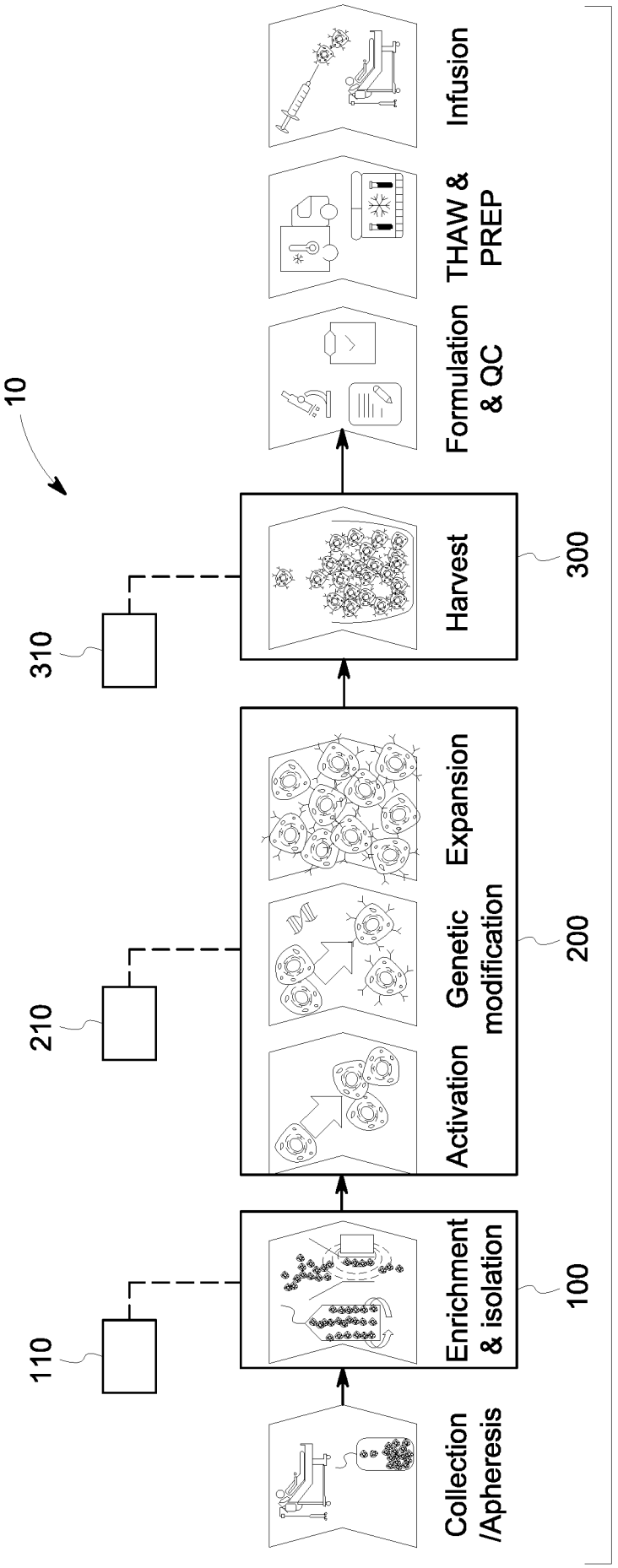

10
110
Collection /Apheresis
Enrichment & isolation
100
210
Activation
Genetic modification
Expansion
200
310
Harvest
300
Formulation & QC
THAW & PREP
Infusion

FIG. 1

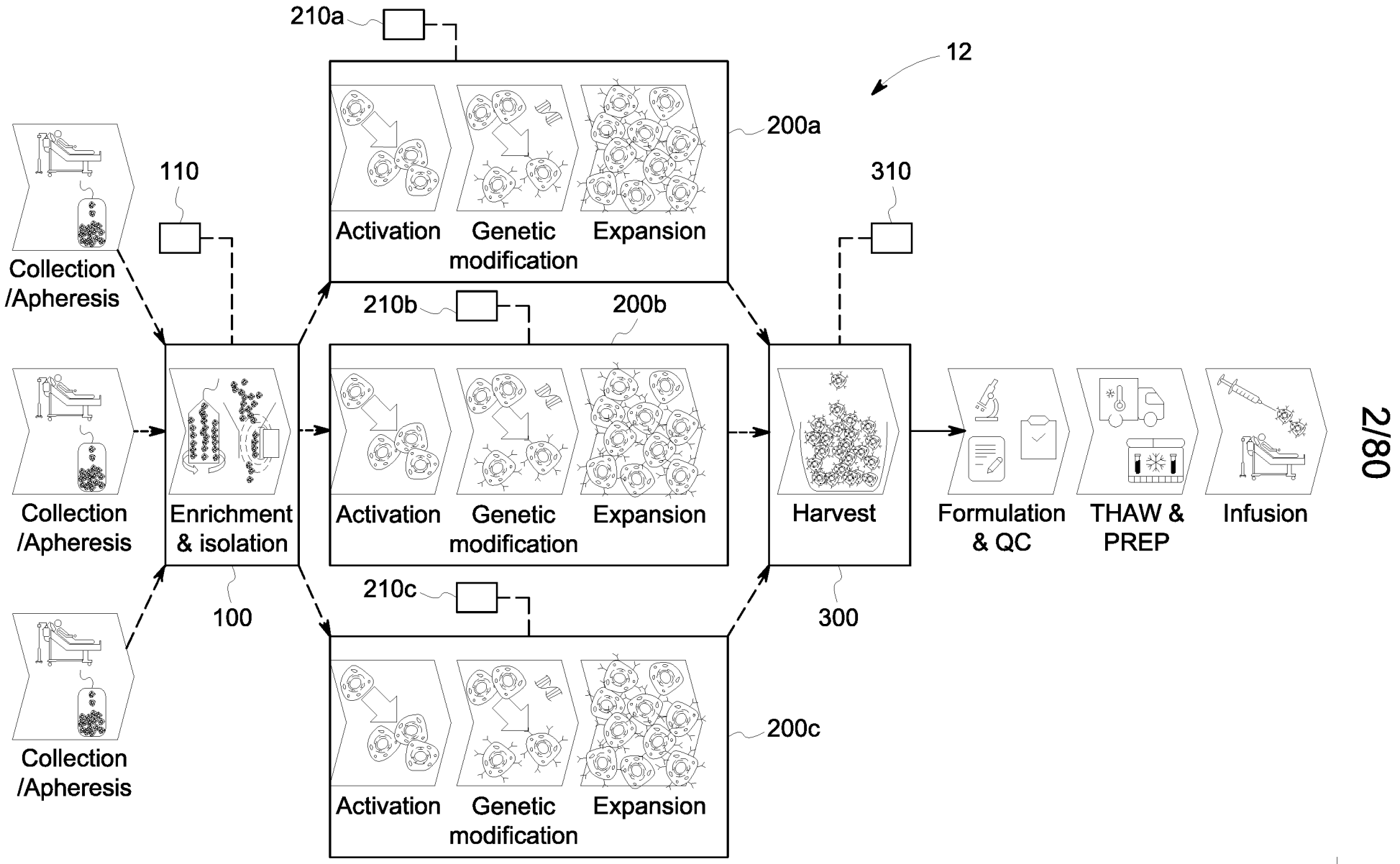

210a
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200a
110
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Collection
/Apheresis
Activation
Genetic
modification
Expansion
210b
200b
Collection
/Apheresis
Enrichment
& isolation
Activation
Genetic
modification
Expansion
Harvest
Formulation
& QC
THAW &
PREP
Infusion
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300
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/Apheresis
200c
Activation
Genetic
modification
Expansion

FIG. 2

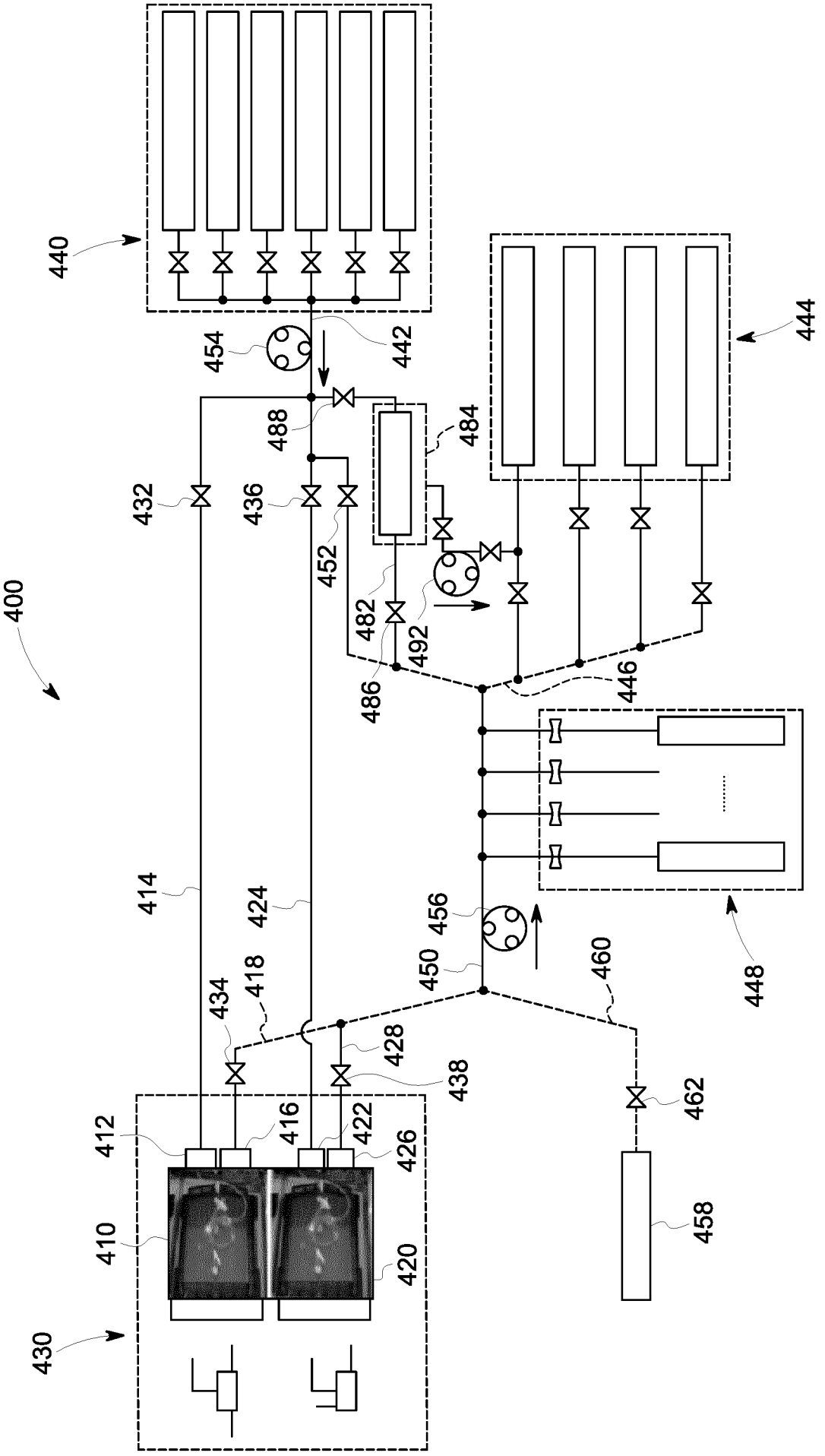

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FIG. 3

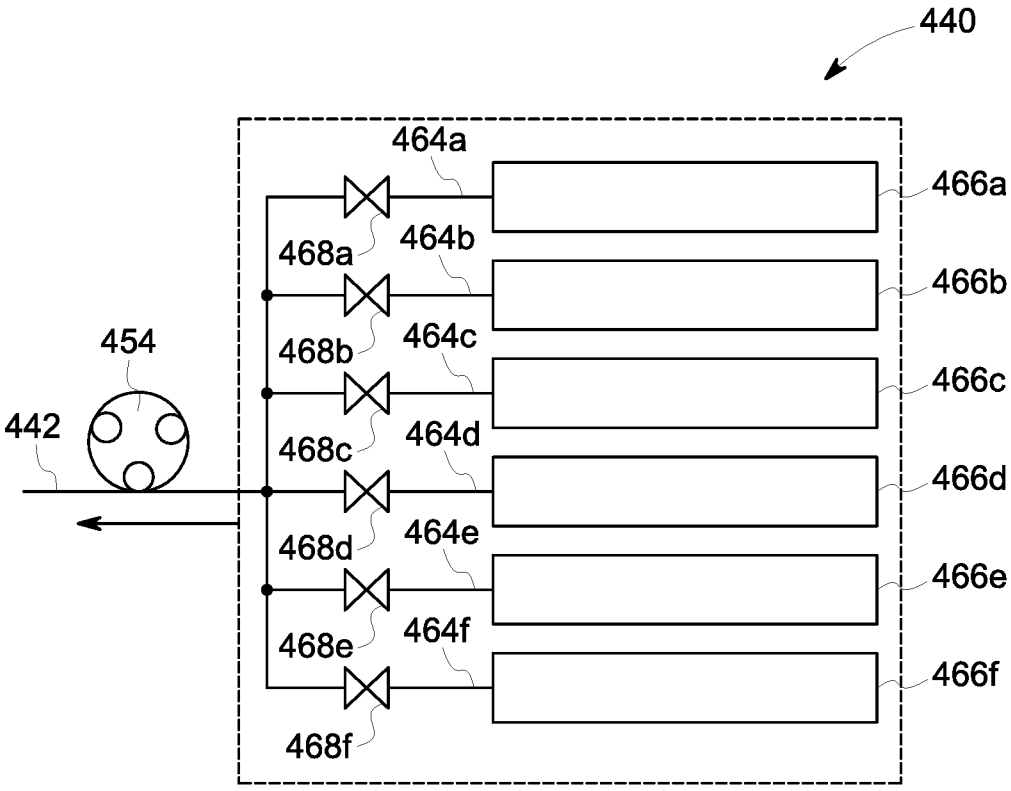

440
464a
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464b
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464c
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FIG. 4

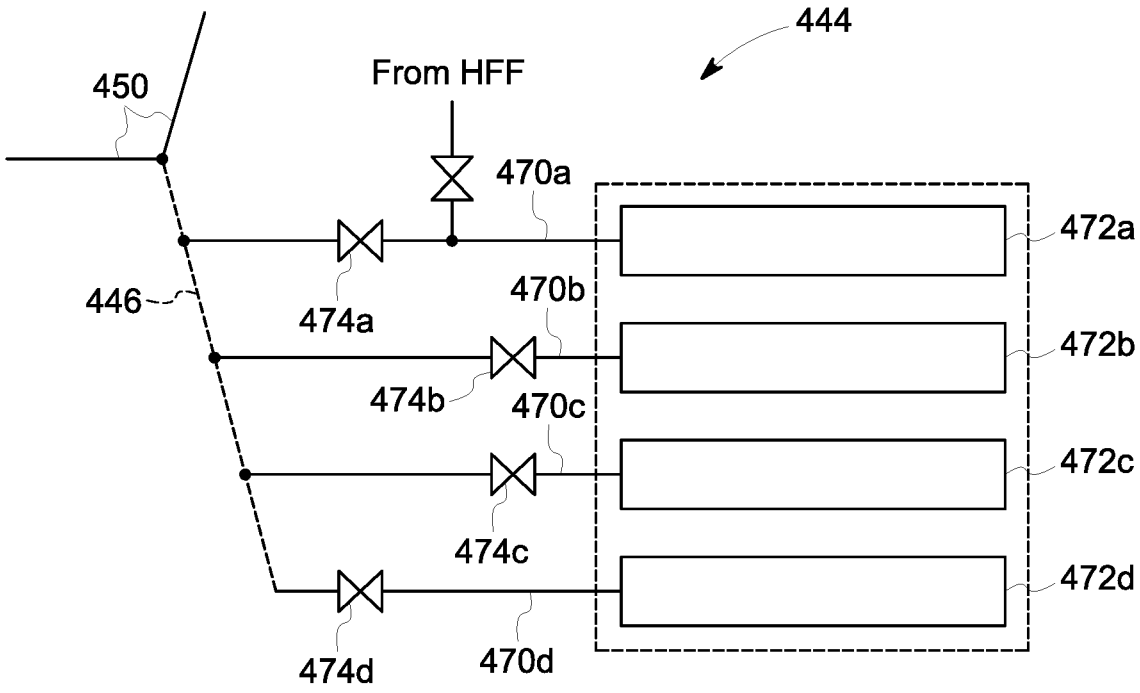

444
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From HFF
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474a
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FIG. 5

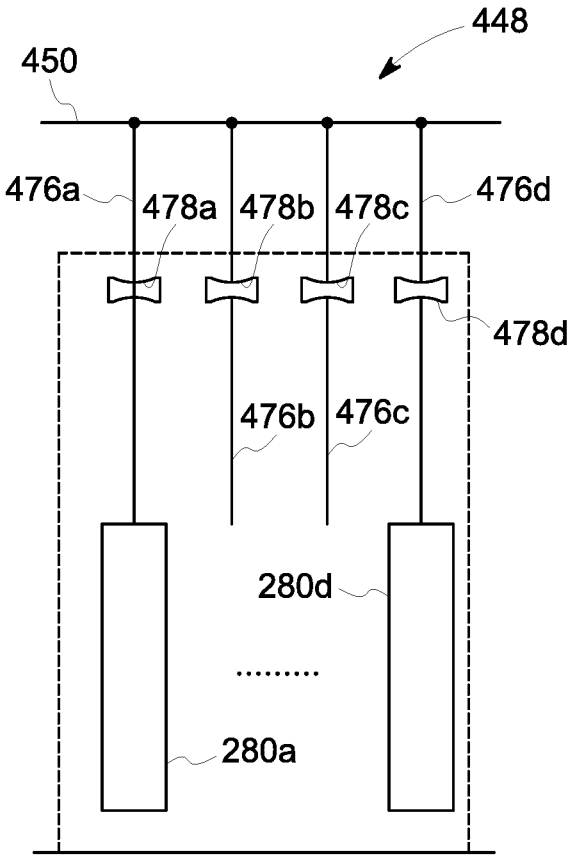

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476a
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FIG. 6

