humidifier 30 is rotated to an angle about 90° from the working upright orientation, such that a rear side thereof indicated at 84, corresponding to the side at which the inlet 32 is located, is below a forward side thereof indicated at **86**, corresponding to the side at which the outlet 10 34 is located. As shown, the body of liquid 78 remains substantially in the second chamber 76 and the level 81 of the liquid body 78 remains below the first aperture 50. Thus, water cannot exit through the inlet 32.

FIG. 13 illustrates when the humidifier 30 is tilted to an 15 angle about 90° from the working upright orientation, such that the forward side **86** is below the rear side **84**. As shown, the body of liquid 78 is disposed within forward portions of the first and second chambers 74, 76. As the level 81 of the body of liquid **78** is at least initially above the level of the 20 aperture 50, liquid will flow through the aperture 50 into the first chamber 74. However, since the inlet 32 is disposed above the level of the body of liquid 78 in this orientation, no liquid exits through the inlet 34.

The humidifier 30 thus ensures that the body of liquid 78 25 is disposed in one of (a) only the second chamber 76, or (b) portions of the first and second chambers 74, 76 at a level below the inlet 32, to prevent liquid from exiting through the inlet 32 at orientations of the humidifier 30 up to an angle of about 90° from the working upright orientation. In the 30° illustrated embodiment, a number of features of the humidifier 30 contribute to ensuing this function. These include relive positions of the inlet 32 and first aperture 50. More particularly, the inlet 32 and first aperture 50 are located on opposing ends of the first chamber 74. Also, the volume of 35 the second chamber 76 is larger than the volume of the first chamber 74, which is assisted by the raised portion 48 of the gasket 38 so that liquid displaced from the first chamber 74 may be accommodated within the second chamber 76 without overflow through aperture **50**. Furthermore, the outlet **34** 40 is located closer to the first aperture 50 than the inlet 32, which assists in ensuing that liquid will exit via the outlet 34, rather than though the inlet 32.

The humidifier 30 therefore substantially prevents or reduces the risk of water exiting through the inlet 32, which 45 may damage the NIPPV or CPAP apparatus, when the humidifier 30 is in other orientations up to an angle of about 90° from its working upright orientation.

It is contemplated that the humidifier 30 may be used as a retrofit or add-on component for a CPAP apparatus. To 50 facilitate this usage, it may be preferable to provide a connecting structure 100 that is configured to connect between the CPAP apparatus and humidifier 30. As shown in FIGS. 14 and 15, the connecting structure 100 includes a housing 102, which provides a generally horizontally 55 so as to be connected to the CPAP apparatus. extending receptacle 104 within which the humidifier 30 may be disposed. The housing 102 provides a base portion 106 that is configured to support the humidifier 310 thereon and a retaining portion 108 configured to secure the humidifier 30 in position. As shown in FIG. 16, the retaining portion 60 108 extends generally parallel to the base portion 106 and is spaced above the base portion 106. Referring back to FIG. 14, the humidifier 30 may be formed with a recess 110 that is open and of a complimentary shape to receive the retaining portion 108 therein.

To facilitate connection of the humidifier 30 to the connecting strut 100, it is contemplated that another embodi**10** 

ment of a humidifier, indicated at 120 in FIG. 16, may include a securing mechanism 122. As shown, the securing mechanism 122 includes a resiliently biased pull member **124** that includes one or more locking lugs **126** extending generally downwardly therefrom. The pull member 124 is disposed at a forward end (assuming the rearward end of the humidifier 120 is adjacent the connecting structure 100) of the humidifier 120 and is resiliently biased by a pair of resilient legs 128. Rearward portions of the legs 128 are relatively securely retained within corresponding pocket structures 130 provided on a bottom side of the humidifier 120. Ribs 132 extend is downwardly from the bottom side of the humidifier 120 and engage an intermediary portion of the legs 128 to define a space between the resilient legs 128 and the bottom side of the humidifier 120. In this manner, the pull member 124 is biased generally downwardly by the resilient legs 128, but may be manually moved (e.g., pulled) upward against a resilient bias of the legs 128.

As shown in FIG. 15, a forward portion of the base portion 106 includes generally upwardly open lug receiving recesses 134 within which the lugs 126 may be disposed when the humidifier 120 is disposed within the receptacle 104. As the humidifier 120 is inserted within receptacle 104, the legs 128 resiliently bias the legs 126 into recesses 134. The lugs 126 and recesses 134 thereby secure the humidifier 120 within the receptacle 104. To remove the humidifier 120 from the receptacle 104, the pull member 124 is pulled upwardly to withdraw the lugs 126 from the recesses 134. The humidifier 120 may then be pulled generally horizontally out of the receptacle 104.