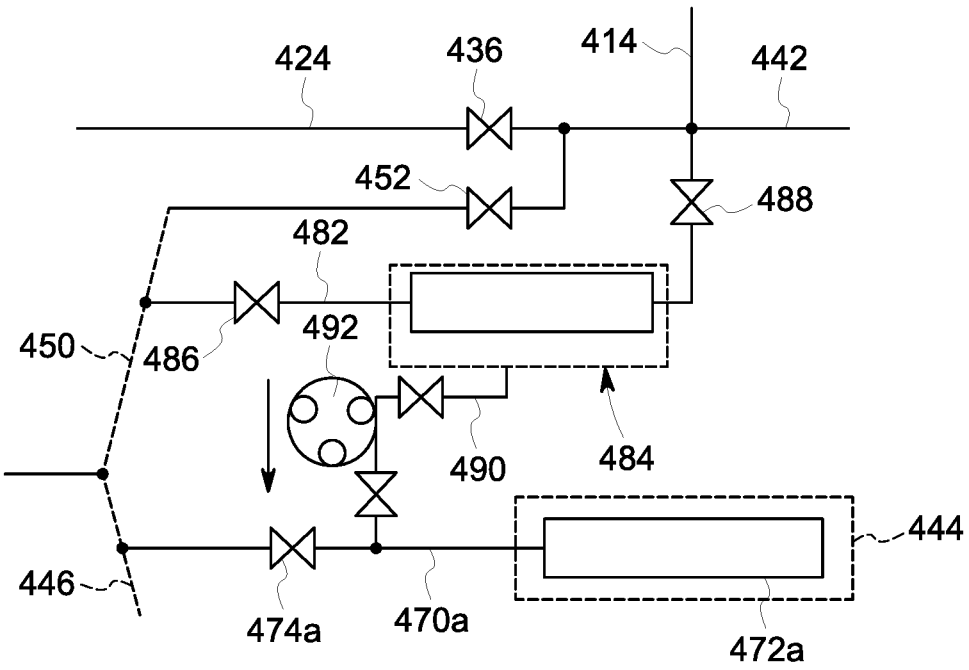

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FIG. 7

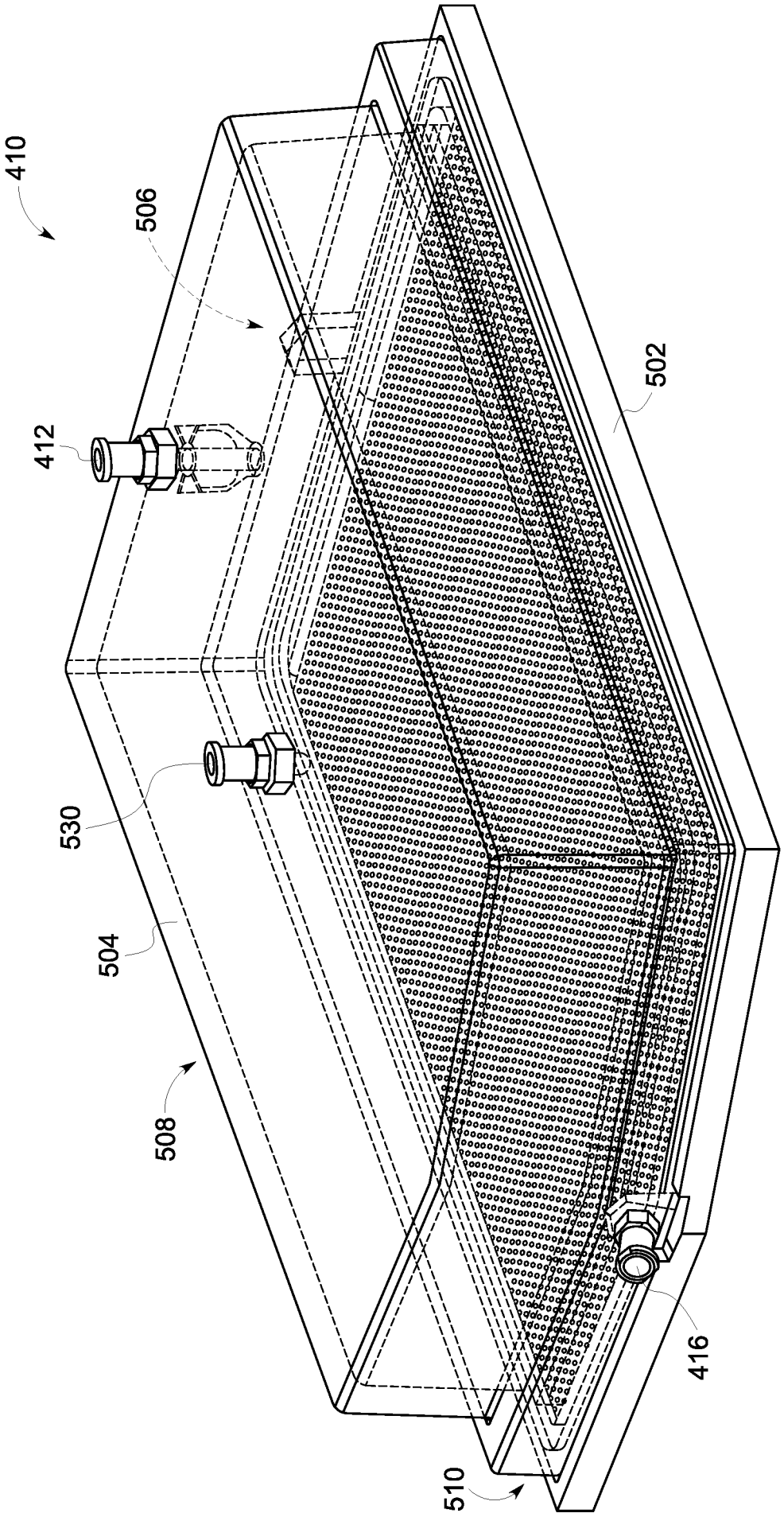


FIG. 8

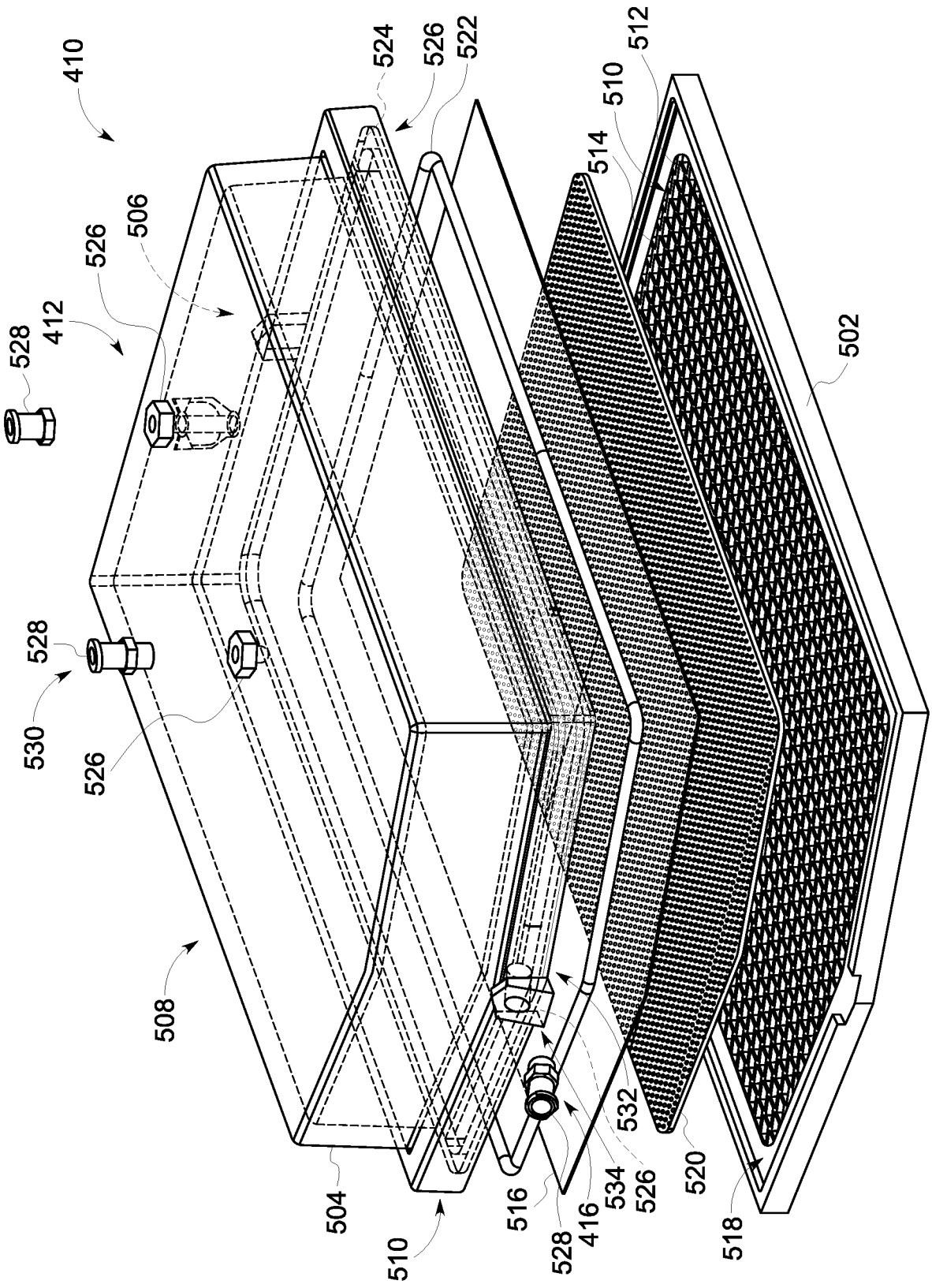

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FIG. 9

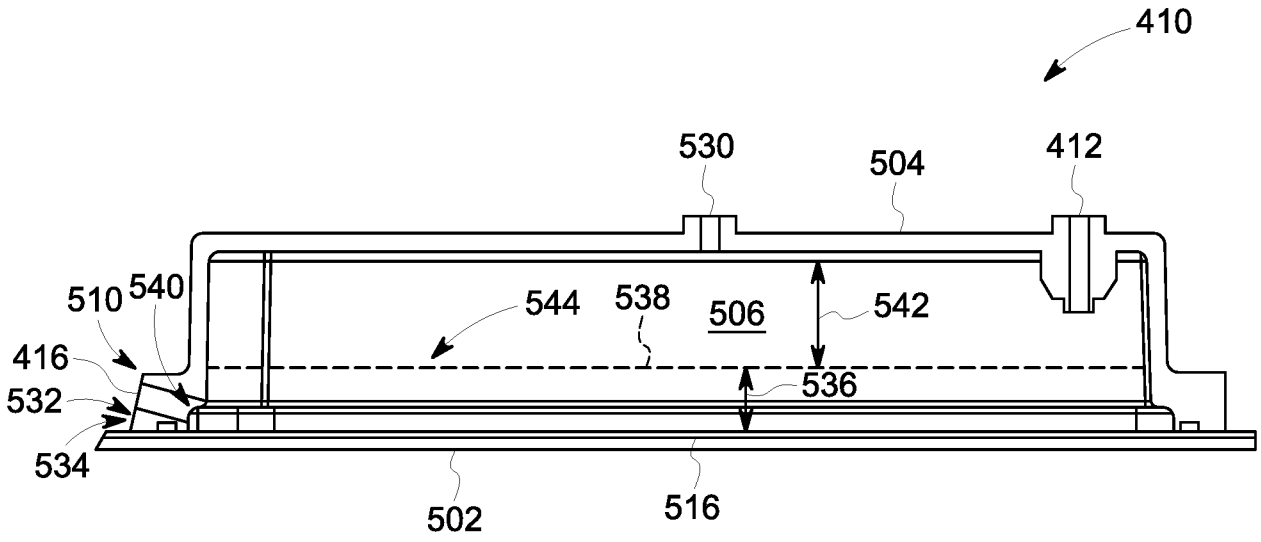


FIG. 10

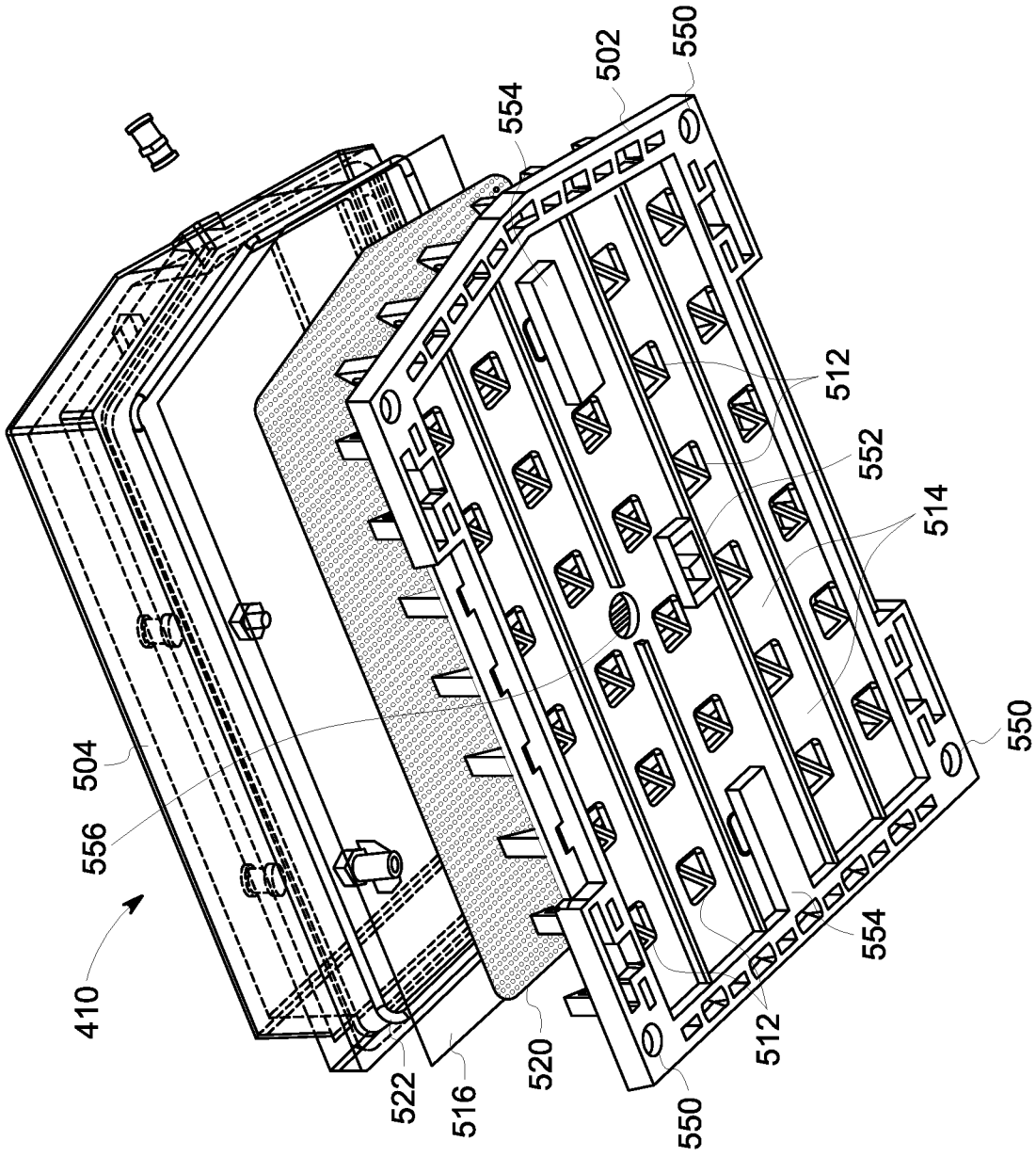

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FIG. 11

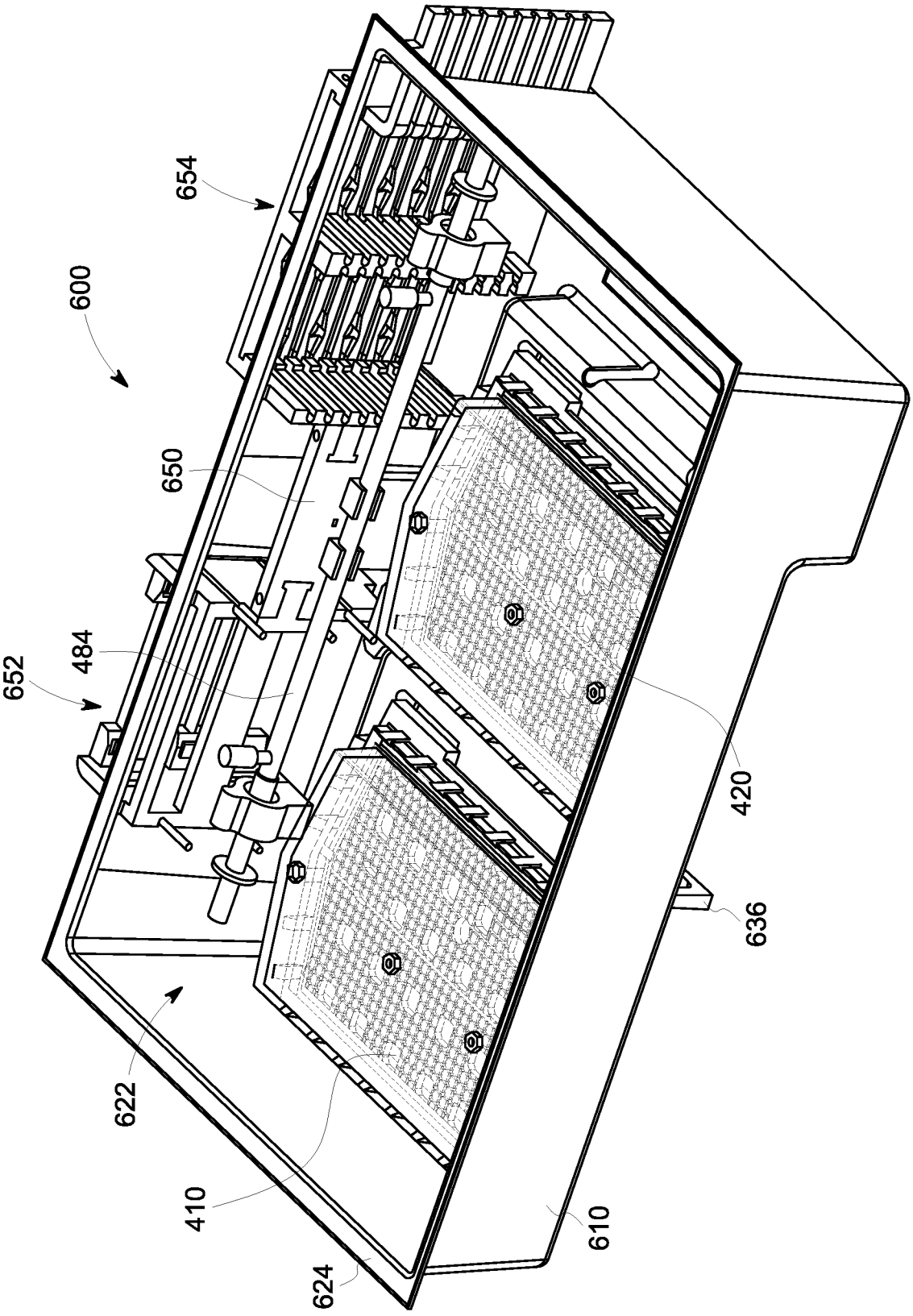


FIG. 12

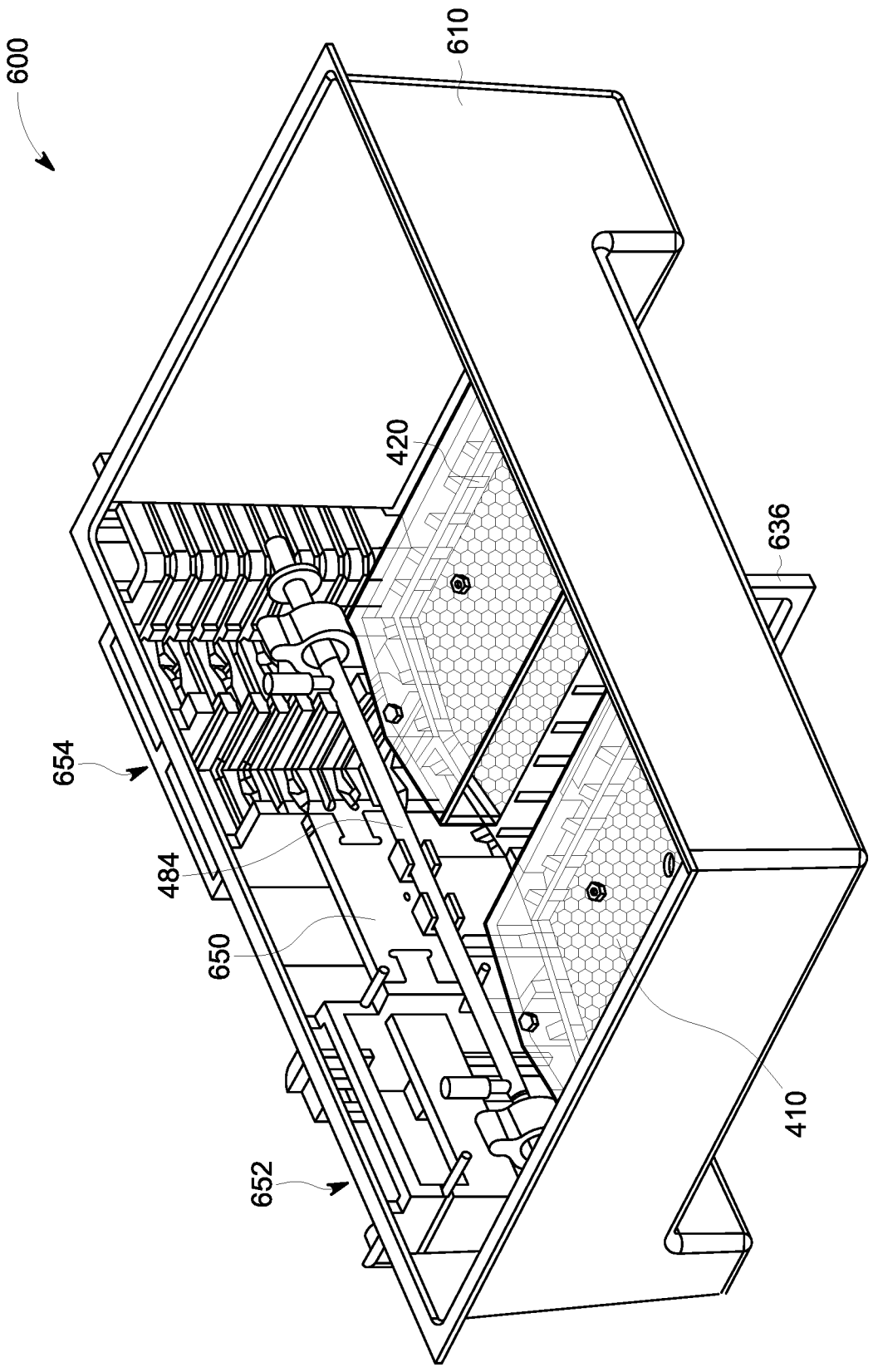


FIG. 13

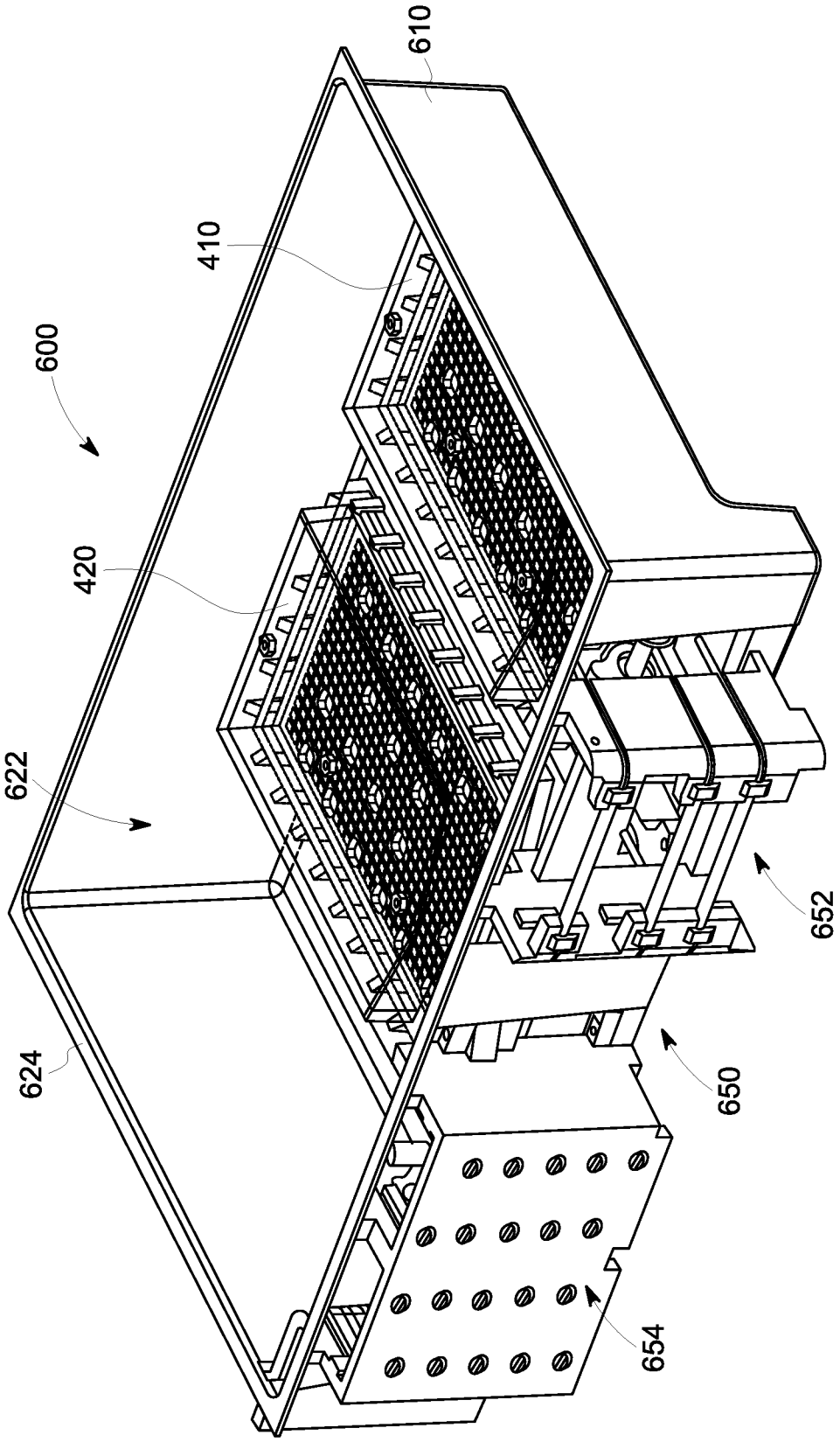


FIG. 14

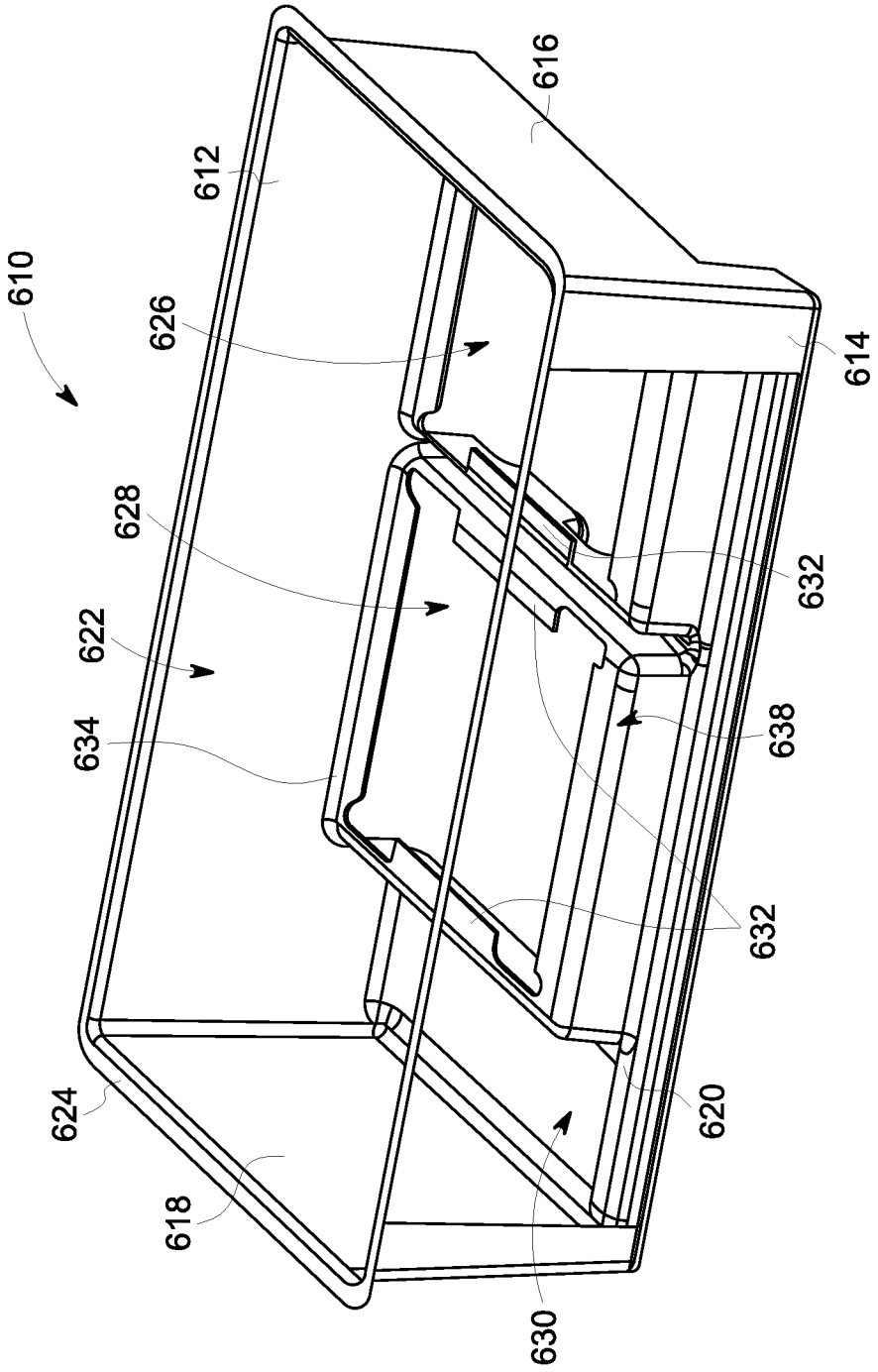


FIG. 15

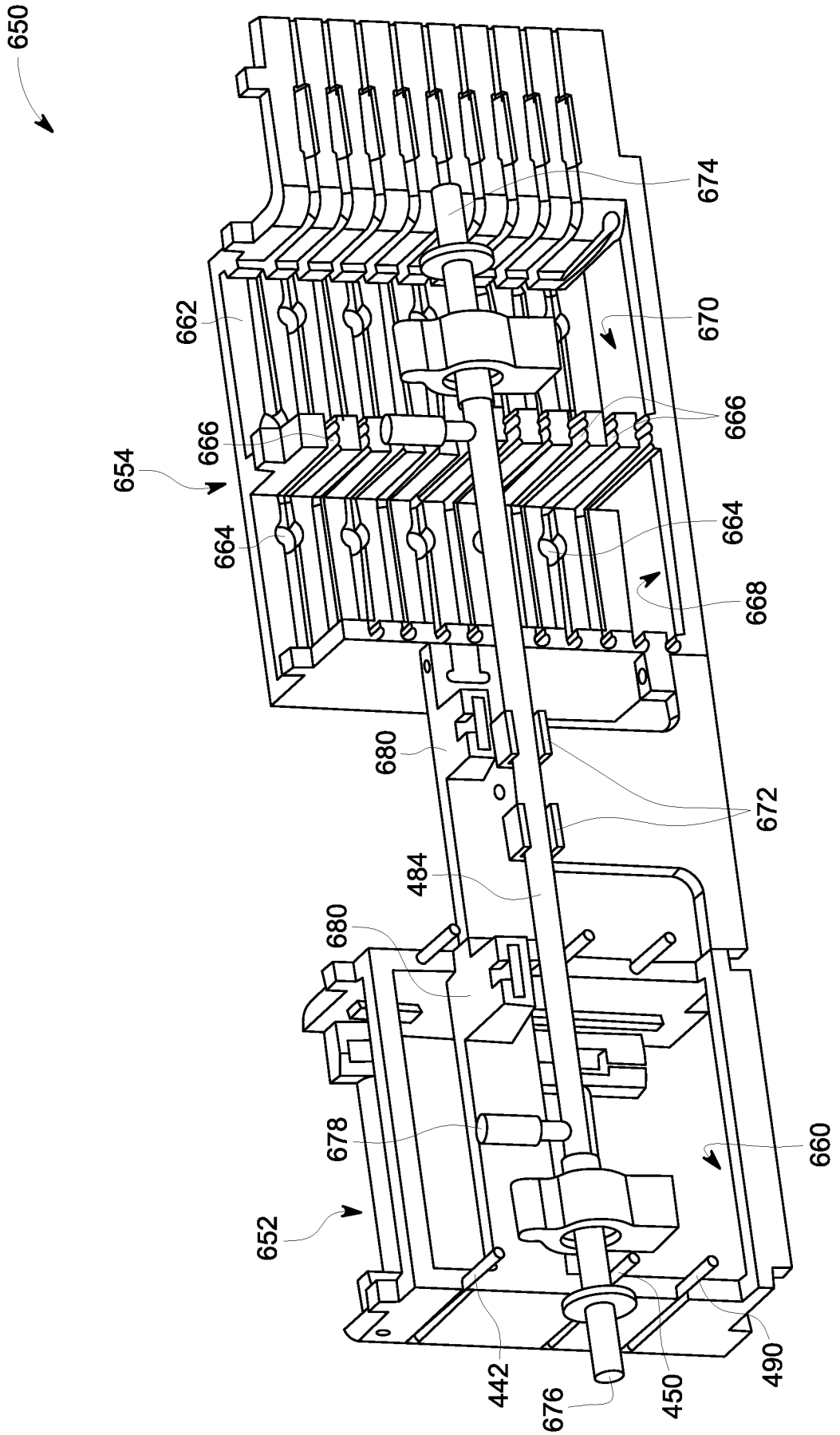

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FIG. 16

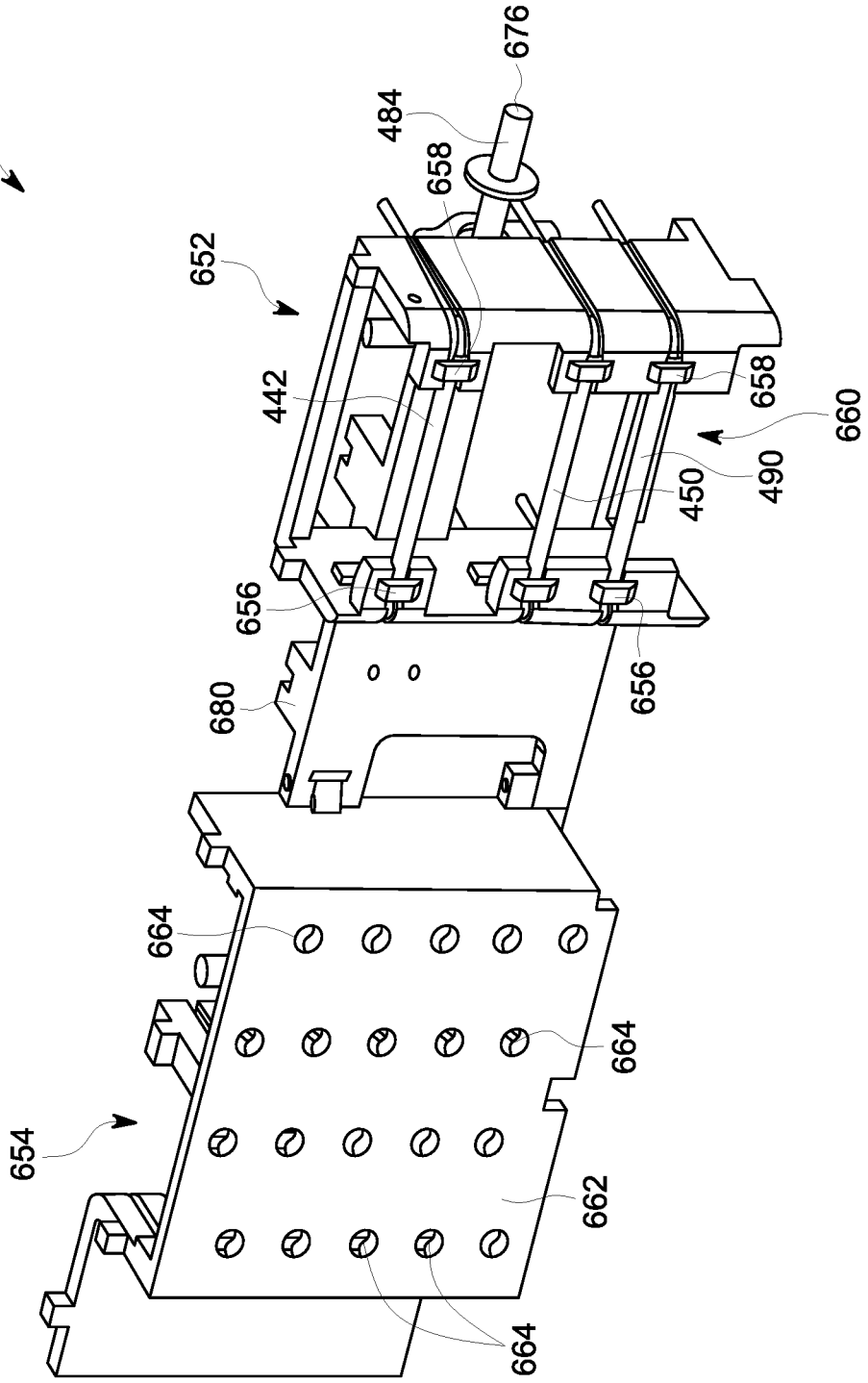

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FIG. 17

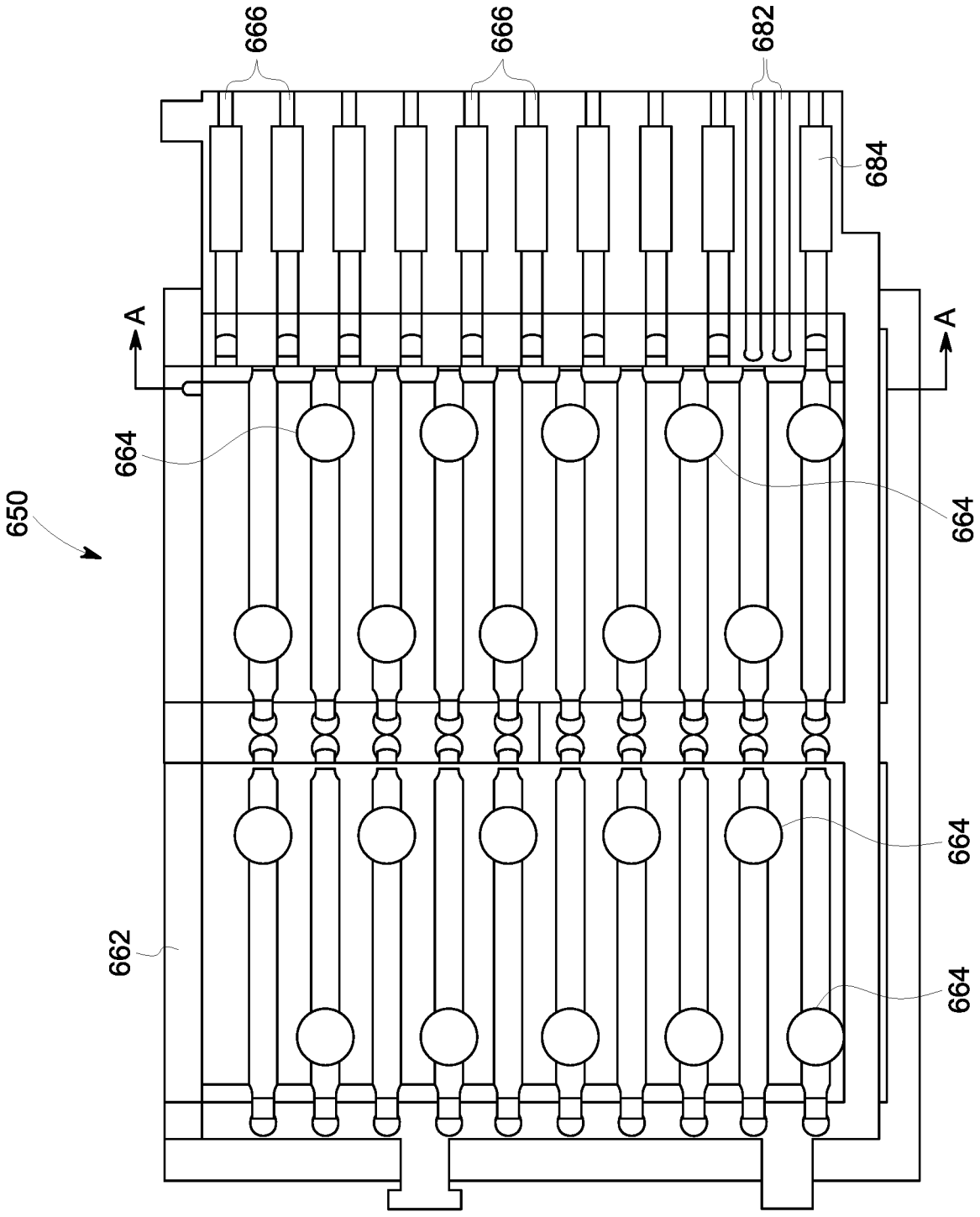


FIG. 18

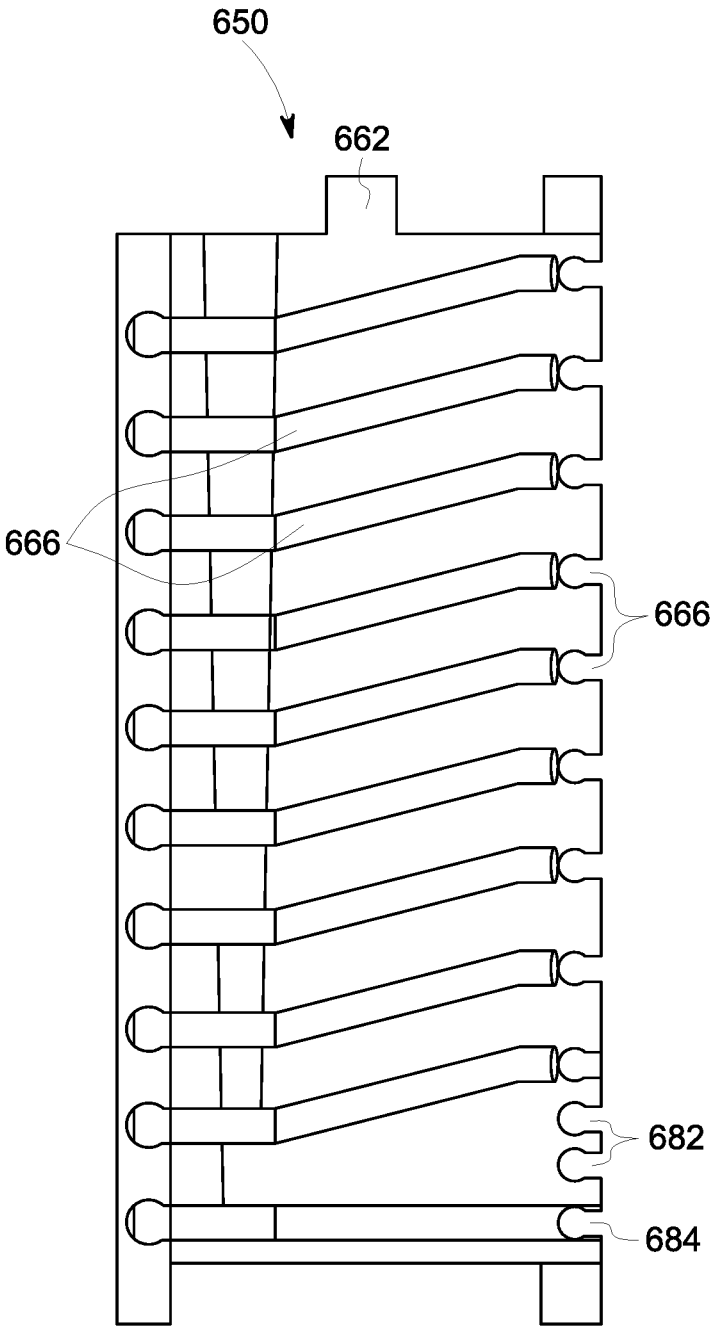


FIG. 19

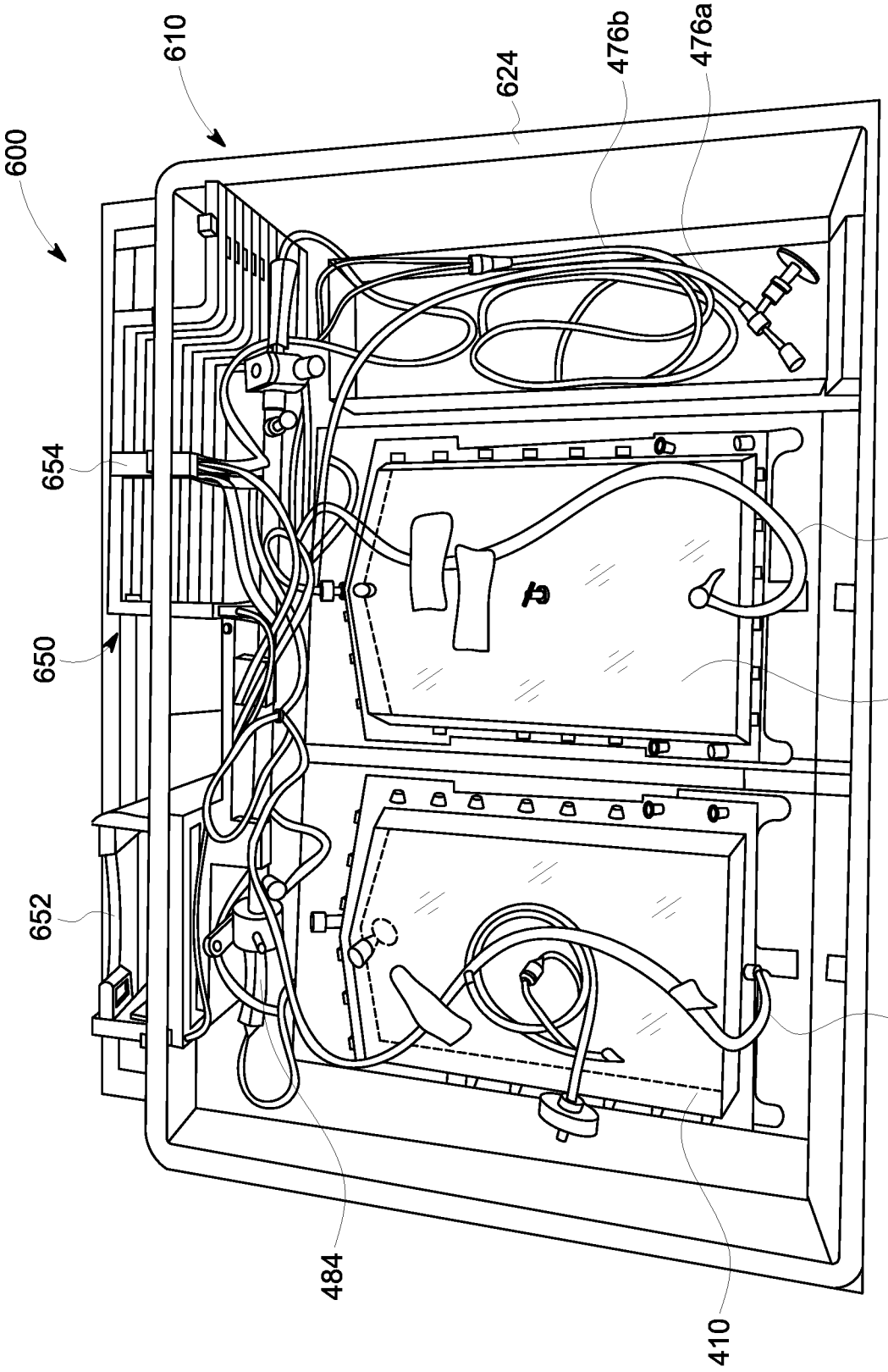


FIG. 20

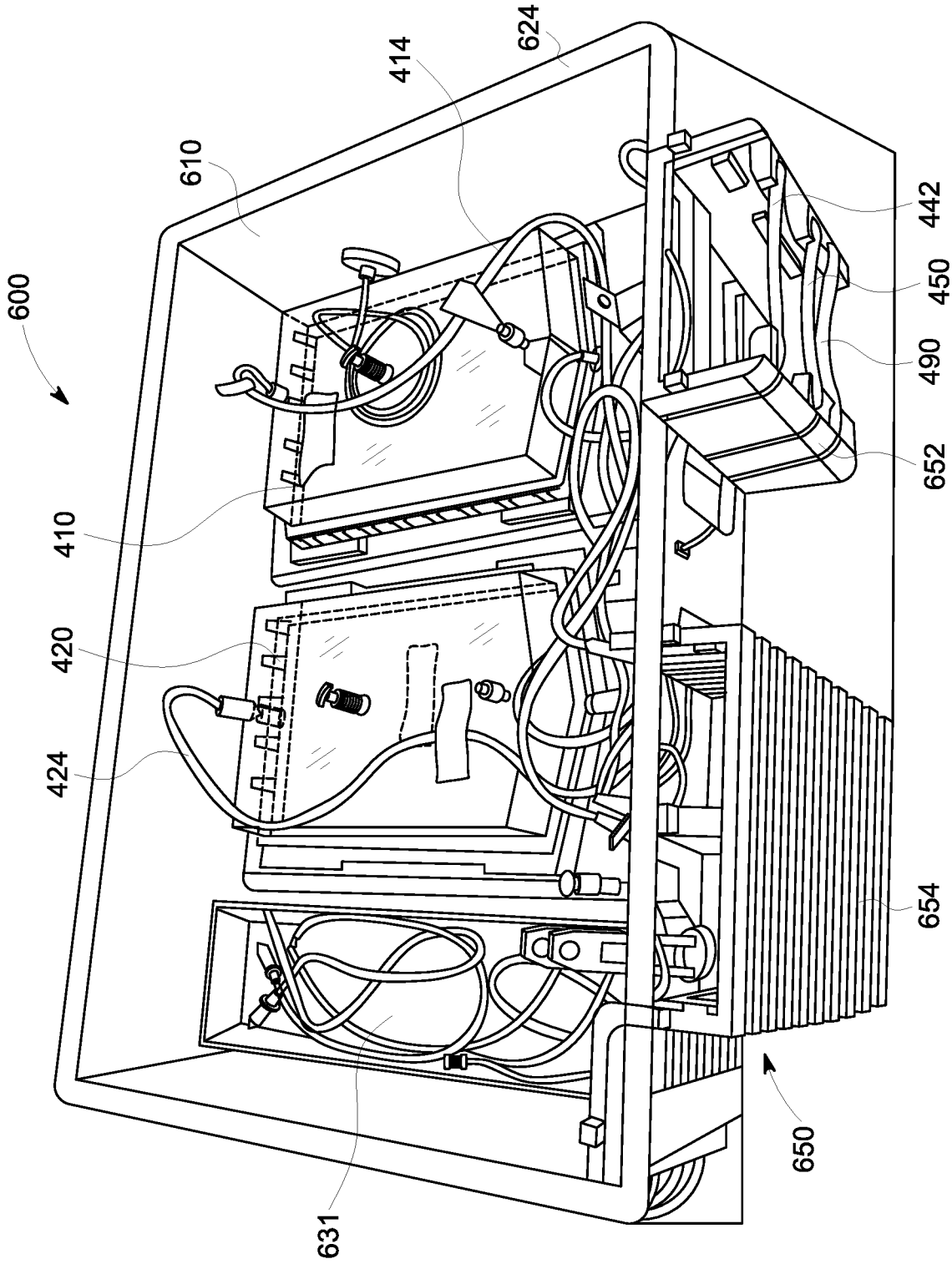


FIG. 21

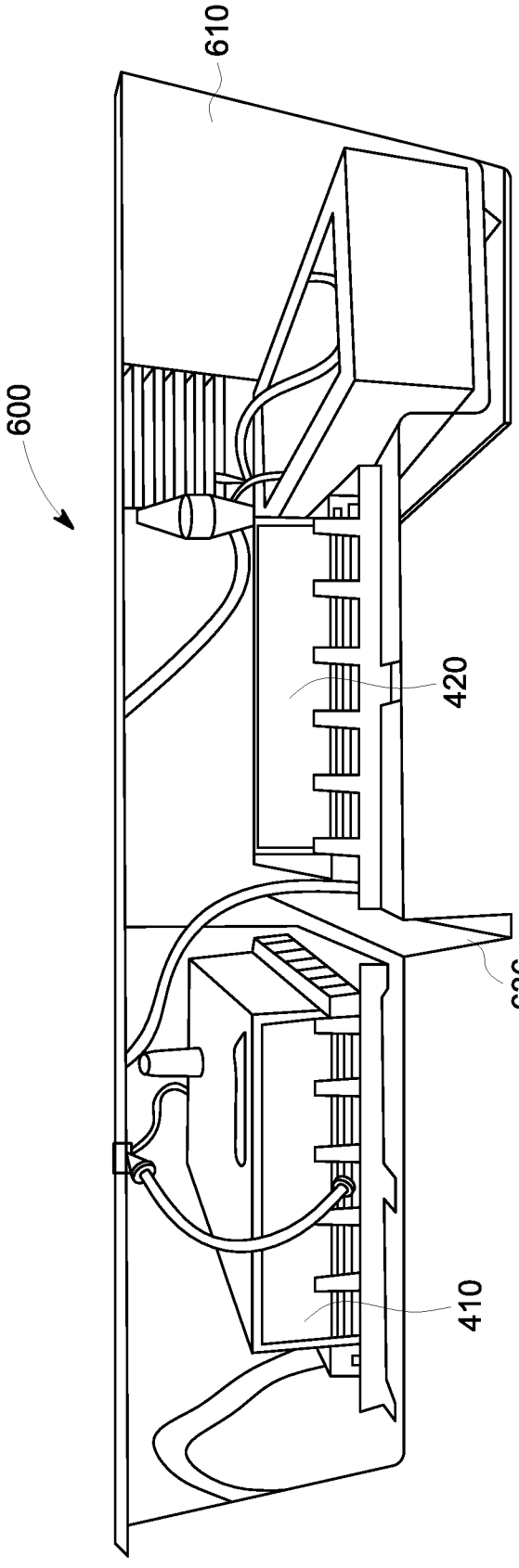


FIG. 22