FIG. 17 shows a rearward side of the connecting structure 100. The rearward side of the connecting structure 100 provides a retaining mechanism 140 to secure the connecting structure 100 to the CPAP apparatus. It is contemplated that the retaining mechanism 140 may include a series of apertures 142 within the rearward portion of the housing 102. The apertures 142 may receive therein, for example, prongs or tabs (not shown) provided by the CPAP apparatus. As shown in FIG. 18, within each aperture 142, a locking member 144 may be provided that is resiliently biased toward a position that partially encloses the respective aperture 142. As also shown in FIG. 18, a button structure 146 may be coupled to the locking members 144, such that manual movement of the button structure 146 moves the locking members 144 out of their biased positions to substantially fully open the apertures 142. It is contemplated that the tabs or prongs on the CPAP apparatus are provided with a groove therein such that when positioned within the apertures 142, the locking members 144 engage within respective grooves to thereby securely and detachably retain the connecting structure 100 to the CPAP apparatus.

Referring back to FIG. 17, the housing 102 of the connecting structure 100 may be provided with an opening 148 that allows the inlet of the humidifier to extend therethrough

In certain circumstances, it may be desirable to provide heated humid air to the respirator mask. Accordingly, another embodiment of the connecting structure, indicated at 150 in is FIG. 19, may include a heater 152. The connecting structure 150 may include a housing 154, which provides a base portion 156 and retaining portion 158, similar to the housing 102 described above. As shown in FIG. 19, the retaining portion 158 may include a controller such as a knob or other selecting device 160 thereon to control a heat 65 setting of the heater 152. It is also contemplated that the controller 160 may include a display device, such as an LCD screen.

As shown in FIG. 20, the base portion 156 may include a heating element 162 thereon. The heating element 162 may be in the form of a substantially flat plate-like resistance heater, which heat generated thereby may be directly controlled by the controller 160. As shown in FIG. 19, another 5 embodiment of the humidifier is indicated at 170. The humidifier 170 is disposed within a receptacle 172 provided by the housing 154. It is contemplated that the humidifier 170 has the same basic construction as the humidifiers 10 and 120 described above. However, it is contemplated that the humidifier 170 may include a heating plate 174 (also referred to as a metallic cap) to facilitate heating of the liquid contained therein. In particular, an opening 176 is provided within a bottom wall **178** of the humidifier **170**. The heating plate 174 is shaped to fit within the opening 176, as shown in FIG. 21. As shown in more detail in FIG. 22, the heating 15 plate 174 includes an upstanding peripheral wall 180 which includes an outwardly extending peripheral lip 182. A resilient seal member **184** is disposed about an outer periphery of the peripheral wall 180 in contact with the peripheral lip 182. A ring-like retaining member 186 may be press-fit onto 20 ity.] the peripheral wall **180** to retain the seal **184** in position on the peripheral wall **180**. The retaining member **186** includes an outwardly extending flange structure **188**. The seal **184** is disposed between the peripheral lip 182 and flange structure **188**. It is contemplated that the retaining member **186** may be press fit onto the heating plate 174, as described above, or may be formed in one piece therewith. The bottom wall 178 of the humidifier 170 is formed with an annular upstanding flange 190 which receives the heating plate 174. It is contemplated that the flange 190 may be slightly tapered inwardly in the upward direction to ease insertion of the heating plate 174. As shown, the flange 190 may include a generally horizontally extending lip structure 192 that vertically retains the heating plate 174.

Referring to FIG. 19, with the humidifier 170 in position within the receptacle 172, a bottom surface of the heating plate 174 is in contact with an upper surface of the heating element 162. In this manner, a heat generated by the heating element 162 is conducively transferred to the heating plate 174. The liquid within the humidifier 170 is exposed to an upper surface of the heating plate 174 and conducts heat 40 therefrom. It is contemplated that a temperature of the liquid within the humidifier 170 may be controlled by manipulation of the controller 160.

It is also contemplated that the heating element **162** may be upwardly resiliently biased to ensure adequate contact between the heating element **162** and the heating plate **174**.

As shown in FIG. 23, a rearward portion of the connecting suture 150 may include a plurality of generally outwardly extending contact elements 194. It is contemplated that the contact element 194 may communicate with a power supply within the CPAP apparatus and/or a controller and/or sensors. In this manner, power may be delivered to the heater 152 directly from the CPAP apparatus. Additionally, a controller within the CPAP apparatus itself may control the heater 152. Furthermore, it is contemplated that sensors within the CPAP apparatus may monitor a heat output of the heater 152. Moreover, it may be possible for a CPAP apparatus to automatically adjust a heat output of the heater 152 based on a measured temperature thereof or of the water within the humidifier or of the breathable air exiting the humidifier.