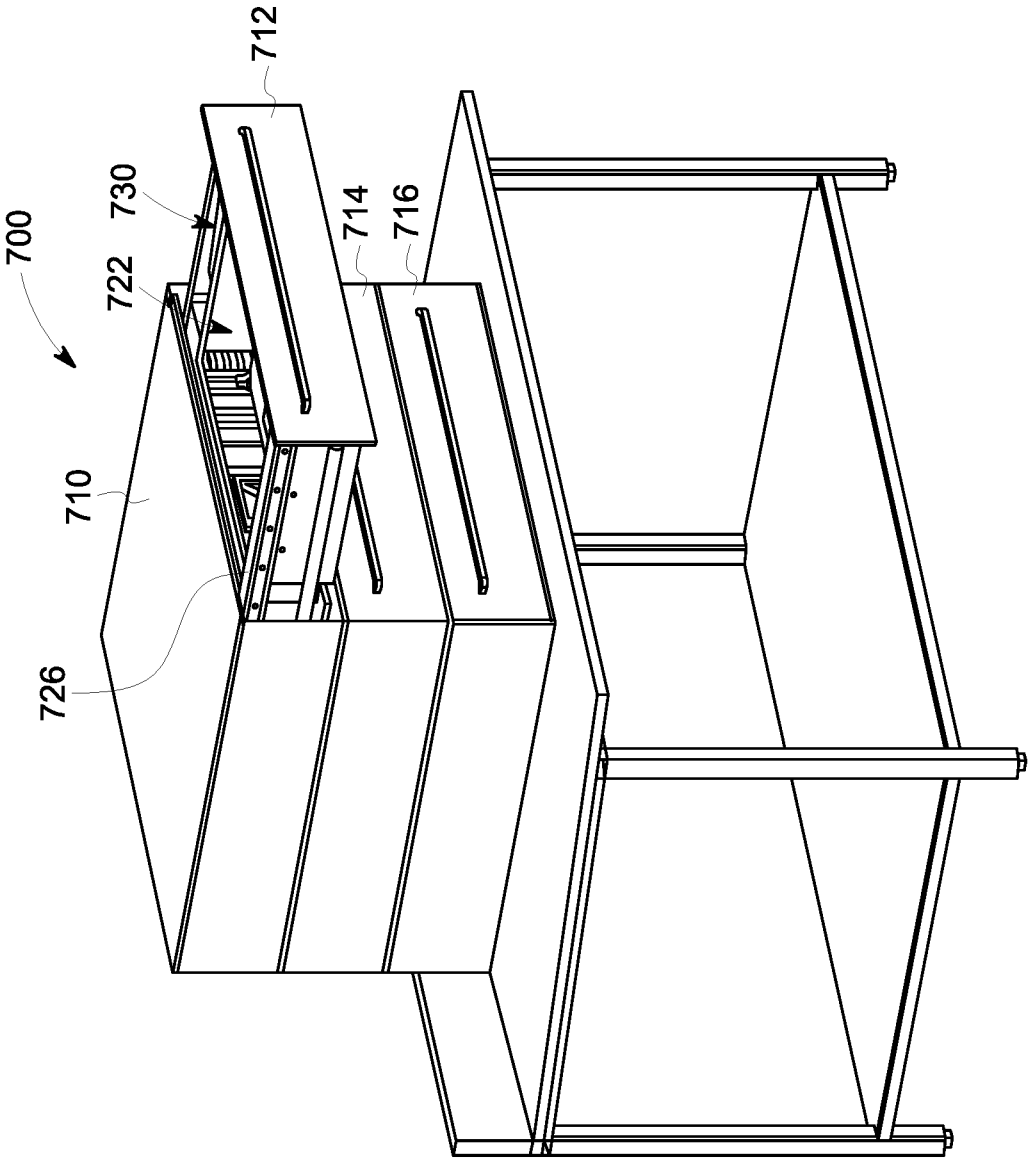


FIG. 23

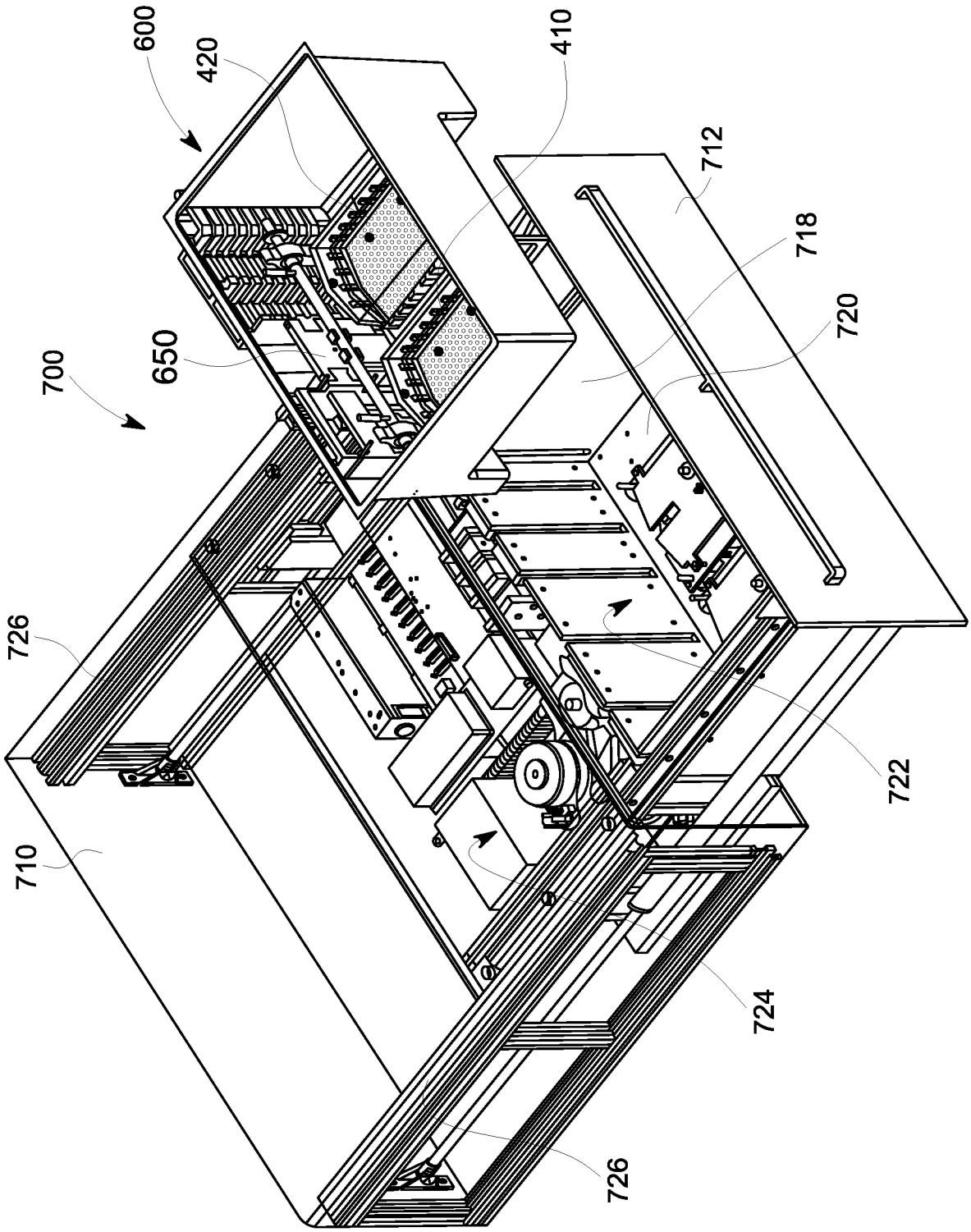


FIG. 24

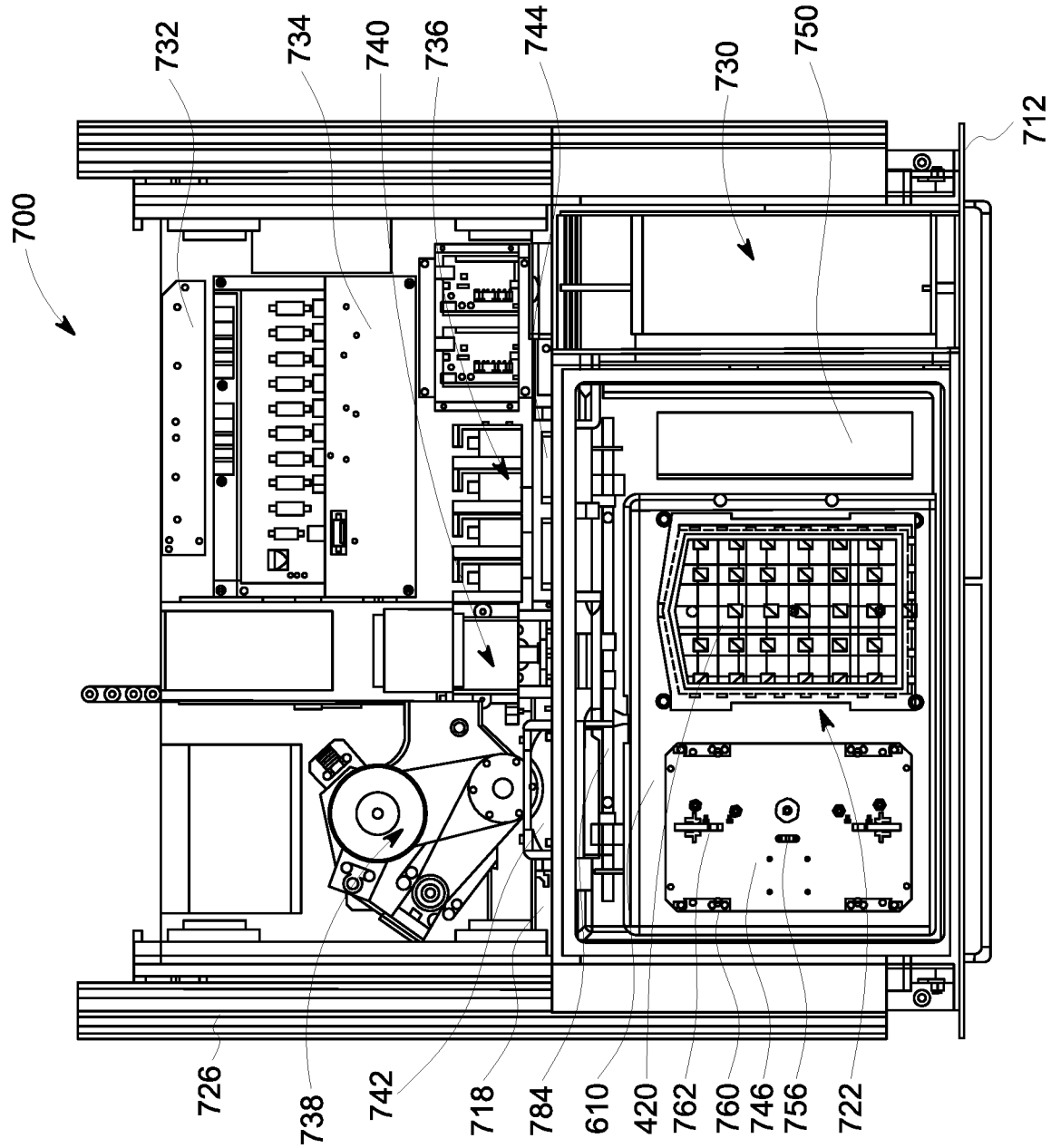

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FIG. 25

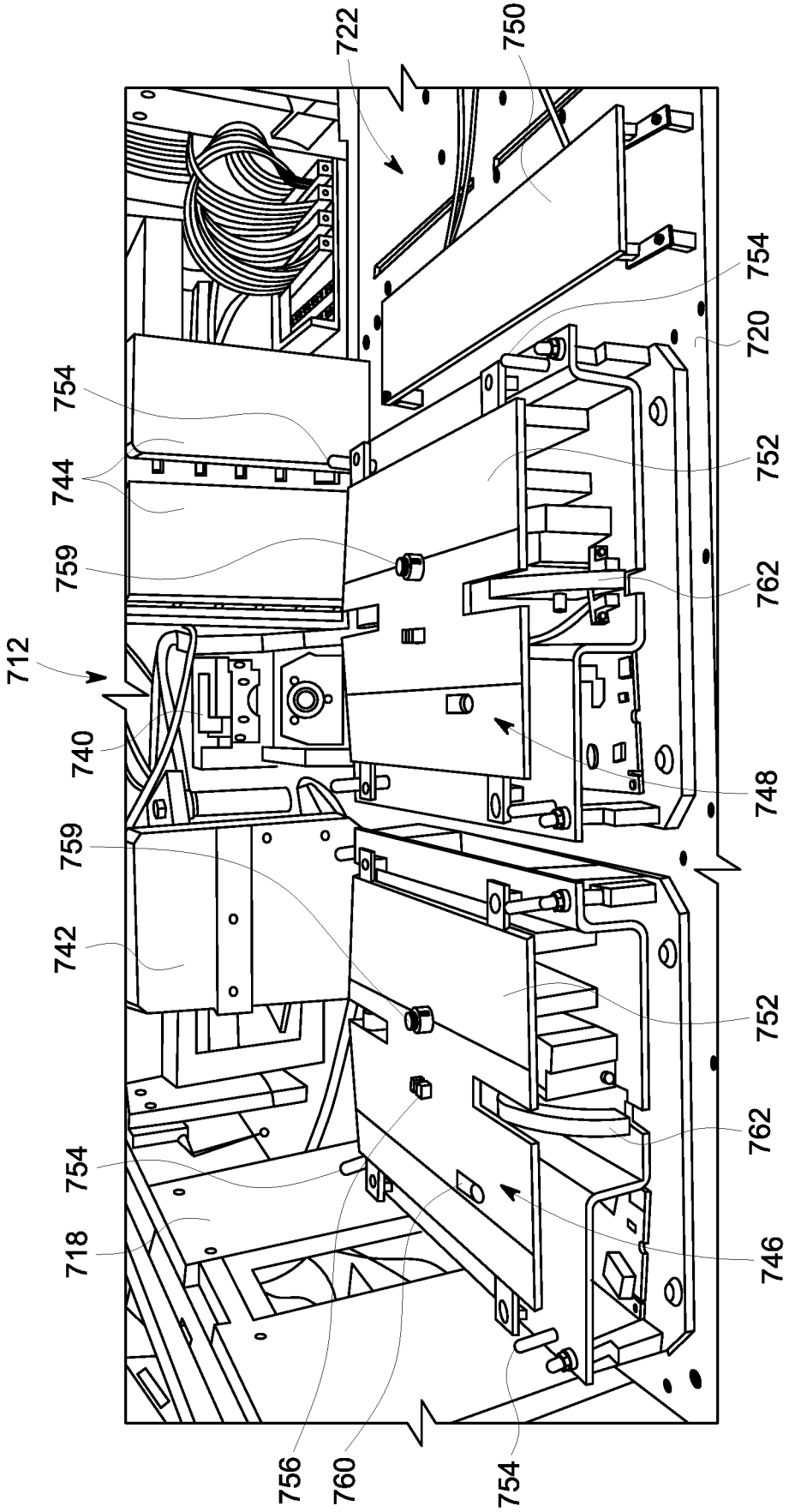

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FIG. 26

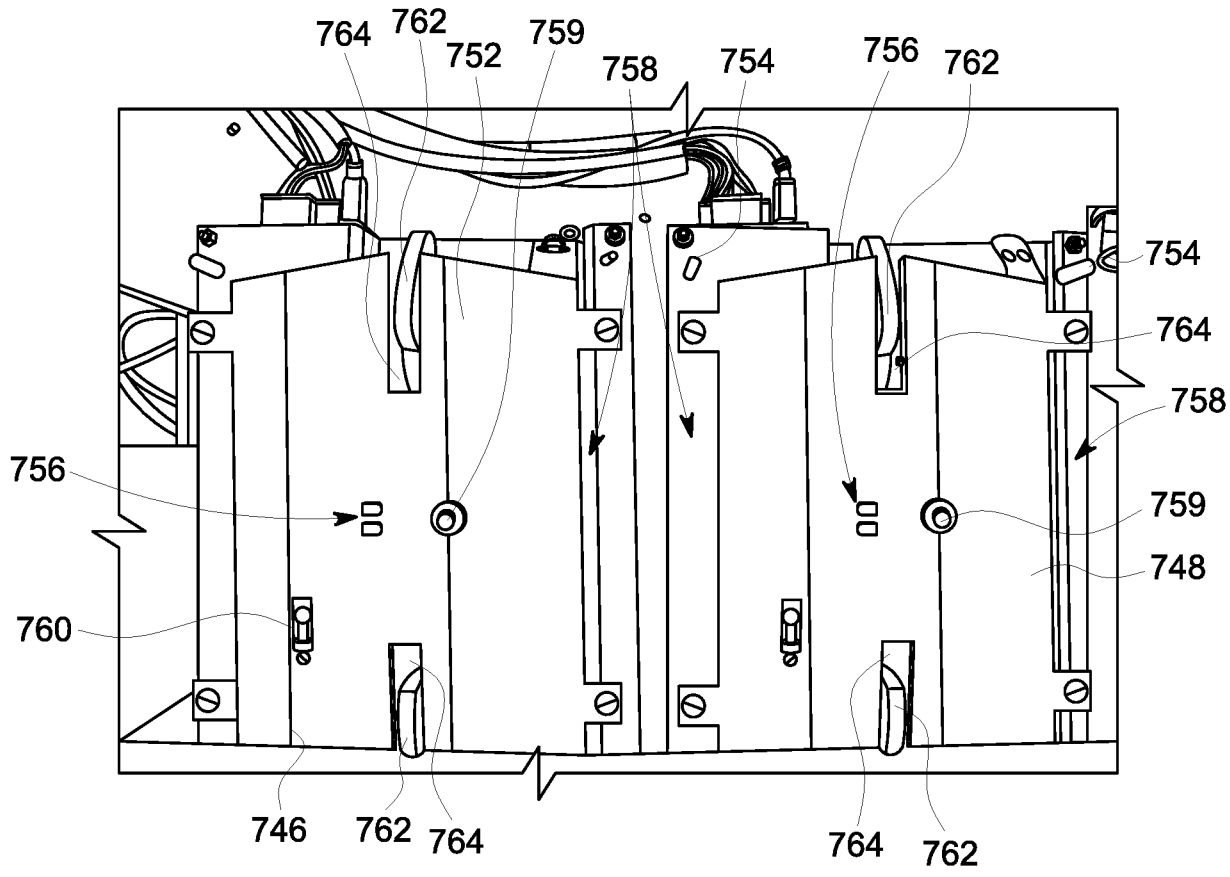

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FIG. 27

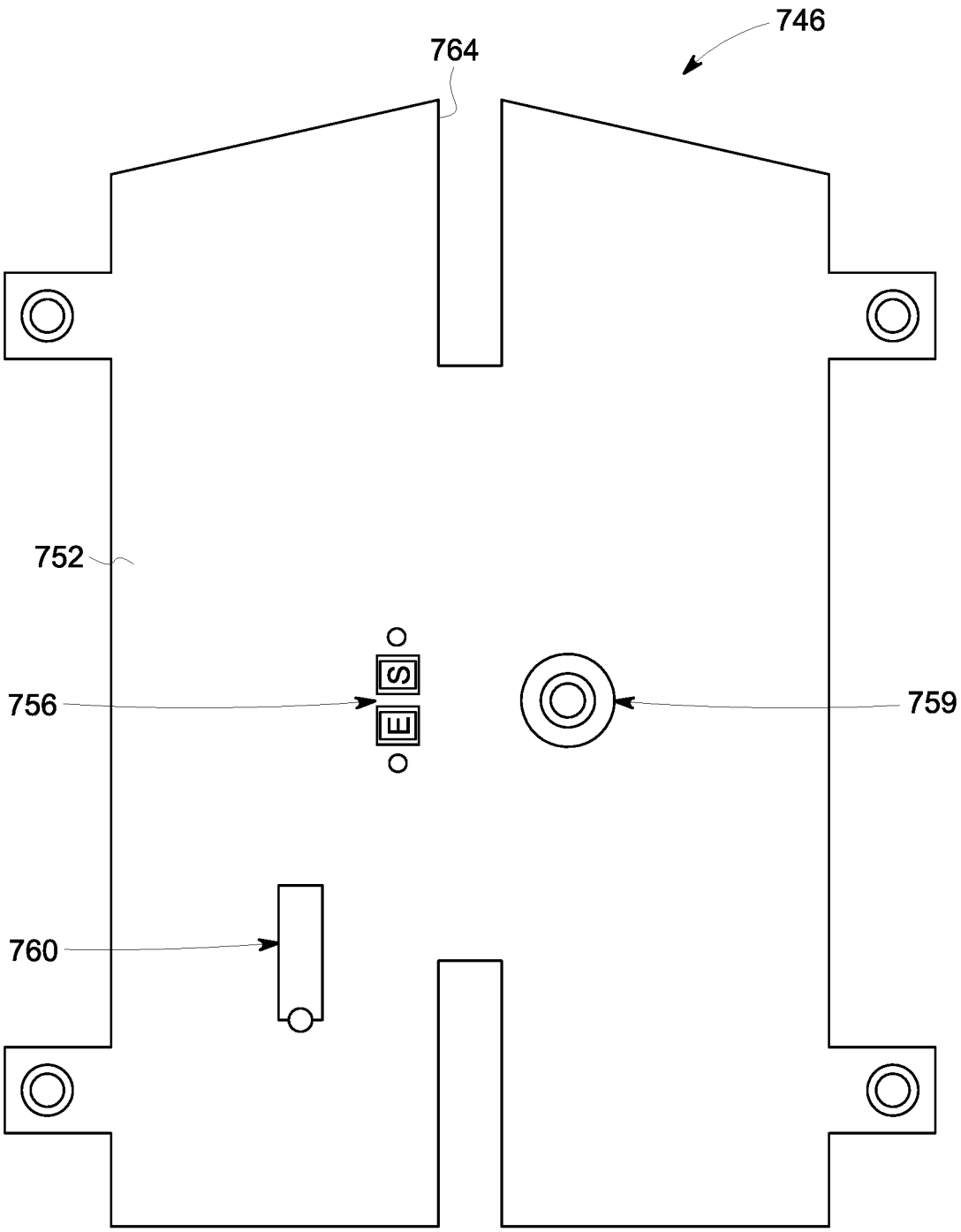


FIG. 28A

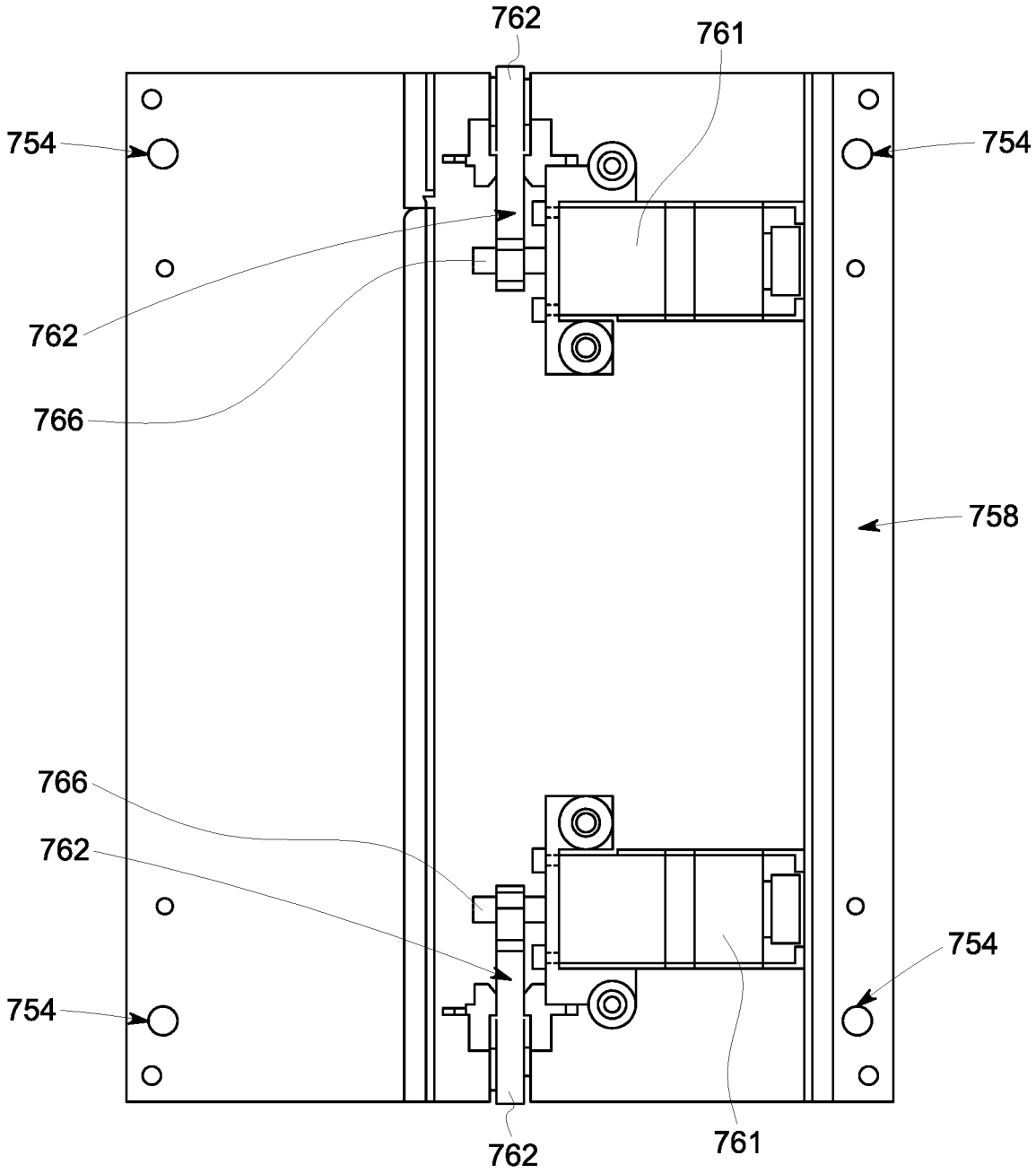


FIG. 28B

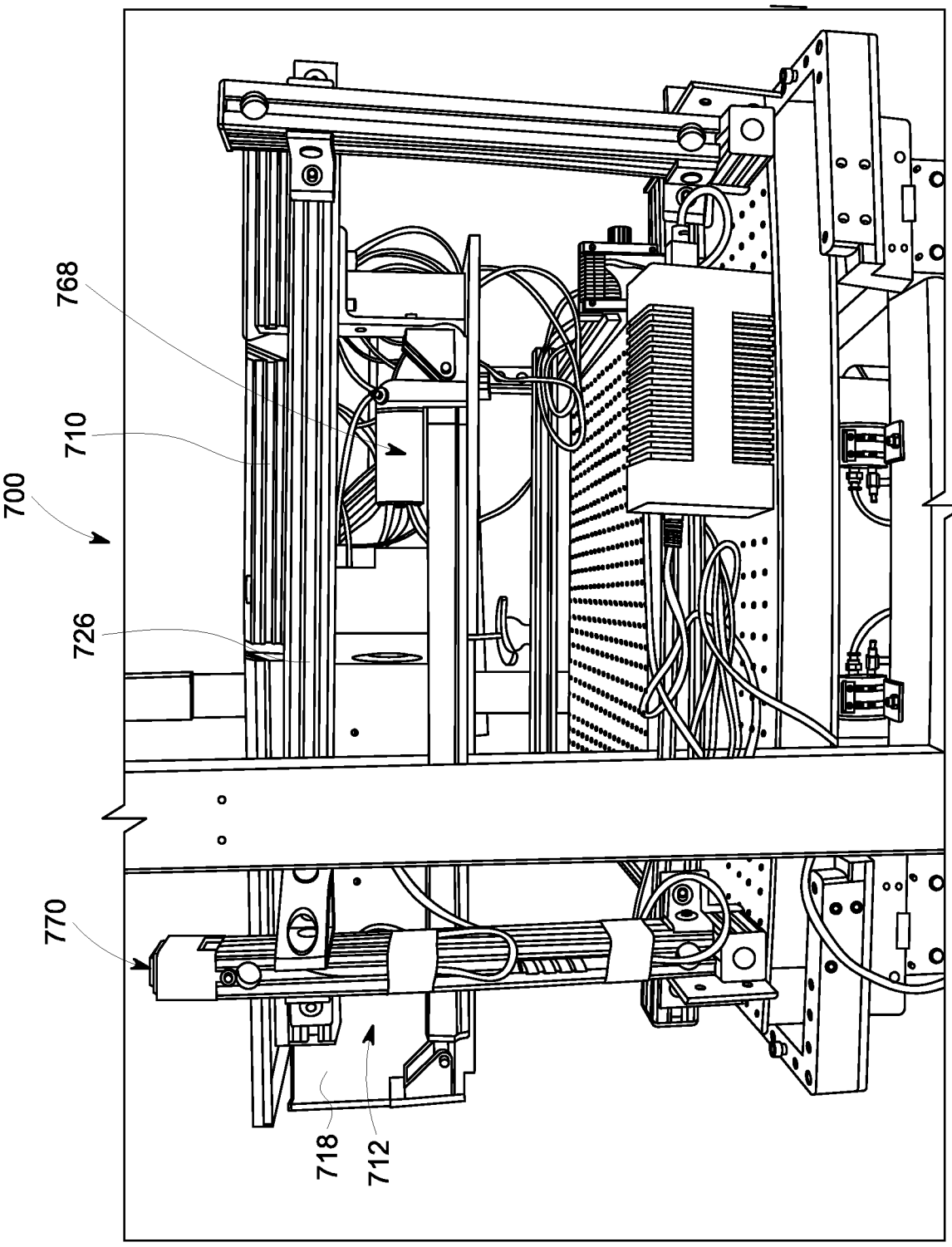