The invention claimed is:

- [1. A humidifier assembly for a CPAP apparatus, comprising
  - a humidifier including
    - a base configured to retain a body of liquid therein, at least a portion of the base being constructed of a heat conducting material,

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a top cover, and

- a seal disposed between the top cover and the base; and a connecting structure configured to connect between the CPAP apparatus and humidifier and allow communication of an outlet of the CPAP apparatus with the inlet of the humidifier, the connecting structure including
  - a housing providing a base portion to support the humidifier thereon, and
  - a retaining mechanism configured to secure the connecting structure to the CPAP apparatus,
- wherein the base portion includes a heating element in contact with the heat conducting material of the base of the humidifier.
- [2. A humidifier assembly according to claim 1, wherein the top cover defines both an inlet and an outlet communicated with an interior of the base, the inlet configured to receive pressurized breathable gas and the outlet configured to deliver the pressurized breathable gas with added humidity.]
- [3. A humidifier assembly according to claim 1, wherein the connecting structure includes a control knob to control a heat setting of the heating element.]
- [4. A humidifier assembly according to claim 1, wherein the connecting structure includes contact elements that communicate with a power supply within the CPAP apparatus.]
- [5. A humidifier assembly according to claim 1, wherein the connecting structure is configured to allow removable attachment of the CPAP apparatus to the humidifier.]
- [6. A humidifier assembly according to claim 1, wherein the heat conducting material is a metallic material.]
- [7. A CPAP apparatus including a humidifier assembly according to claim 1.]
- 8. A humidification chamber for connecting to a respiratory therapy device to provide respiratory therapy, the humidification chamber comprising:
  - a bottom surface constructed of a heat conductive material, wherein the bottom surface is configured to be positioned over a heating element of the respiratory therapy device;
  - a wall extending from the bottom surface and defining a volume to hold water in the humidification chamber;
  - a top surface, the bottom surface, wall, and top surface together enclosing the volume;
  - a chamber inlet configured to receive pressurized breathable gas from the respiratory therapy device when the humidification chamber is connected to the respiratory therapy device, the chamber inlet shaped to mate with an output of the respiratory therapy device through which the pressurized breathable gas is received;
  - a chamber outlet configured to supply the pressurized breathable gas with added humidity for delivery to a patient to provide respiratory therapy; and
  - an obstruction within the chamber that is positioned between the bottom surface and the top surface, wherein the obstruction has a maximum horizontal dimension that is greater than a maximum vertical dimension of the obstruction, wherein the obstruction extends at least partially across an interior of the humidification chamber along a horizontal plane, wherein the obstruction defines, at least partially, one or more fluid inlet passageways between the chamber inlet and the water contained in the humidification chamber, the one or more fluid inlet passageways causing the pressurized breathable gas received through the chamber inlet to be, at least partially,

diverted around the obstruction before reaching the water contained in the humidification chamber for added humidification.

- 9. The humidification chamber of claim 8, wherein the one or more fluid inlet passageways are defined by the obstruc- 5 tion and the top surface.
- 10. The humidification chamber of claim 8, wherein the one or more fluid inlet passageways are defined by the obstruction and the wall.
- 11. The humidification chamber of claim 8, wherein the one or more fluid inlet passageways are defined by the obstruction, the top surface, and the wall.
- 12. The humidification chamber of claim 8, wherein the one or more fluid inlet passageways being at least partially offset from the chamber inlet so as to cause the at least partial diversion of the of the pressurized breathable gas.
- 13. The humidification chamber of claim 8, wherein the obstruction further defines, at least partially, one or more fluid outlet passageways between the water contained in the 20 humidification chamber and the chamber outlet, the one or more fluid outlet passageways causing the pressurized breathable gas with added humidification to be, at least partially, diverted around the obstruction before being expelled through the chamber outlet.
- 14. The humidification chamber of claim 13, wherein the one or more fluid outlet passageways are defined by the obstruction and the top surface.
- 15. The humidification chamber of claim 13, wherein the one or more fluid outlet passageways are defined by the obstruction and the wall.
- 16. The humidification chamber of claim 13, wherein the one or more fluid outlet passageways are defined by the obstruction, the top surface, and the wall.
- 17. The humidification chamber of claim 13, wherein the one or more fluid outlet passageways being at least partially offset from the chamber outlet so as to cause the at least partial diversion of the of the pressurized breathable gas with added humidification.
- 18. The humidification chamber of claim 8, further comprising:
  - an internal vertical wall positioned within the interior of the humidification chamber and extending at least partially below the obstruction, wherein the internal vertical wall at least partially obstructs flow of the pressurized breathable gas between the chamber inlet and the chamber outlet.
- 19. The humidification chamber of claim 18, wherein the internal vertical wall extends across the interior of the  $_{50}$  humidification chamber.
- 20. The humidification chamber of claim 19, wherein the internal vertical wall divides a portion of the interior of the humidification chamber below the obstruction into an inlet section and an outlet section, wherein the inlet section corresponds to the chamber inlet and the outlet section corresponds to the chamber outlet, the internal vertical wall at least partially obstructing the flow of the pressurized breathable gas between the inlet section and the outlet section.