FIG. 29

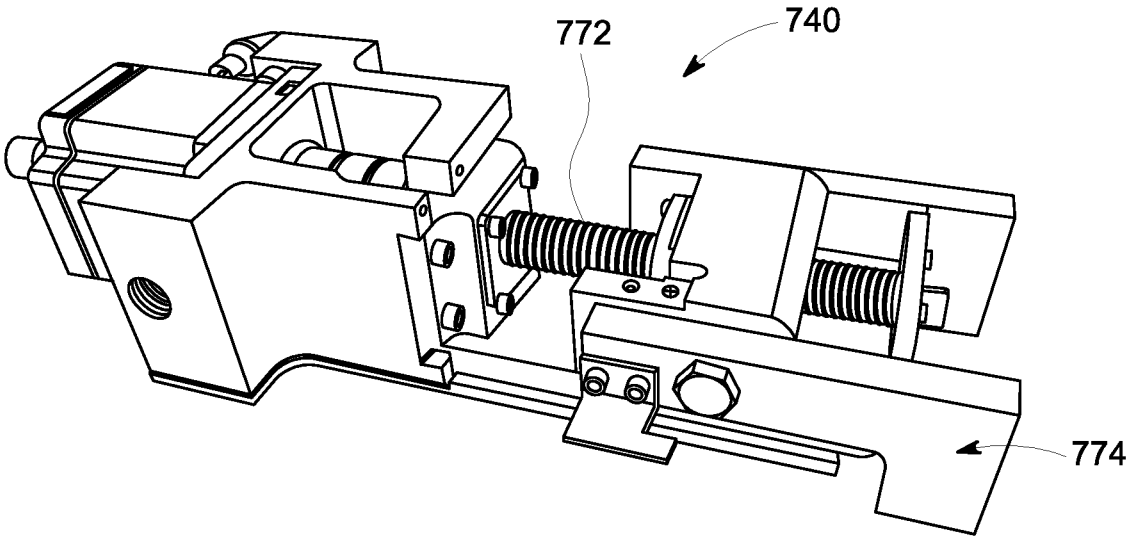


FIG. 30

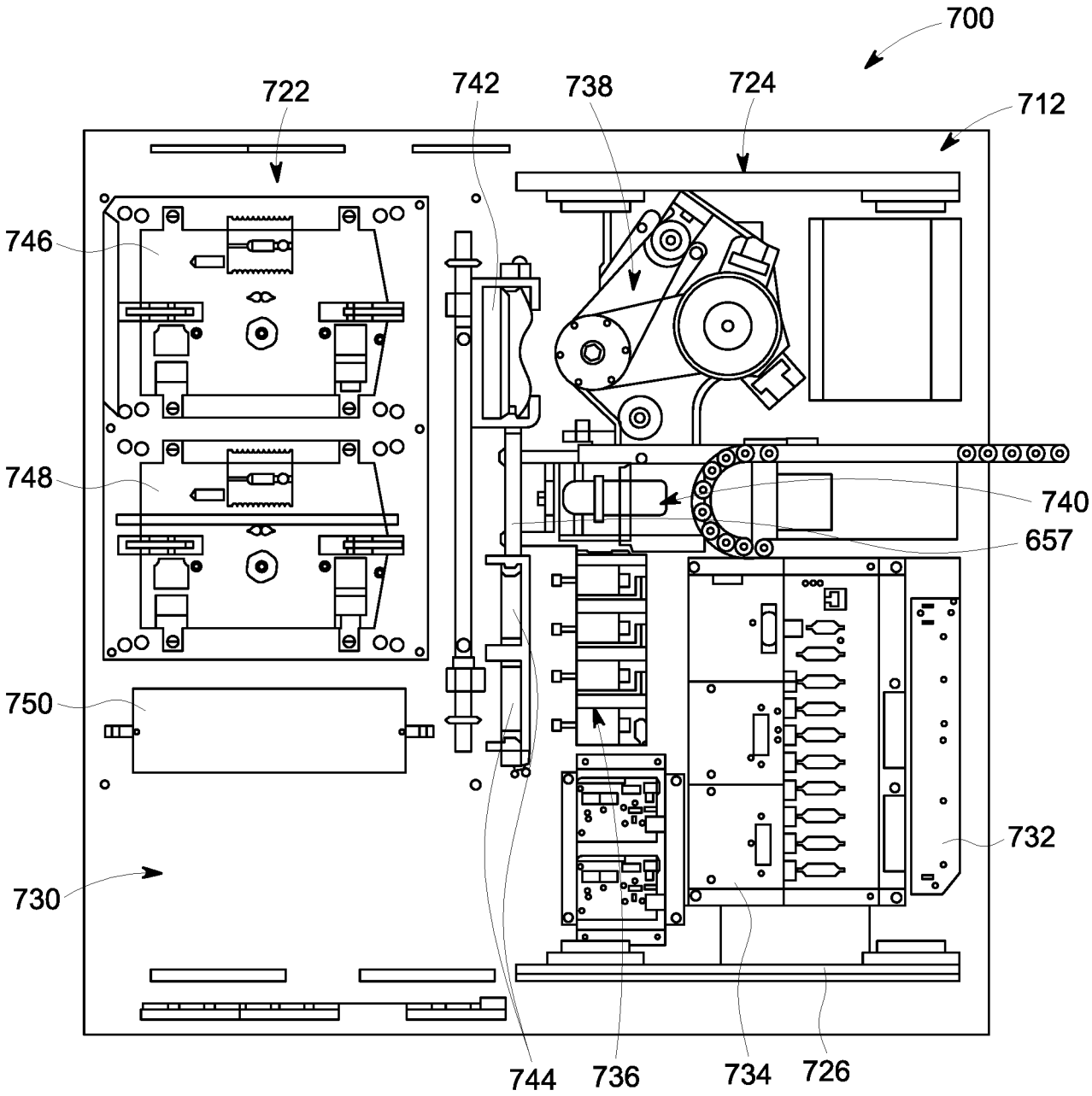

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FIG. 31

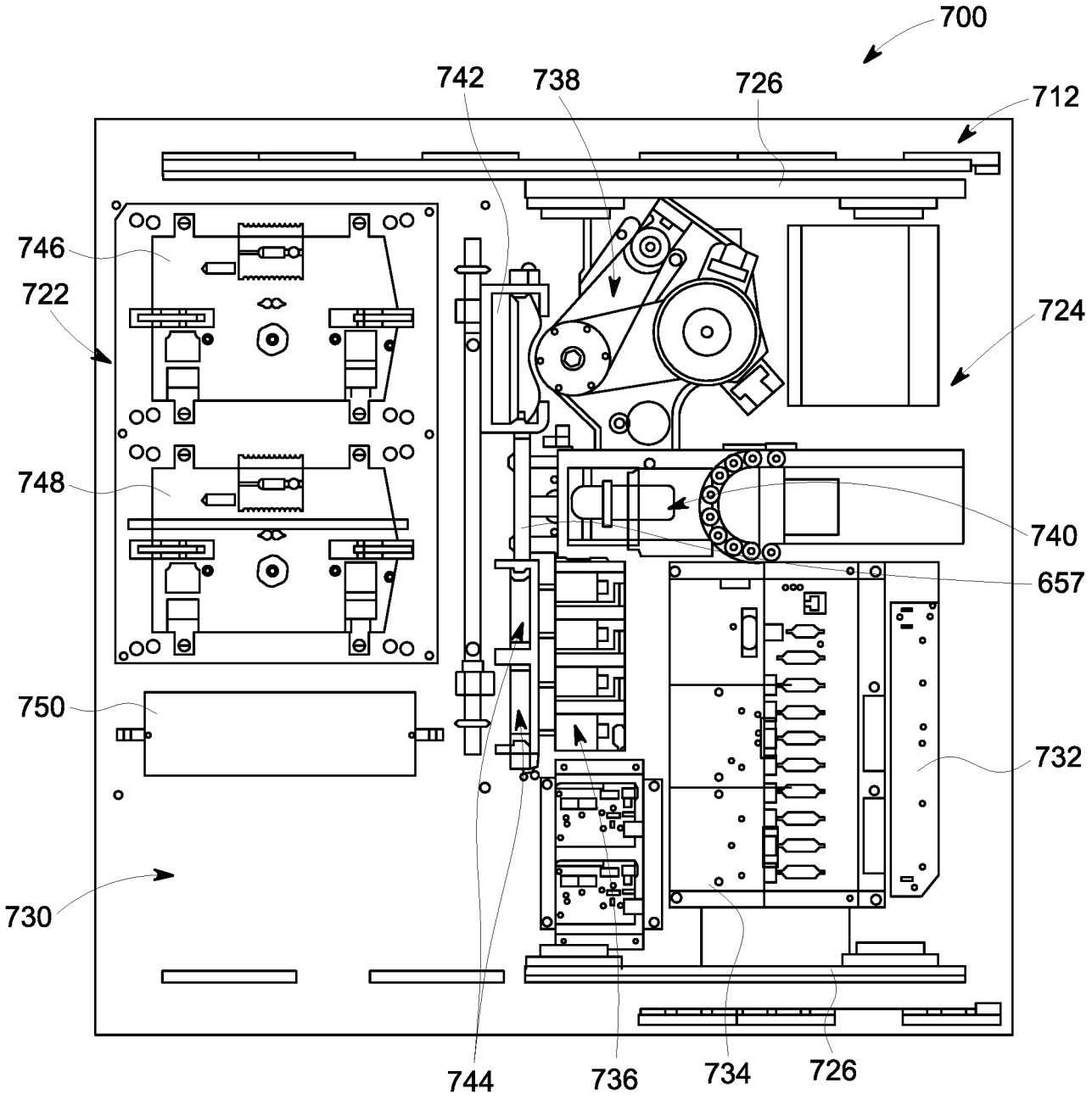

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FIG. 32

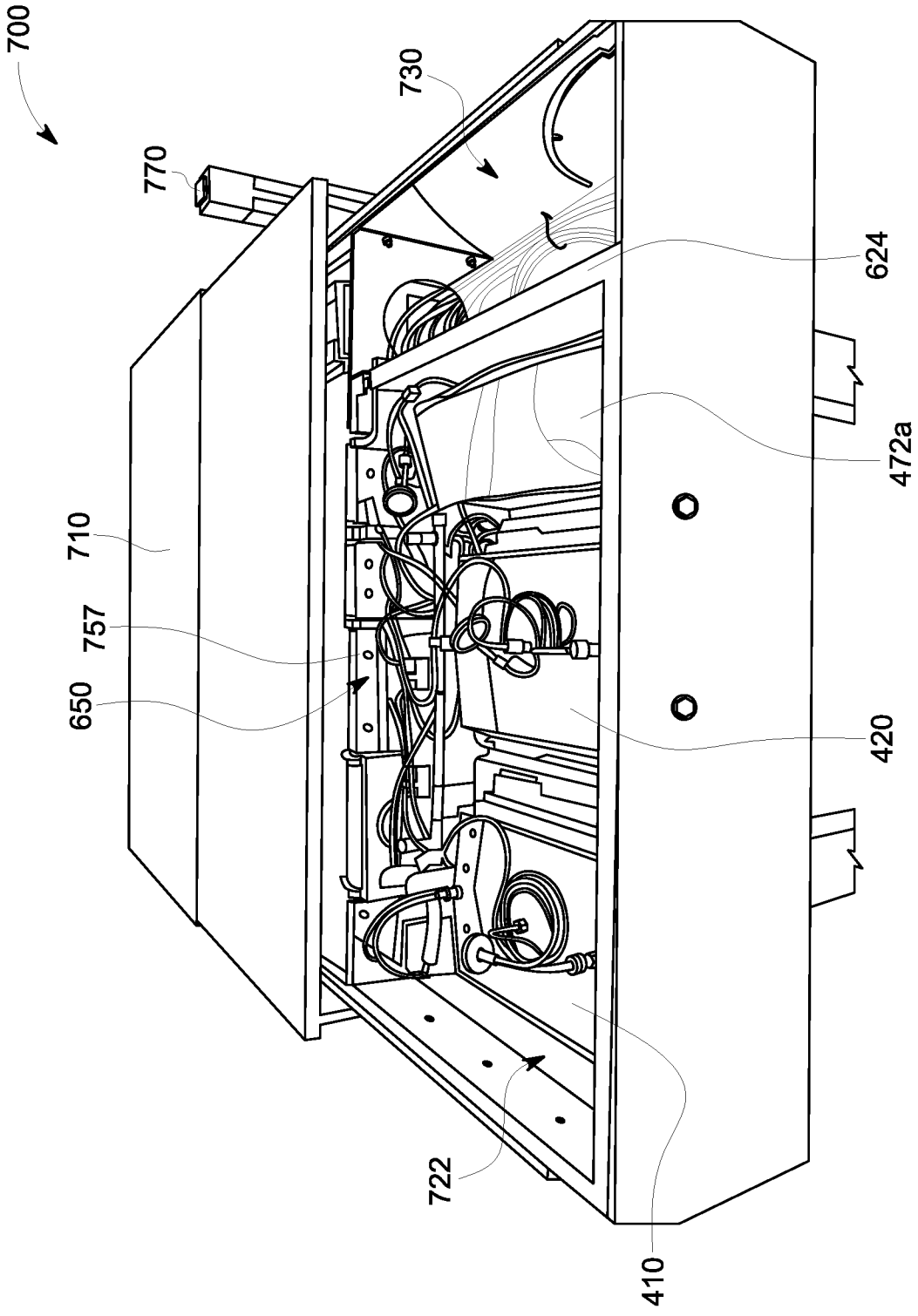


FIG. 33

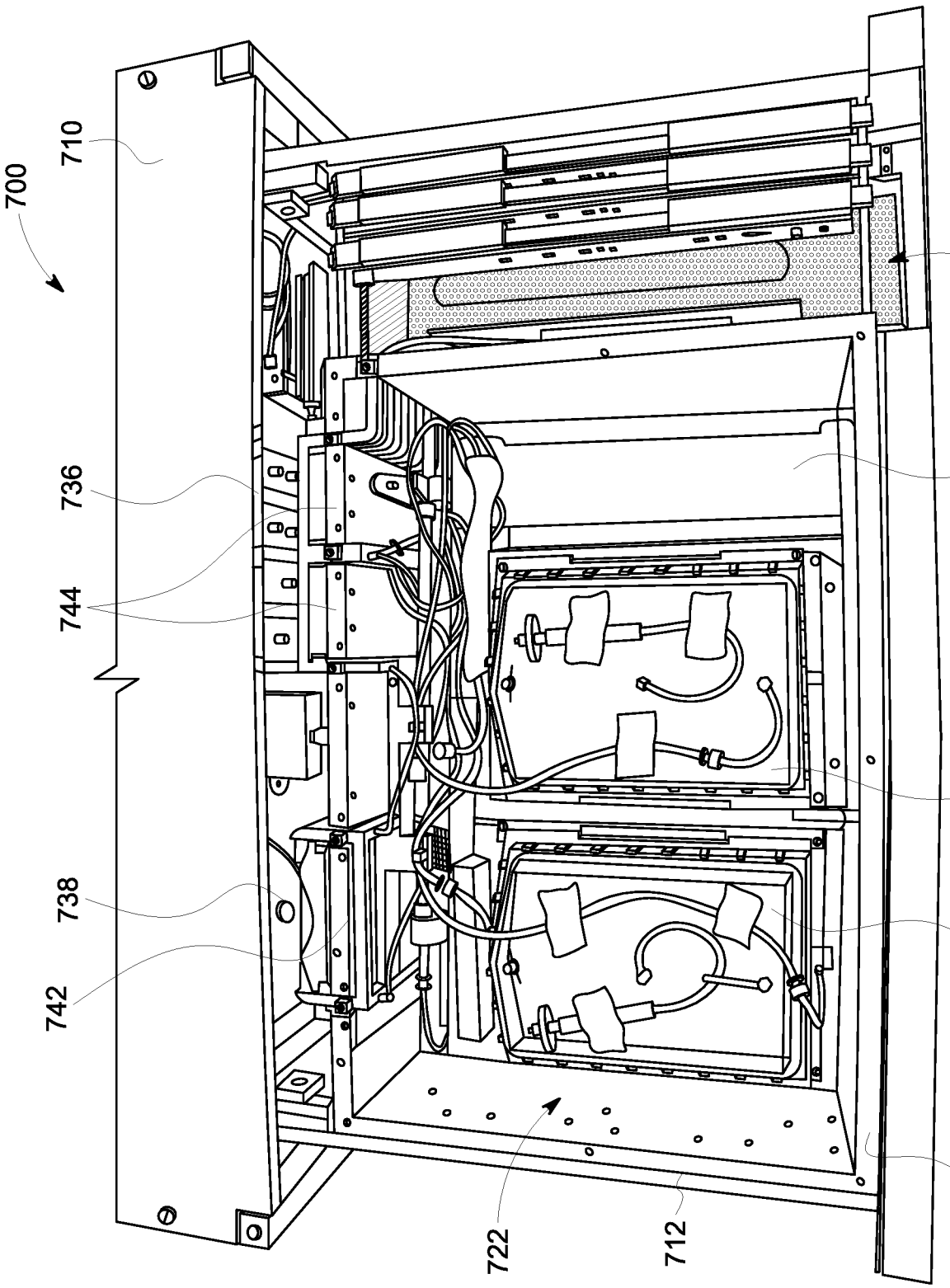


FIG. 34

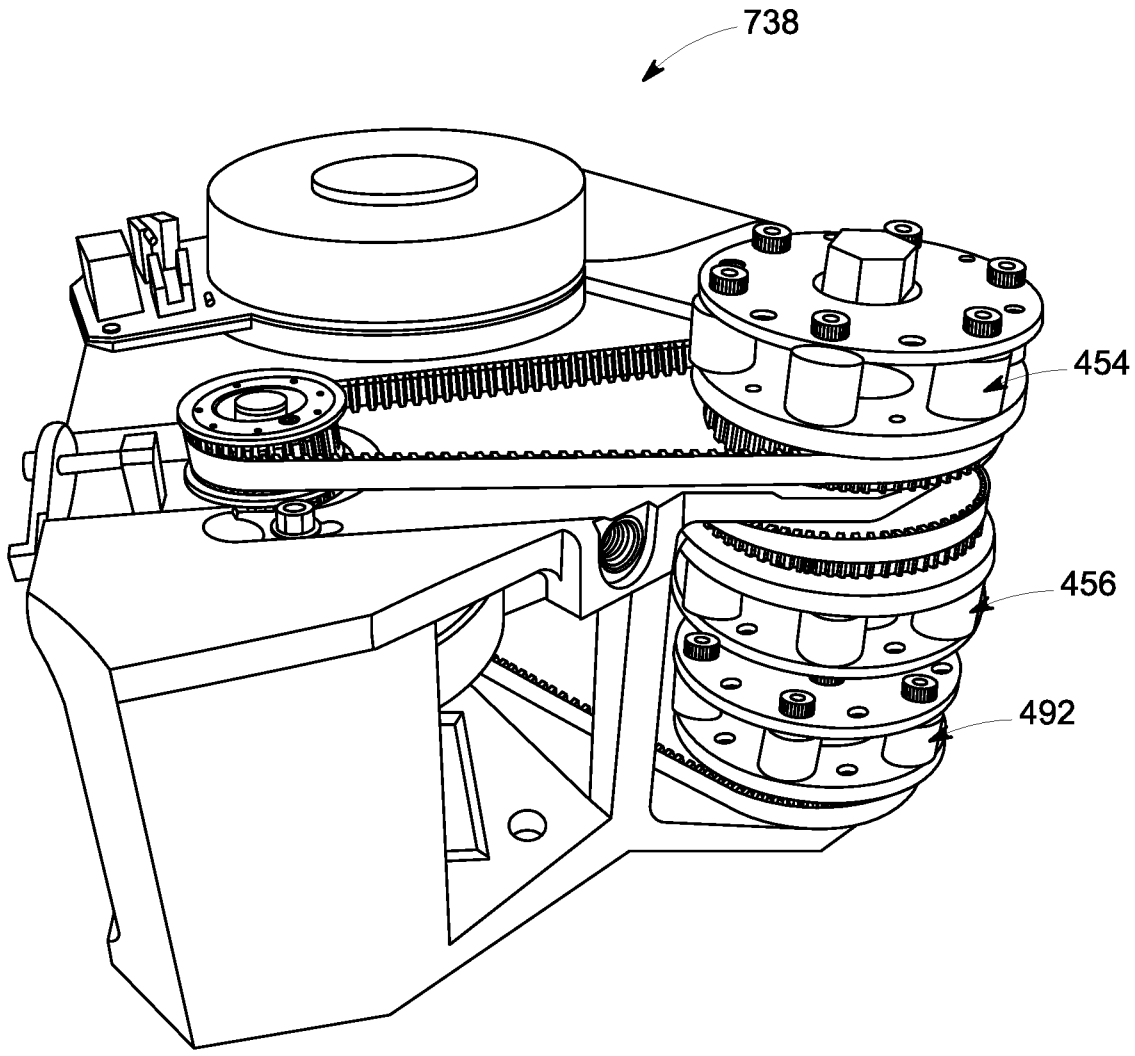


FIG. 35

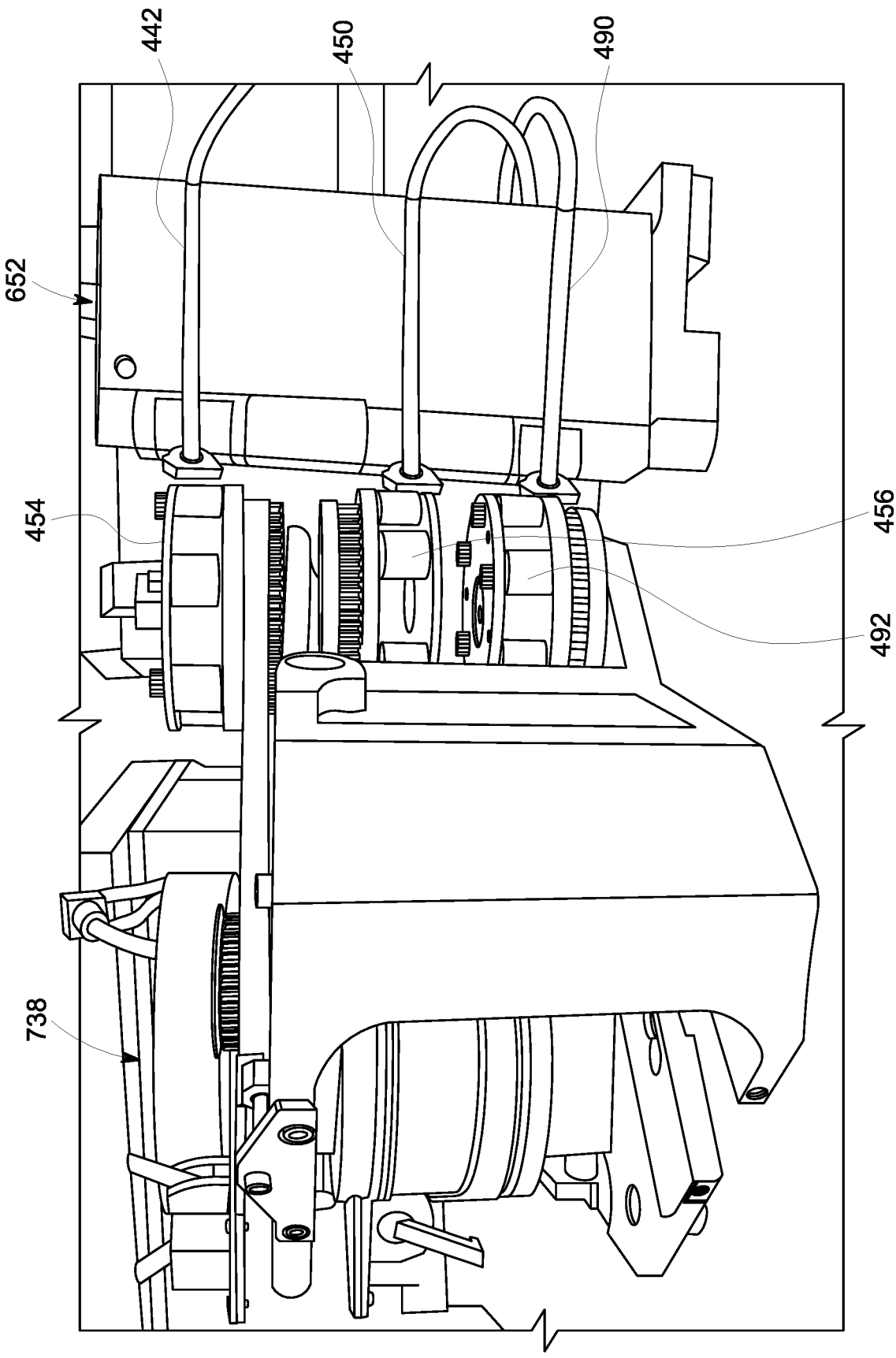


FIG. 36

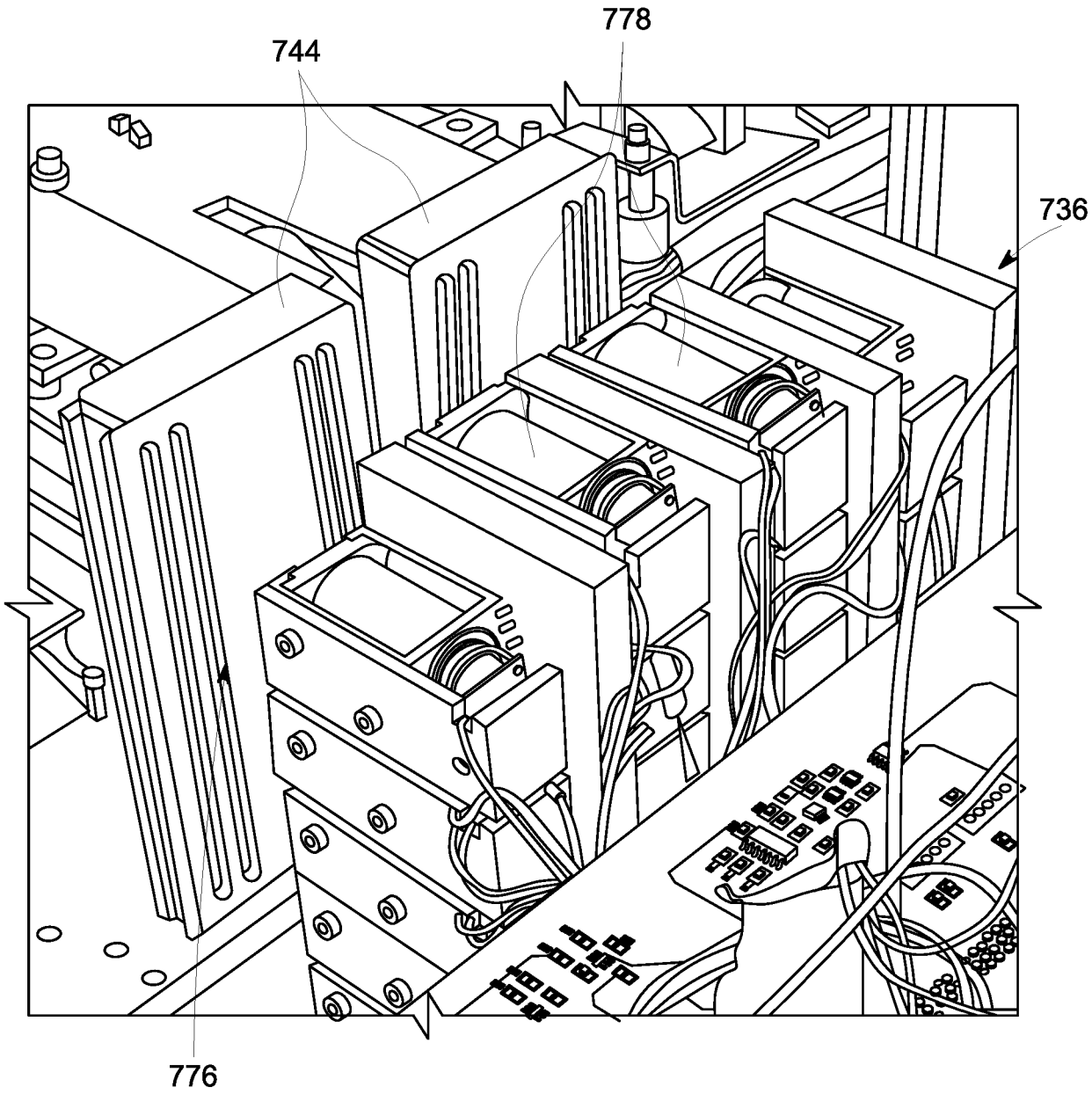


FIG. 37

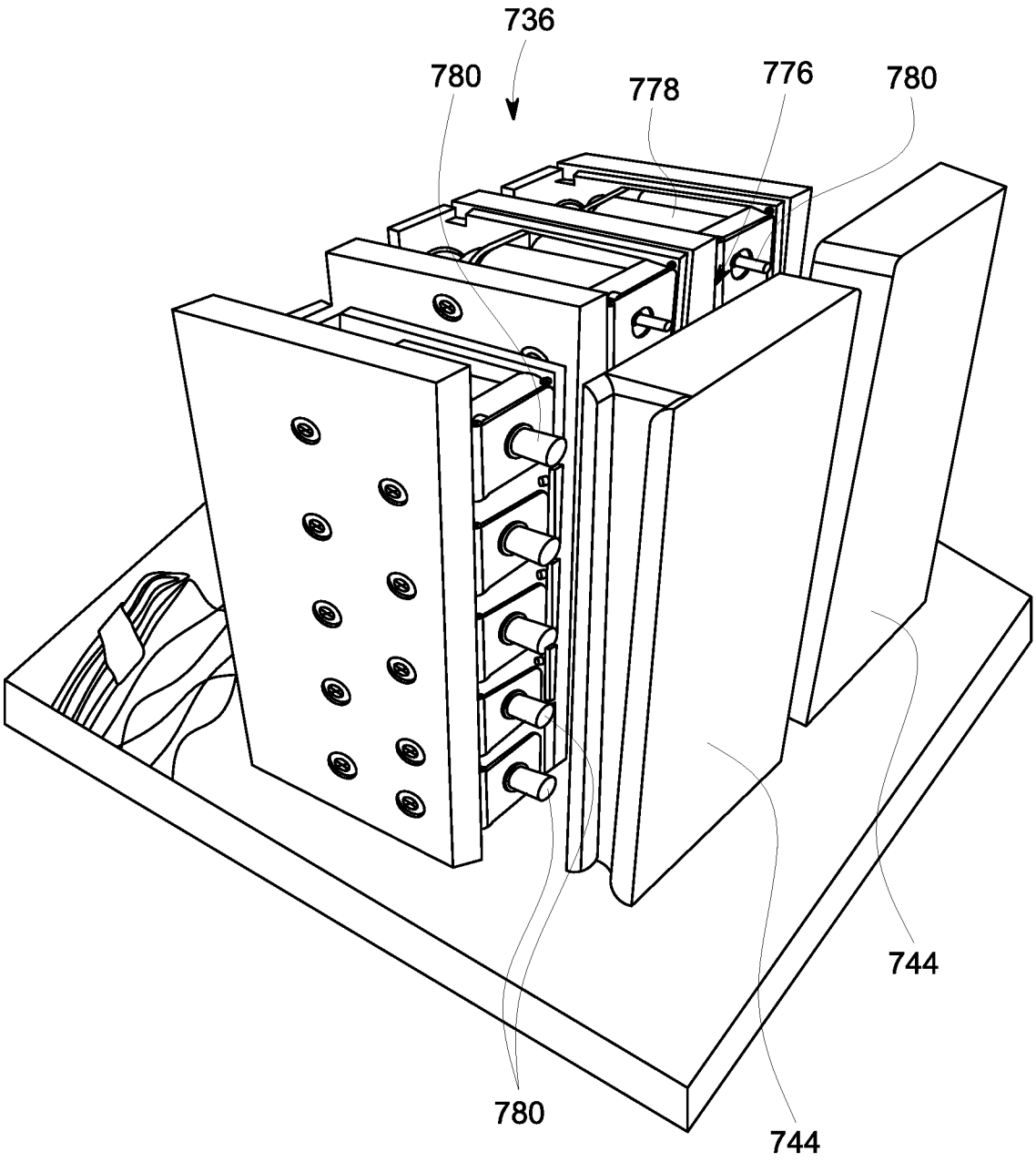