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21. The humidification chamber of claim 8, further comprising:

an internal vertical wall positioned within the interior of the humidification chamber and extending at least partially above the obstruction, wherein the internal vertical wall extends across the interior of the humidification chamber.

22. The humidification chamber of claim 21, wherein the internal vertical wall divides a portion of the interior of the humidification chamber above the obstruction into an inlet section and an outlet section, wherein the inlet section corresponds to the chamber inlet and the outlet section corresponds to the chamber outlet, the internal vertical wall blocks the flow of the pressurized breathable gas from the inlet section to the outlet section causing the pressurized breathable gas to flow around the obstruction.

23. The humidification chamber of claim 21, wherein the internal vertical wall extends from the top surface of the humidification chamber.

24. The humidification chamber of claim 8, wherein the humidification chamber is sized and shaped to both (i) establish a fluid connection between the chamber inlet and the output of the respiratory therapy device when the humidification chamber mounts within a recess of the respiratory therapy device, and (ii) position the bottom surface of the humidification chamber over the heating element of the respiratory therapy device when the humidification chamber mounts within a recess of the respiratory therapy device.

25. The humidification chamber of claim 24, wherein the humidification chamber is configured to be positioned in the recess by horizontally sliding the humidification chamber into the recess.

26. The humidification chamber of claim 24, further comprising means for retaining the humidification chamber positioned in the recess.

27. The humidification chamber of claim 26, wherein the respiratory therapy device includes complementary means for retaining the humidification chamber positioned in the recess.

28. The humidification chamber of claim 8, further comprising means for removably connecting the chamber inlet to the output of the respiratory therapy device.

29. The humidification chamber of claim 8, further comprising means for removably connecting the chamber outlet to a means for delivering the pressurized breathable gas with added humidity to the patient.

30. The humidification chamber of claim 8, wherein the respiratory therapy device includes means for controlling the respiratory therapy provided to the patient.

31. The humidification chamber of claim 8, further comprising means for adding water to the humidification chamber.

32. The humidification chamber of claim 8, further comprising means for preventing spillage of water out of the chamber inlet when the bottom surface of the humidification chamber is in an angled orientation relative to horizontal.

33. The humidification chamber of claim 8, further comprising means for preventing spillage of water out of the chamber outlet when the bottom surface the humidification chamber is in an angled orientation relative to horizontal.

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## UNITED STATES PATENT AND TRADEMARK OFFICE

## CERTIFICATE OF CORRECTION

PATENT NO. : RE48,095 E

APPLICATION NO : 16/232883

APPLICATION NO. : 16/232883

DATED : July 14, 2020

INVENTOR(S) : Virr et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification

At Column 1, under the heading "CROSS REFERENCE TO RELATED APPLICATIONS," replace Lines 16-25 (approx.), with the following:

--NOTICE: More than one reissue application has been filed for the reissue of U.S. Patent No. 7,614,398 B2. The reissue applications are U.S. Reissue Patent Application No. 16/232,883 (the present application), filed December 26, 2018, now U.S. Reissue Patent No. RE48,095 E, issued July 14, 2020, which is a continuation reissue application of U.S. Reissue Patent Application Serial No. 16/231,286, filed on December 21, 2018, now U.S. Reissue Patent No. RE48,118 E, issued July 28, 2020, which is a continuation reissue application of U.S. Reissue Patent Application Serial No. 15/706,811, filed on September 18, 2017, now U.S. Reissue Patent No. RE48,149 E, issued August 11, 2020, which is a continuation reissue application of U.S. Reissue Patent Application Serial No. 15/182,919, filed on June 15, 2016, now U.S. Reissue Patent No. RE46,571 E, issued October 17, 2017, which is a continuation reissue application of U.S. Reissue Patent Application Serial No. 13/944,960, filed on July 18, 2013, now U.S. Reissue Patent No. RE46,079 E, issued July 26, 2016, which is a continuation reissue application of U.S. Reissue Patent Application Serial No. 13/100,783, filed on May 4, 2011, now U.S. Reissue Patent No. RE44,453 E, issued August 27, 2013, which is a reissue application of U.S. Patent Application No. 11/181,807, filed July 15, 2005, now U.S. Patent No. 7,614,398 B2, issued November 10, 2009, which is a continuation of U.S. Patent Application Serial No. 10/467,382, filed on August 7, 2003, now U.S. Patent No. 6,935,337 B2, issued August 30, 2005,--

> Signed and Sealed this Nineteenth Day of January, 2021

> > Andrei Iancu

Director of the United States Patent and Trademark Office