FIG. 38

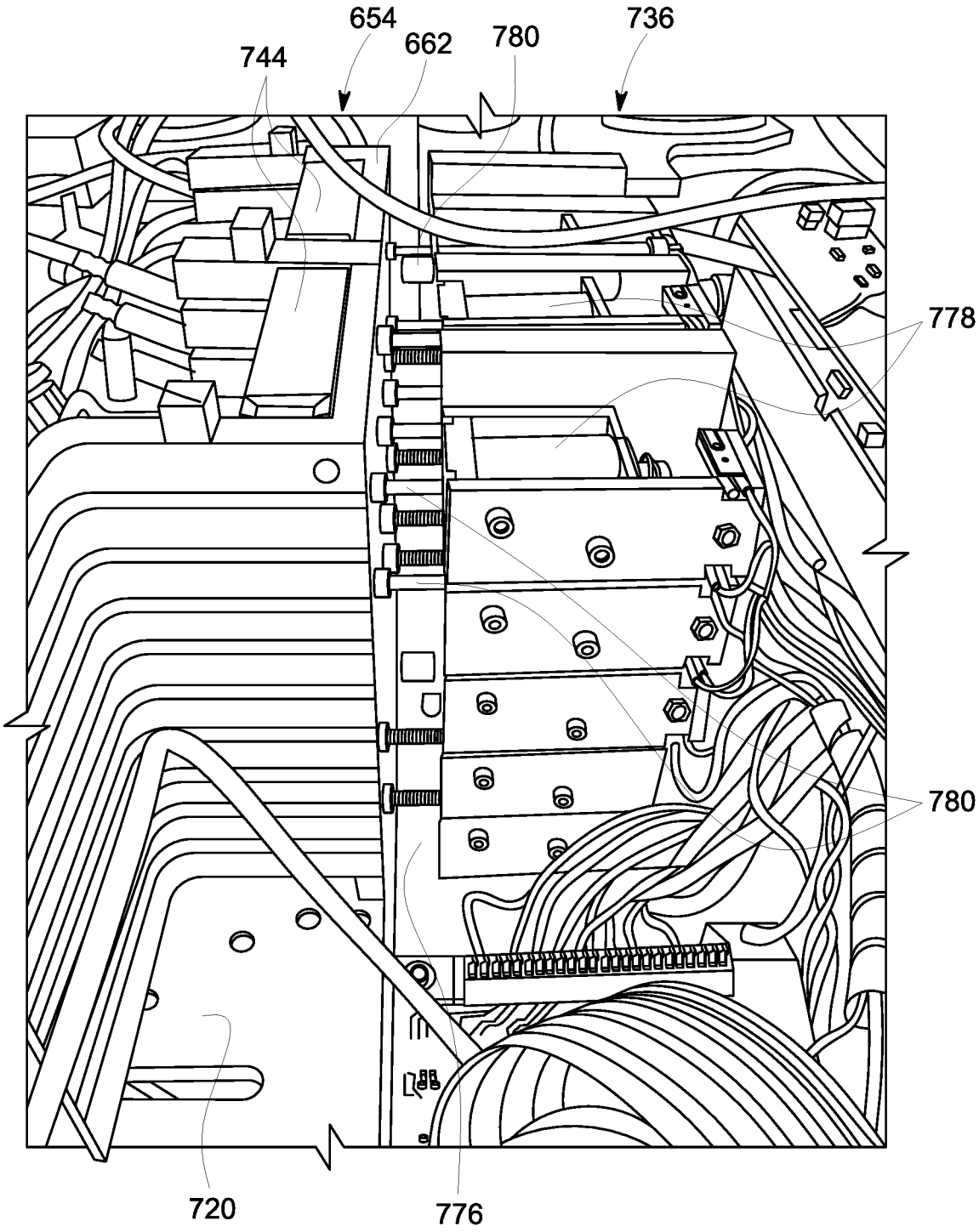


FIG. 39

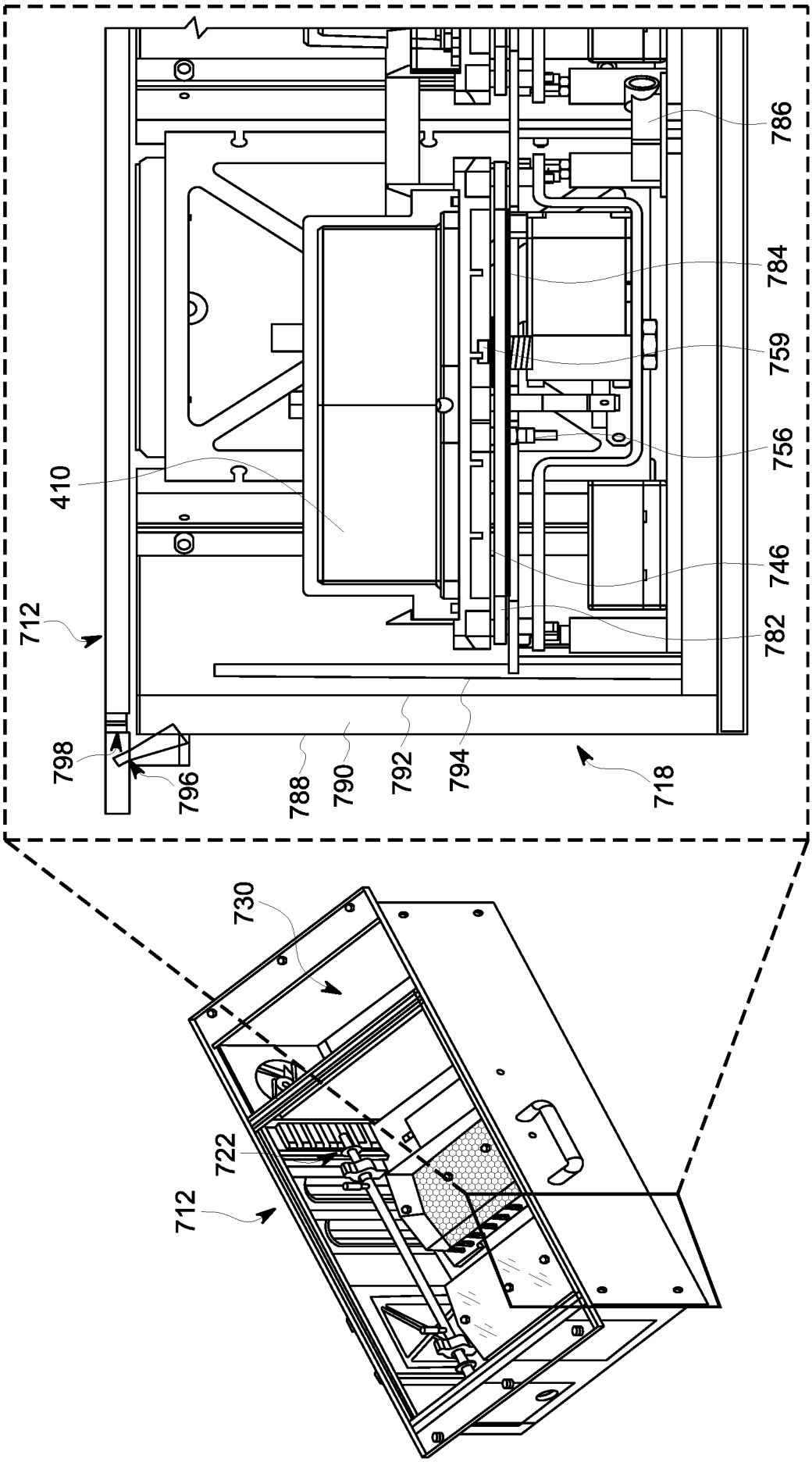

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FIG. 40

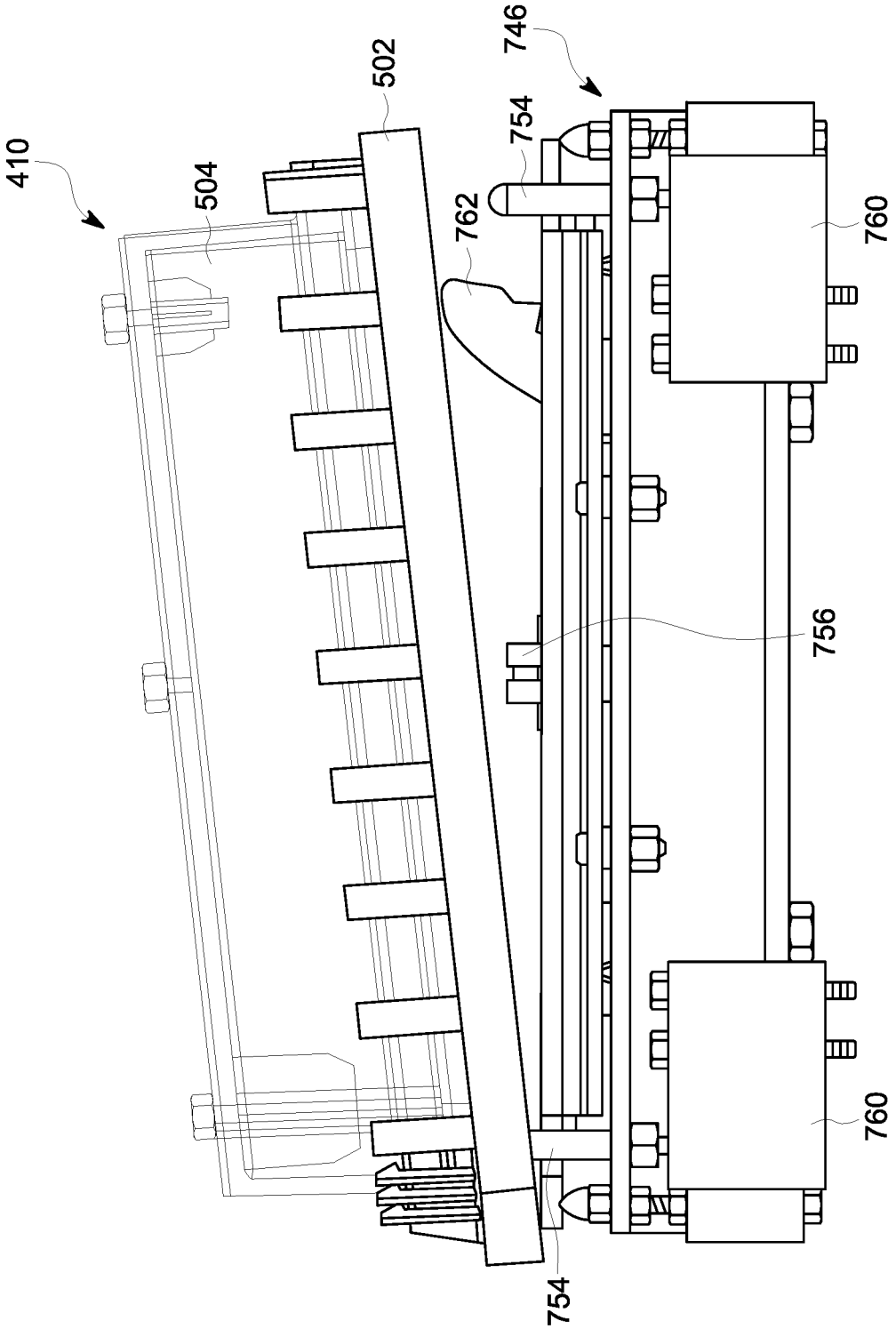


FIG. 41

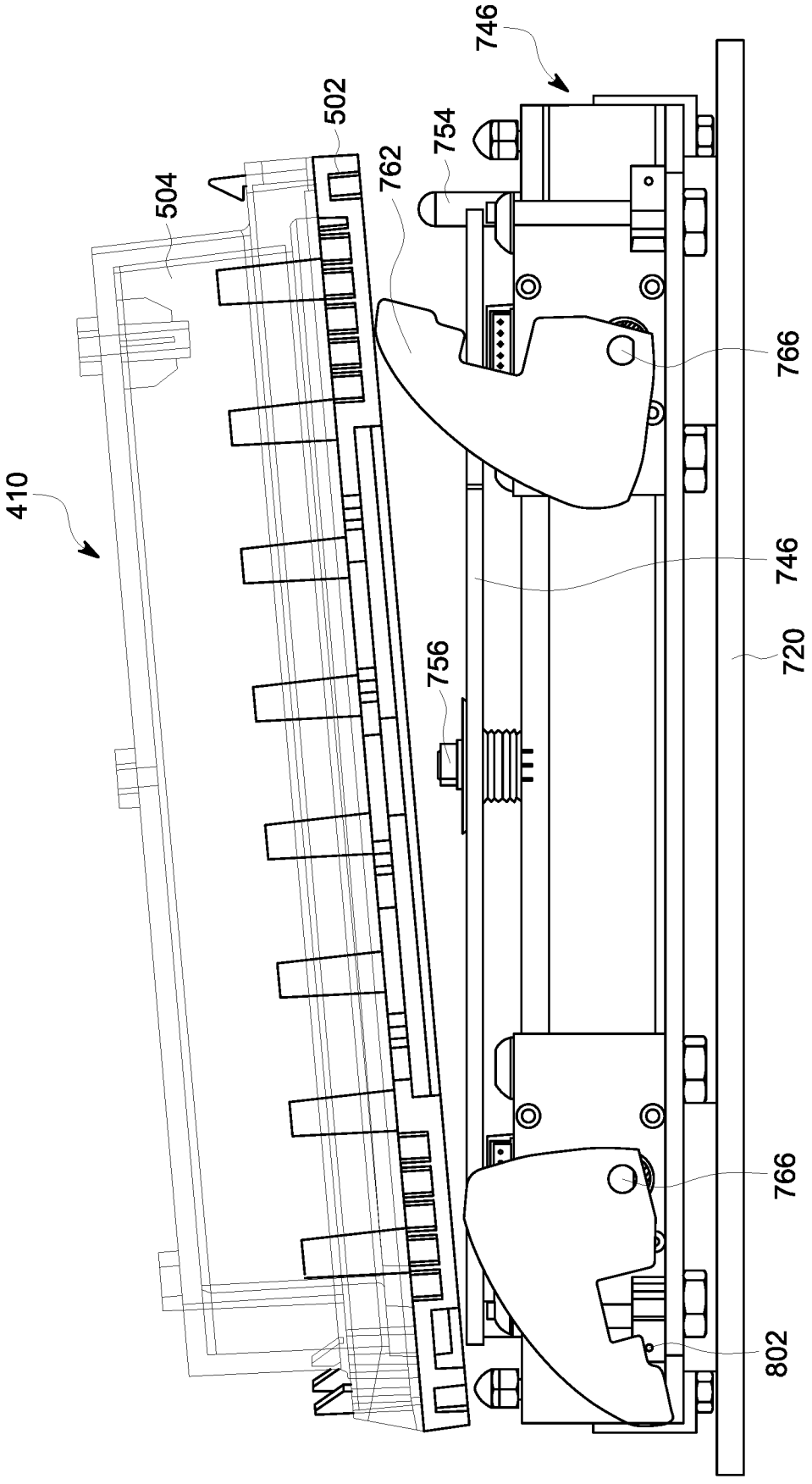


FIG. 42

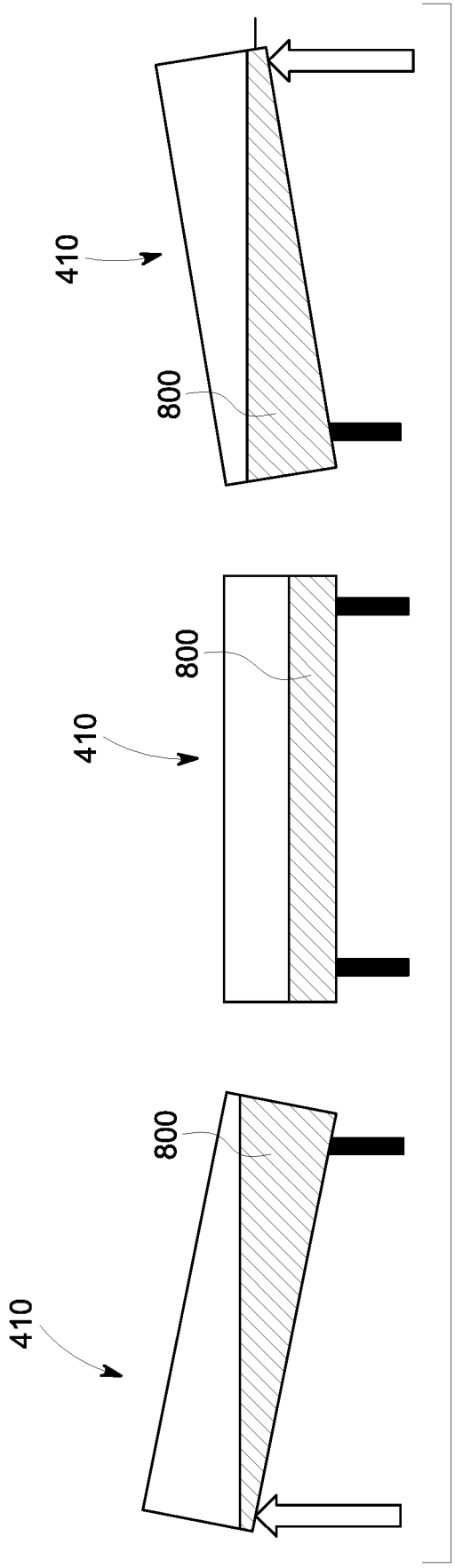


FIG. 43

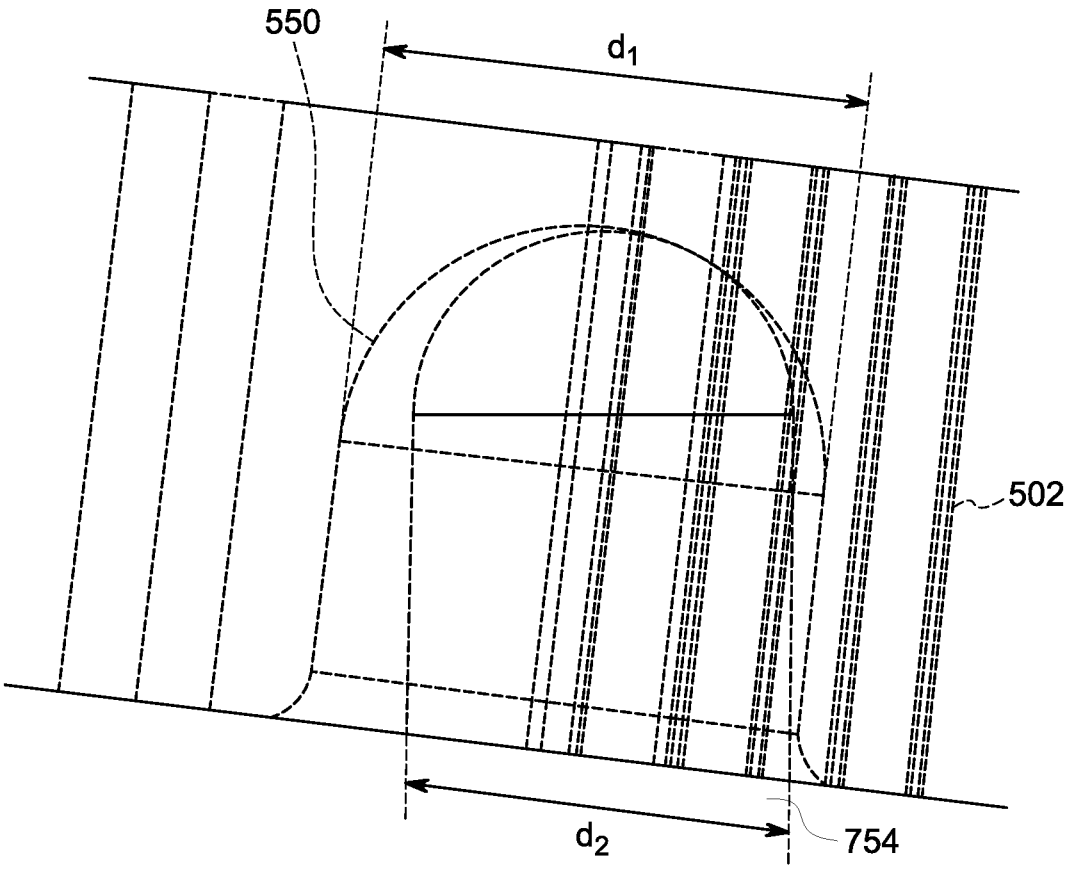


FIG. 44

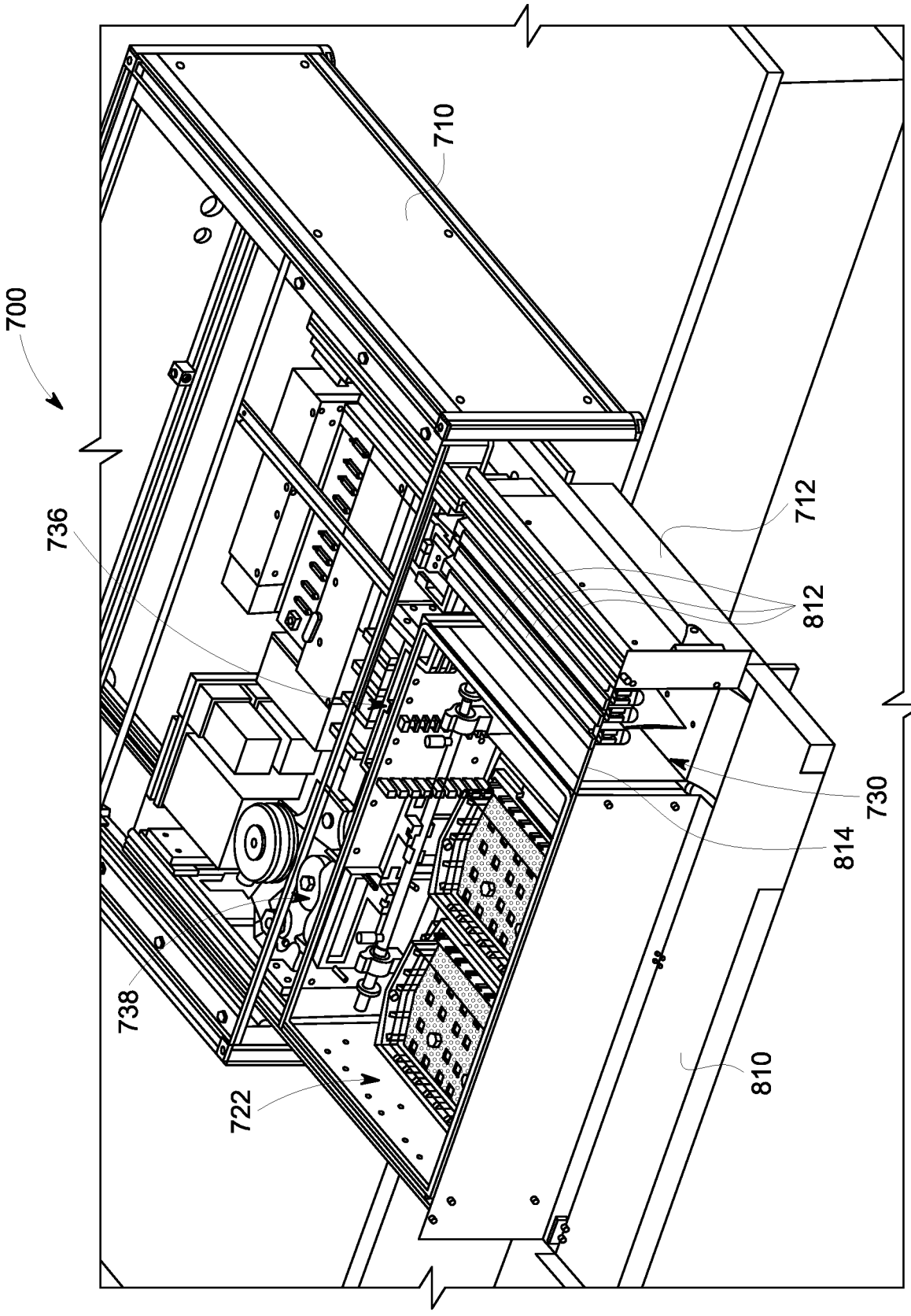


FIG. 45

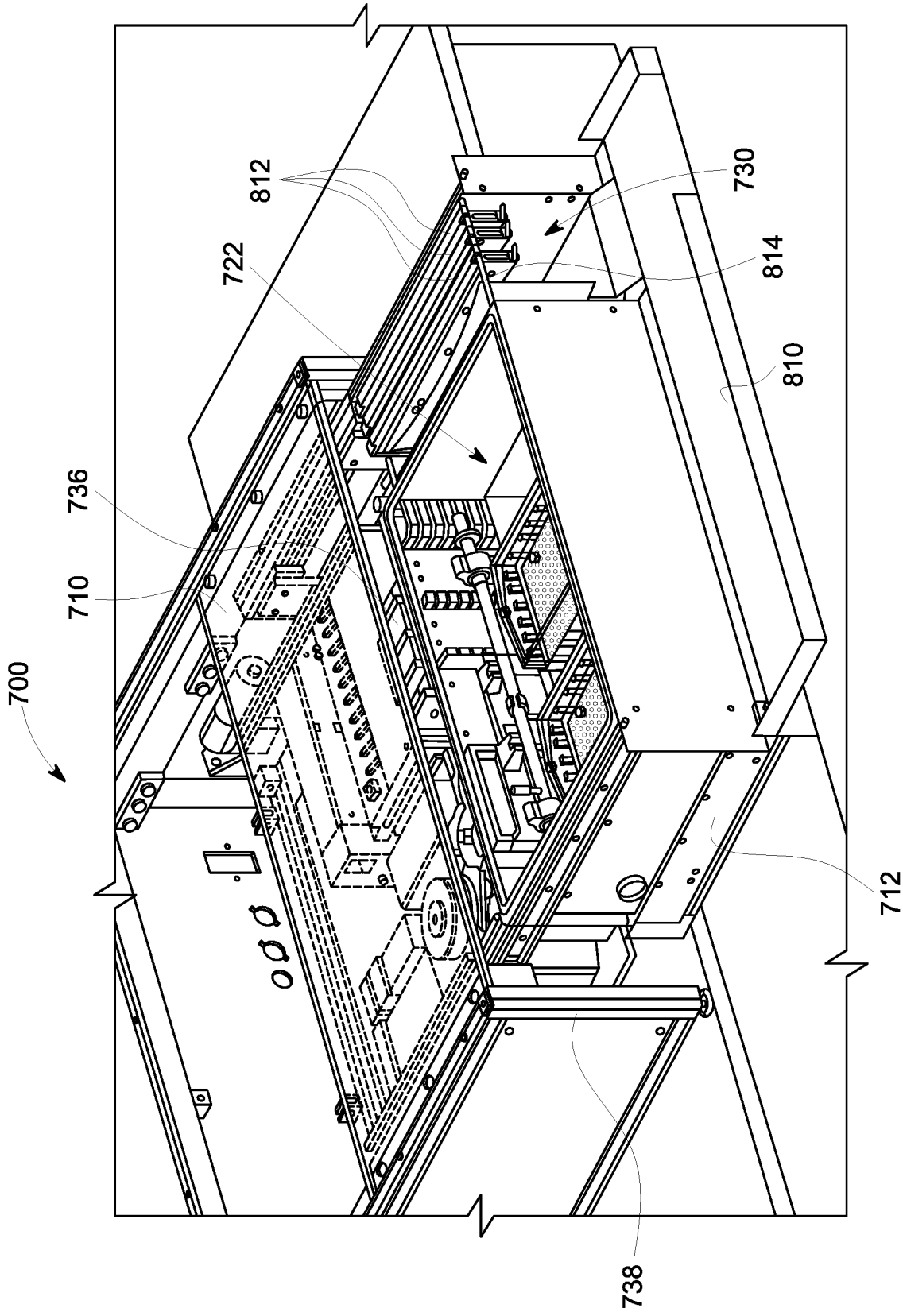


FIG. 46

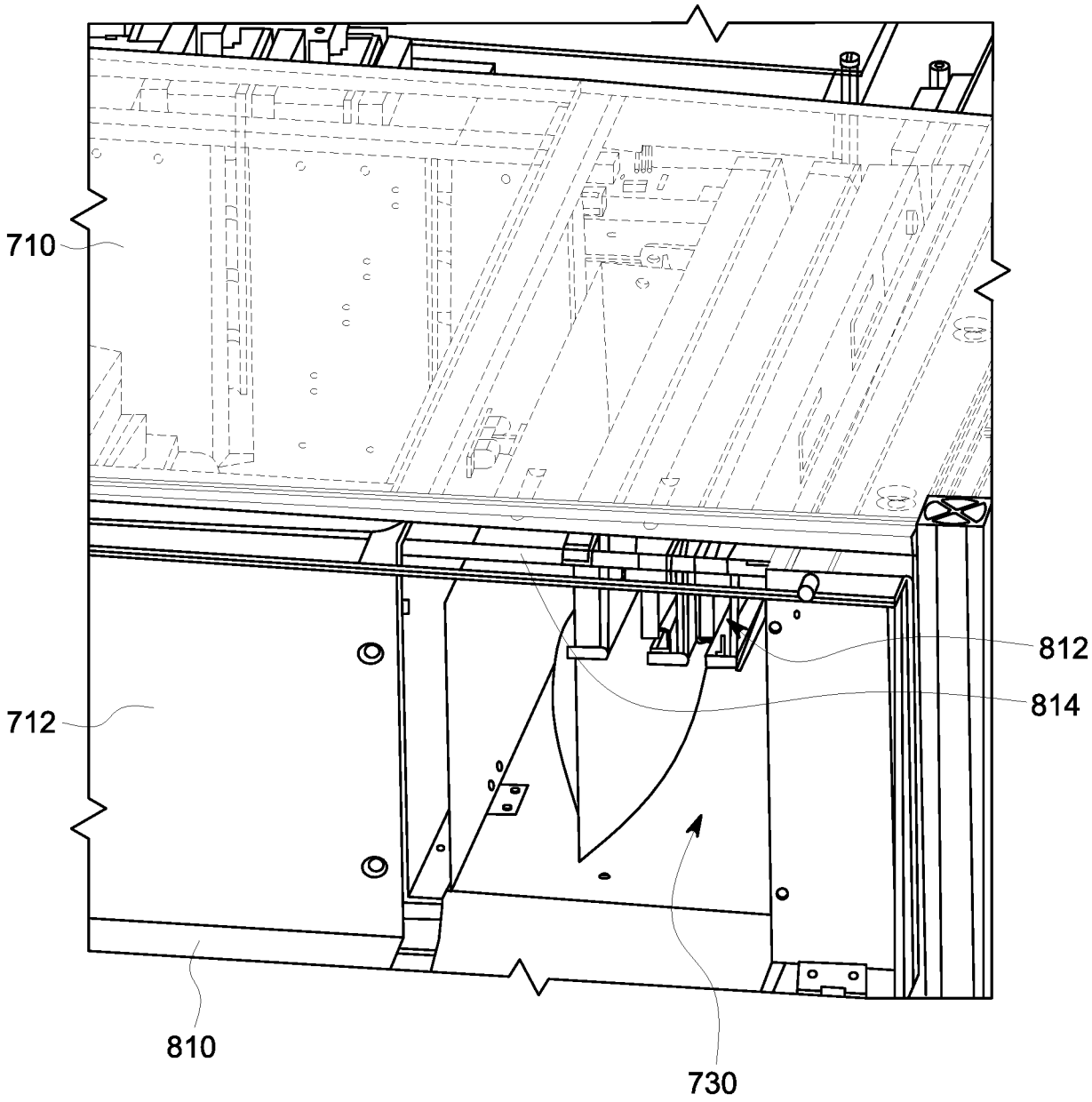


FIG. 47

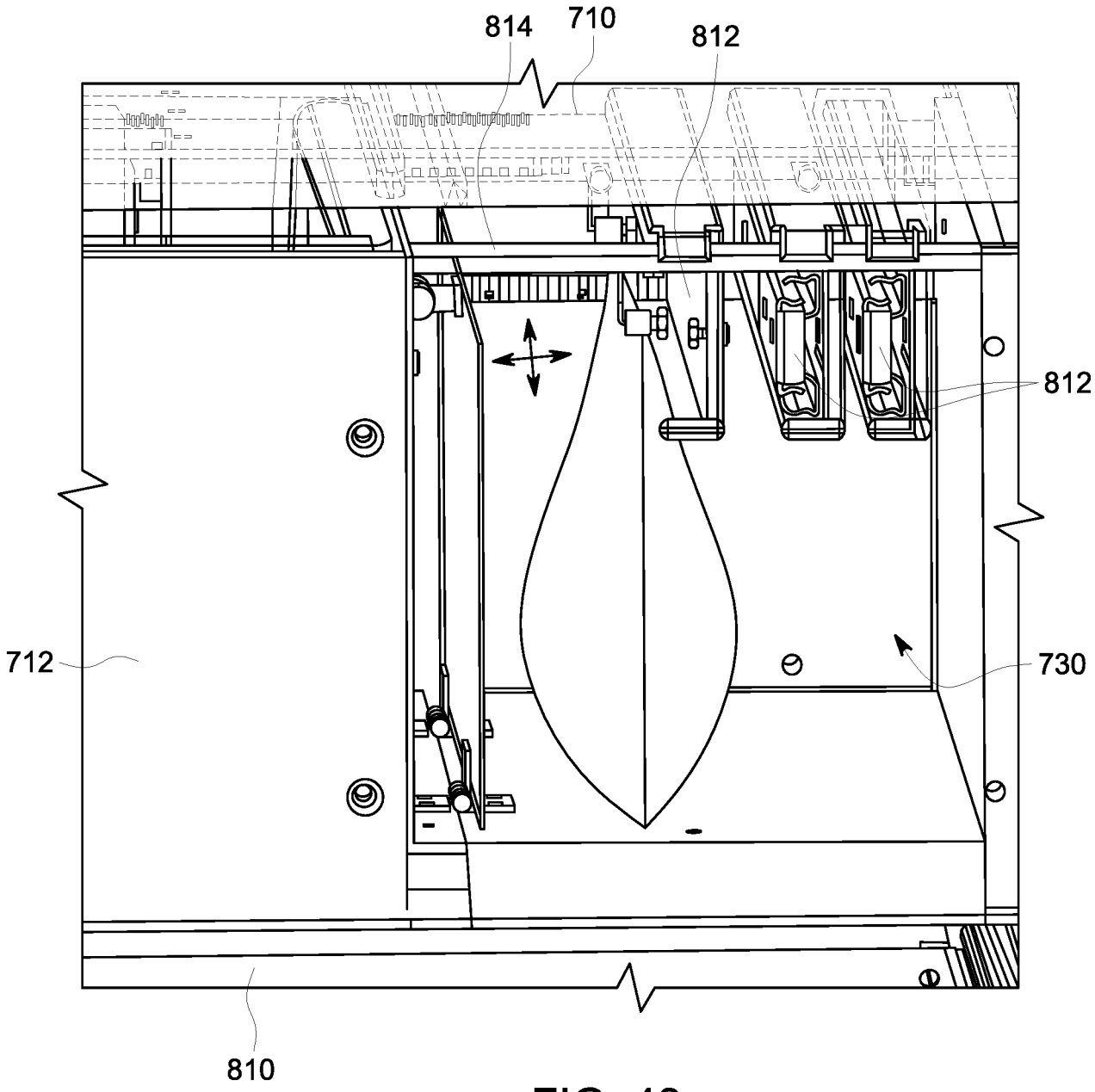


FIG. 48

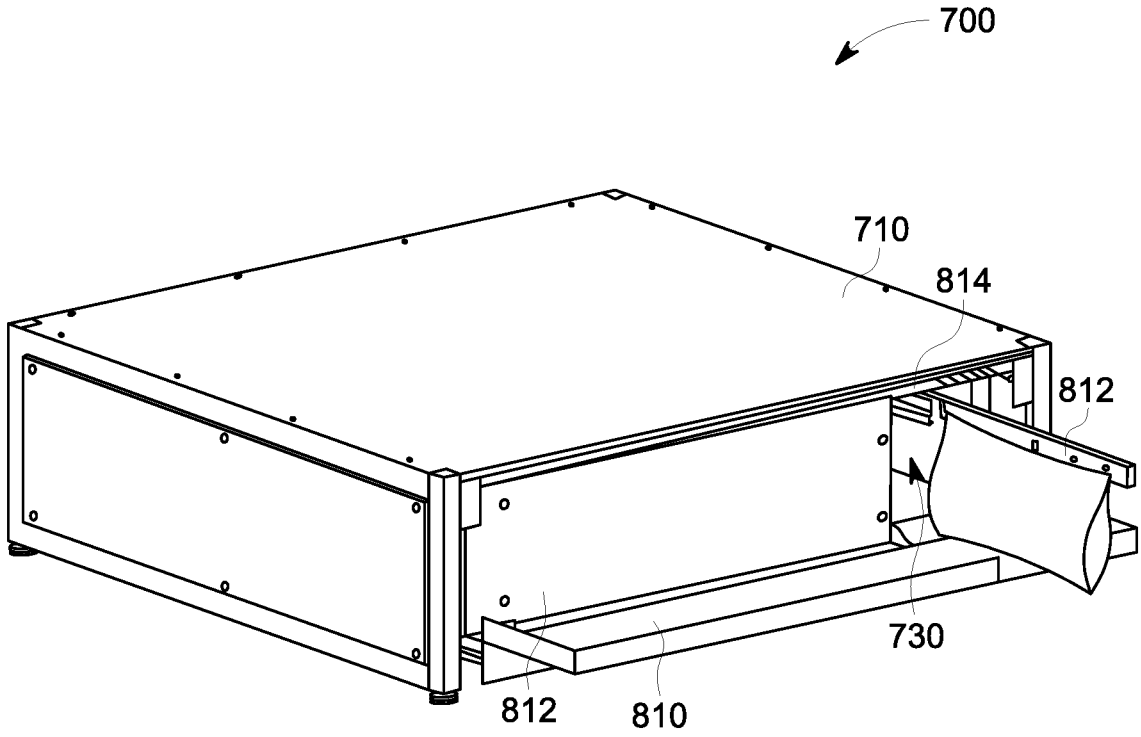


FIG. 49

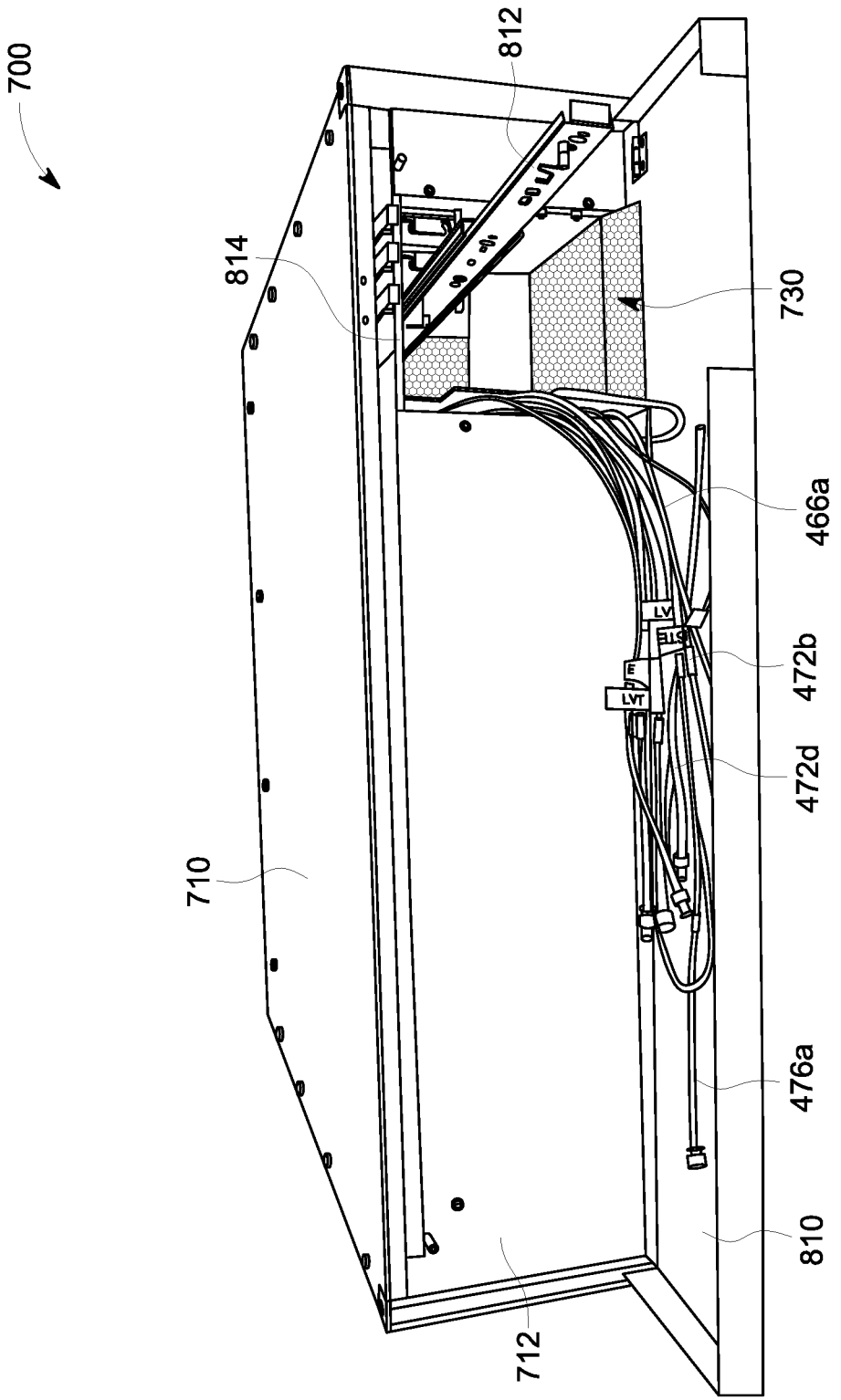


FIG. 50

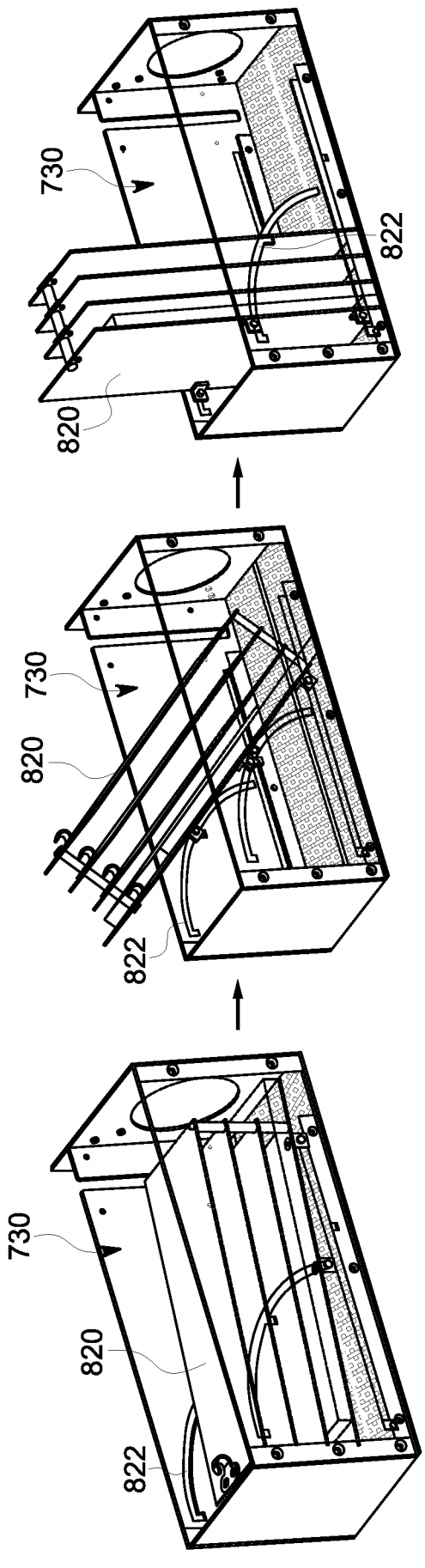


FIG. 51

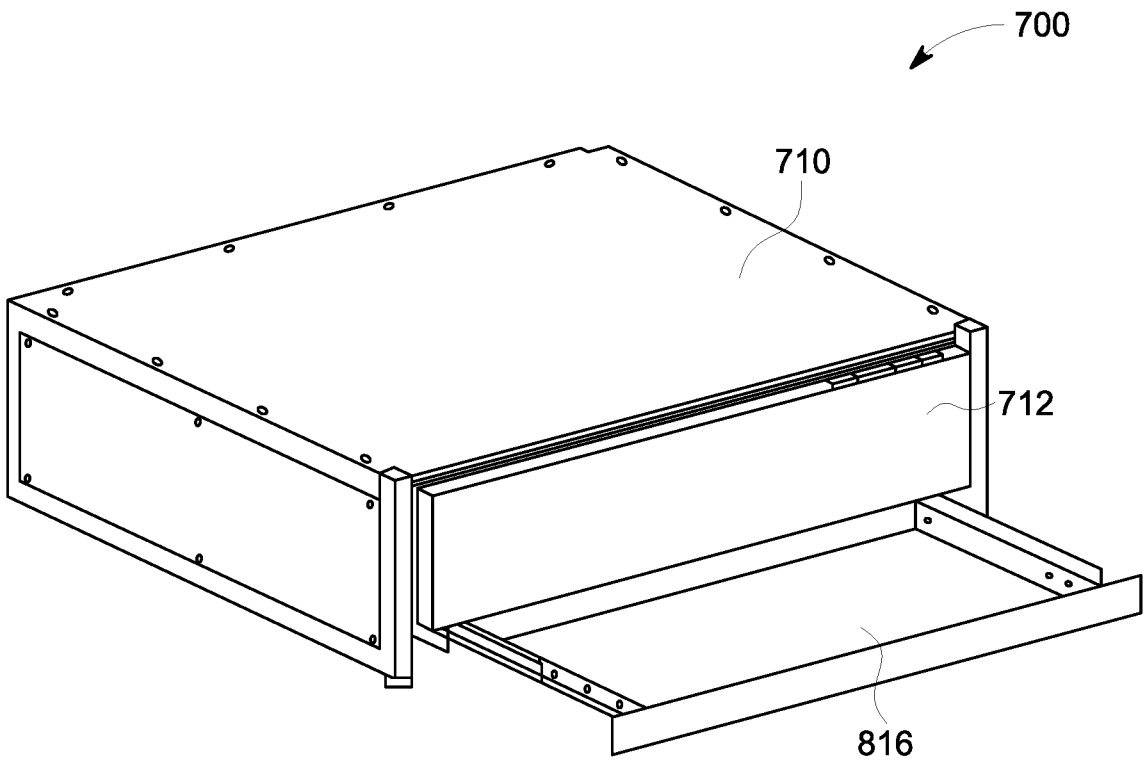


FIG. 52

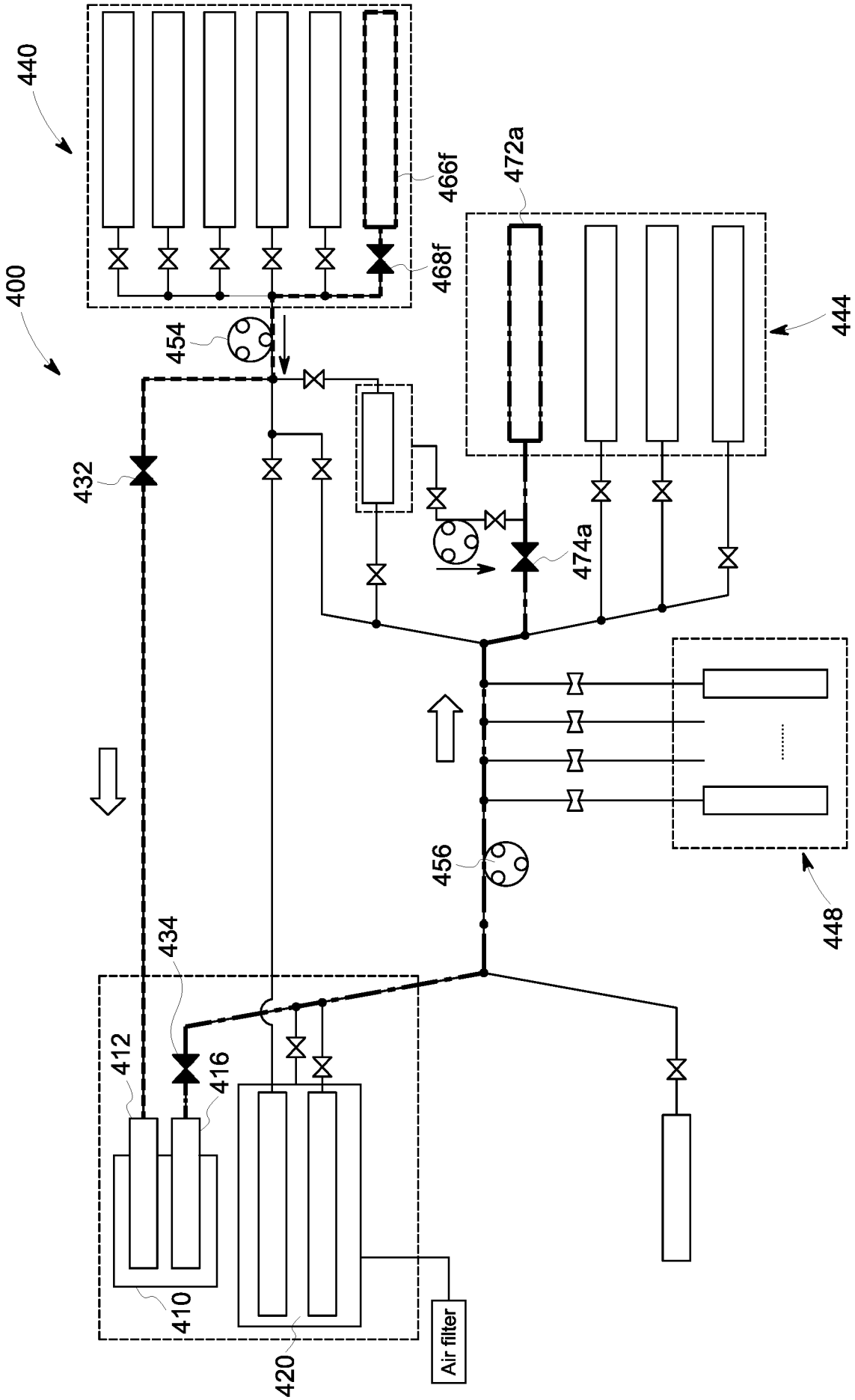

440
400
466f
472a
468f
444
454
432
474a
448
456
434
412
416
410
420
Air filter

FIG. 53

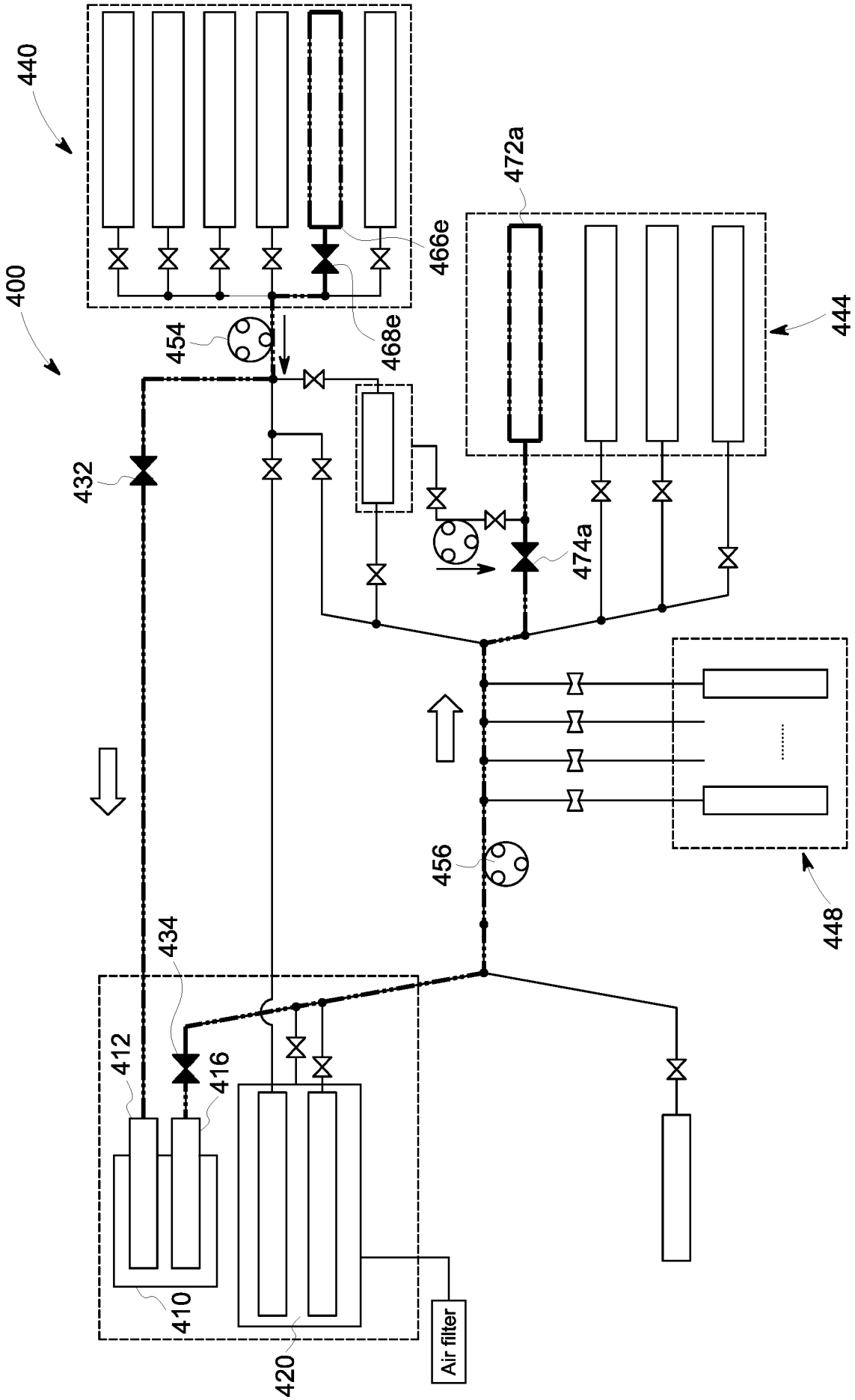

440
400
472a
466e
468e
454
444
432
474a
456
448
434
412
416
410
420
Air filter

FIG. 54

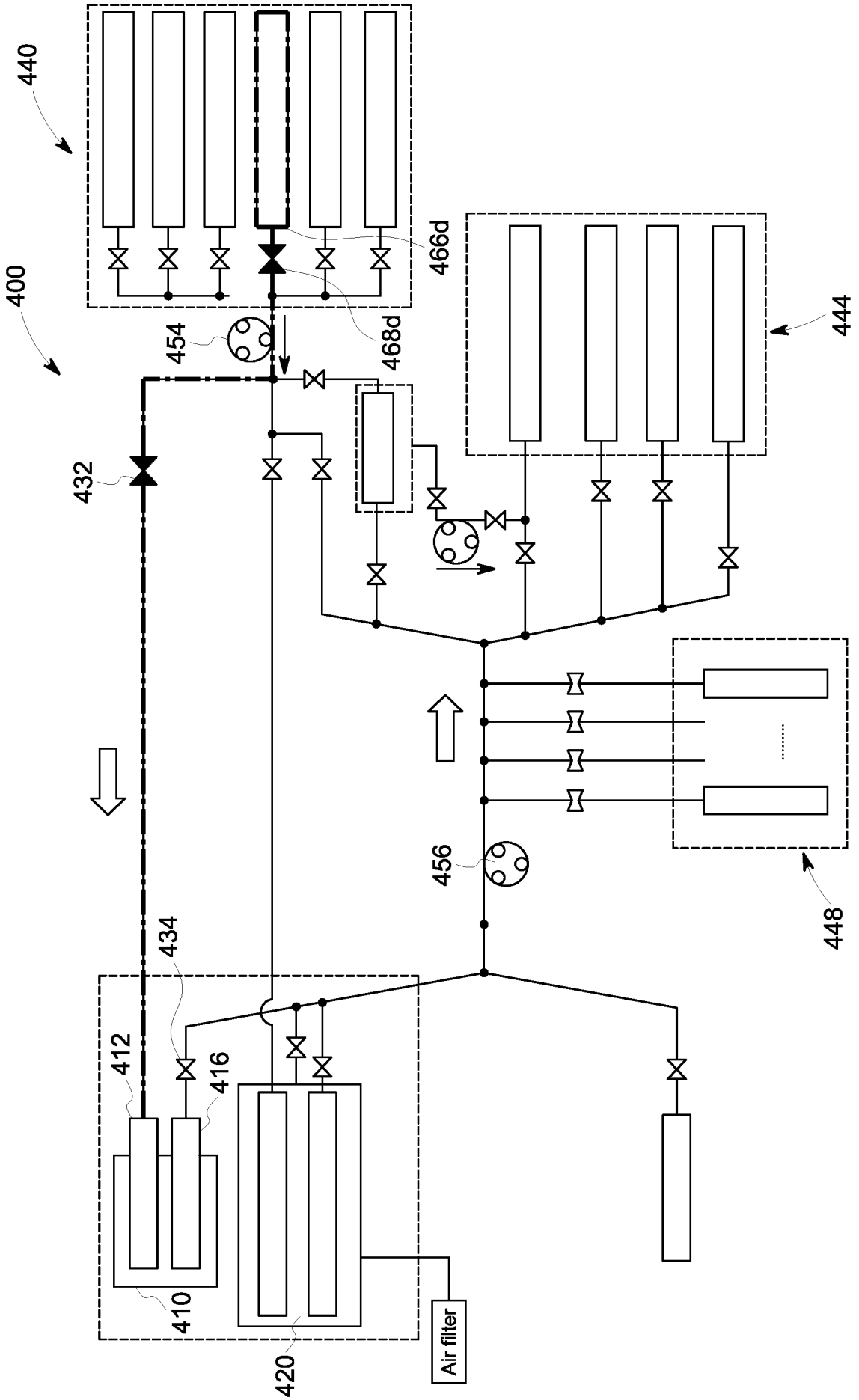

440
400
466d
468d
454
444
432
456
448
434
412
416
410
420
Air filter

FIG. 55

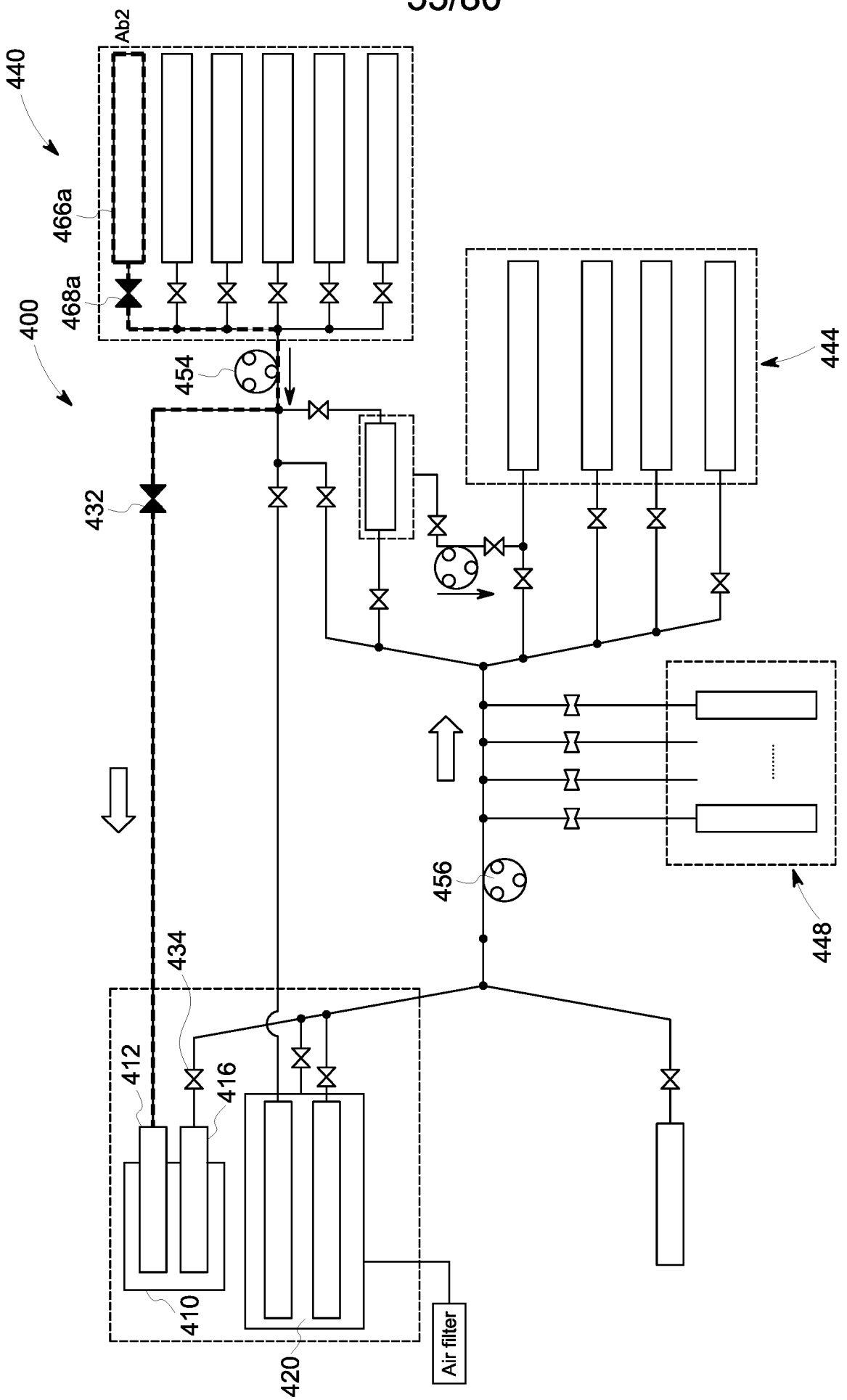

Ab2
440
466a
468a
400
454
444
432
456
448
434
412
416
410
420
Air filter

FIG. 56

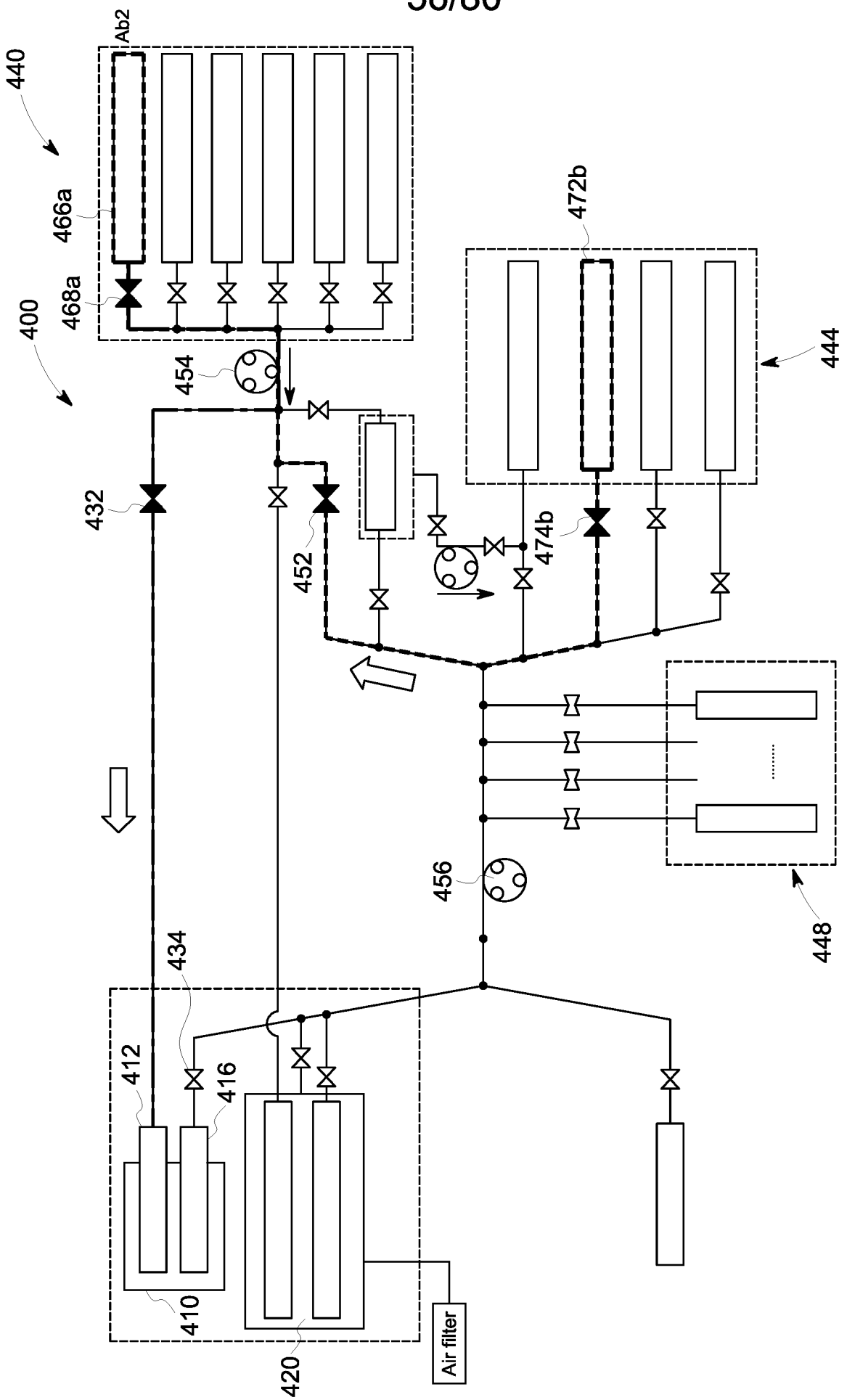

440
Ab2
466a
468a
400
454
472b
444
432
452
474b
448
456
434
412
416
410
420
Air filter

FIG. 57

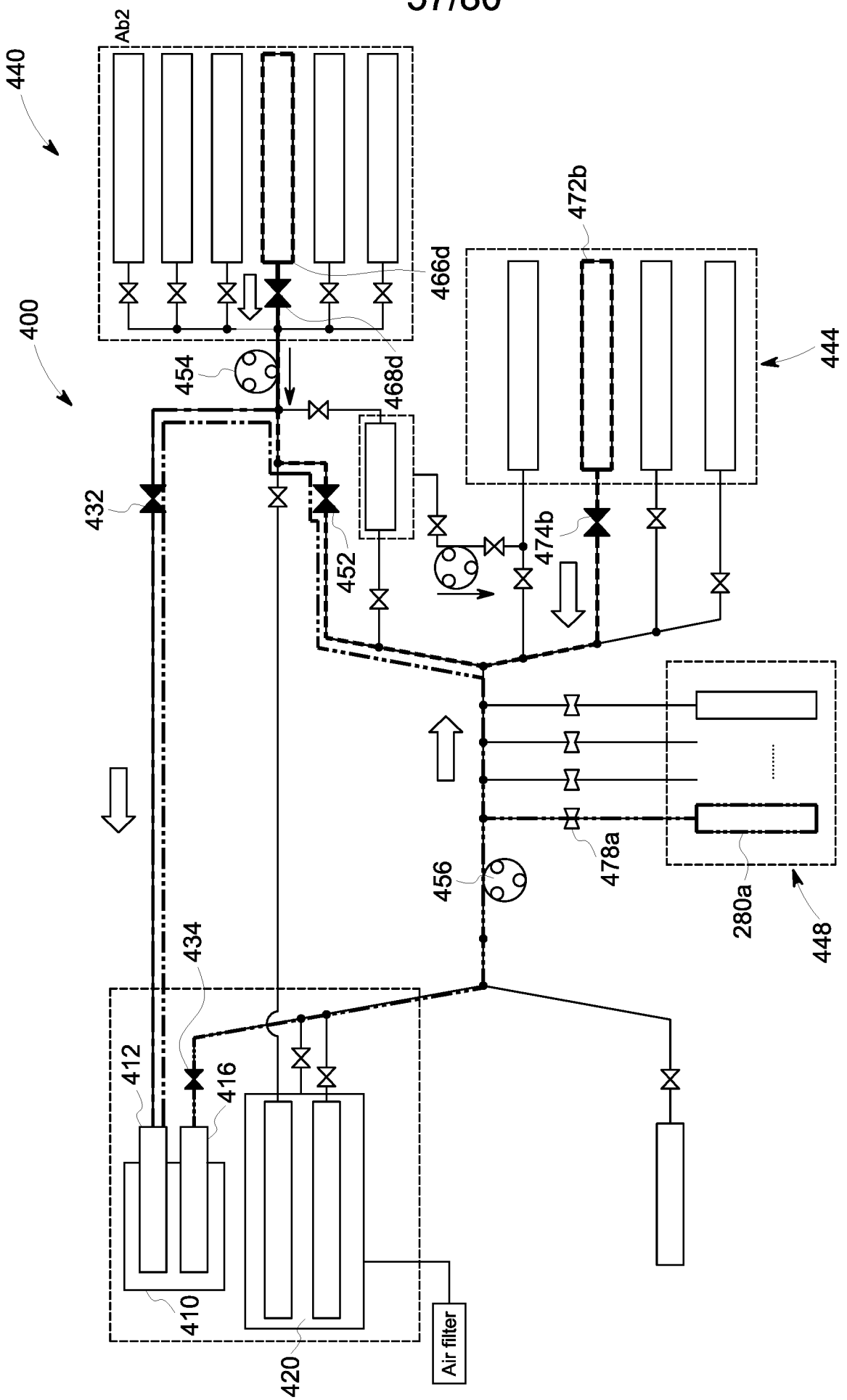

440
Ab2
400
466d
472b
444
454
468d
432
452
474b
478a
456
280a
448
434
412
416
410
420
Air filter

FIG. 58

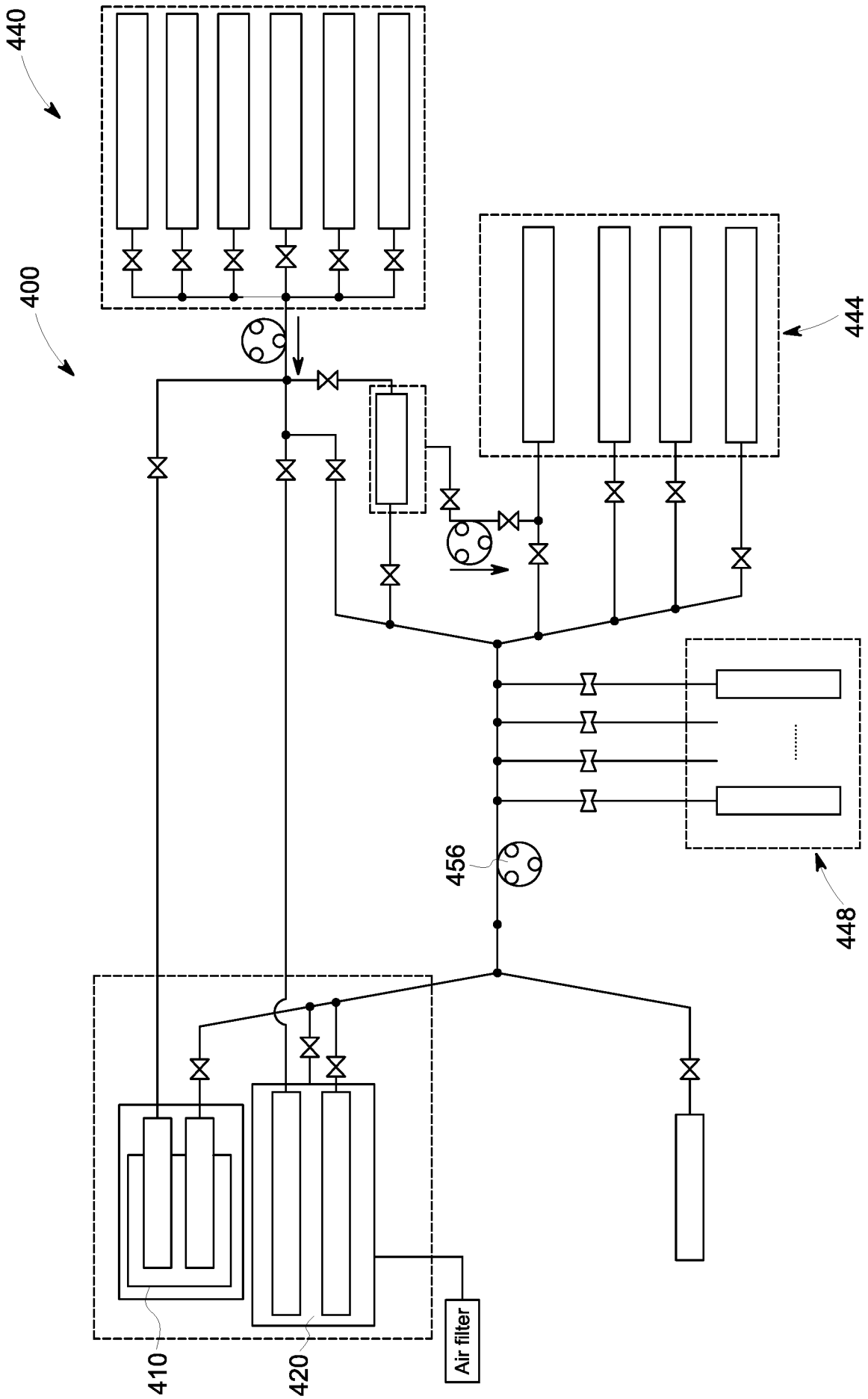


FIG. 59

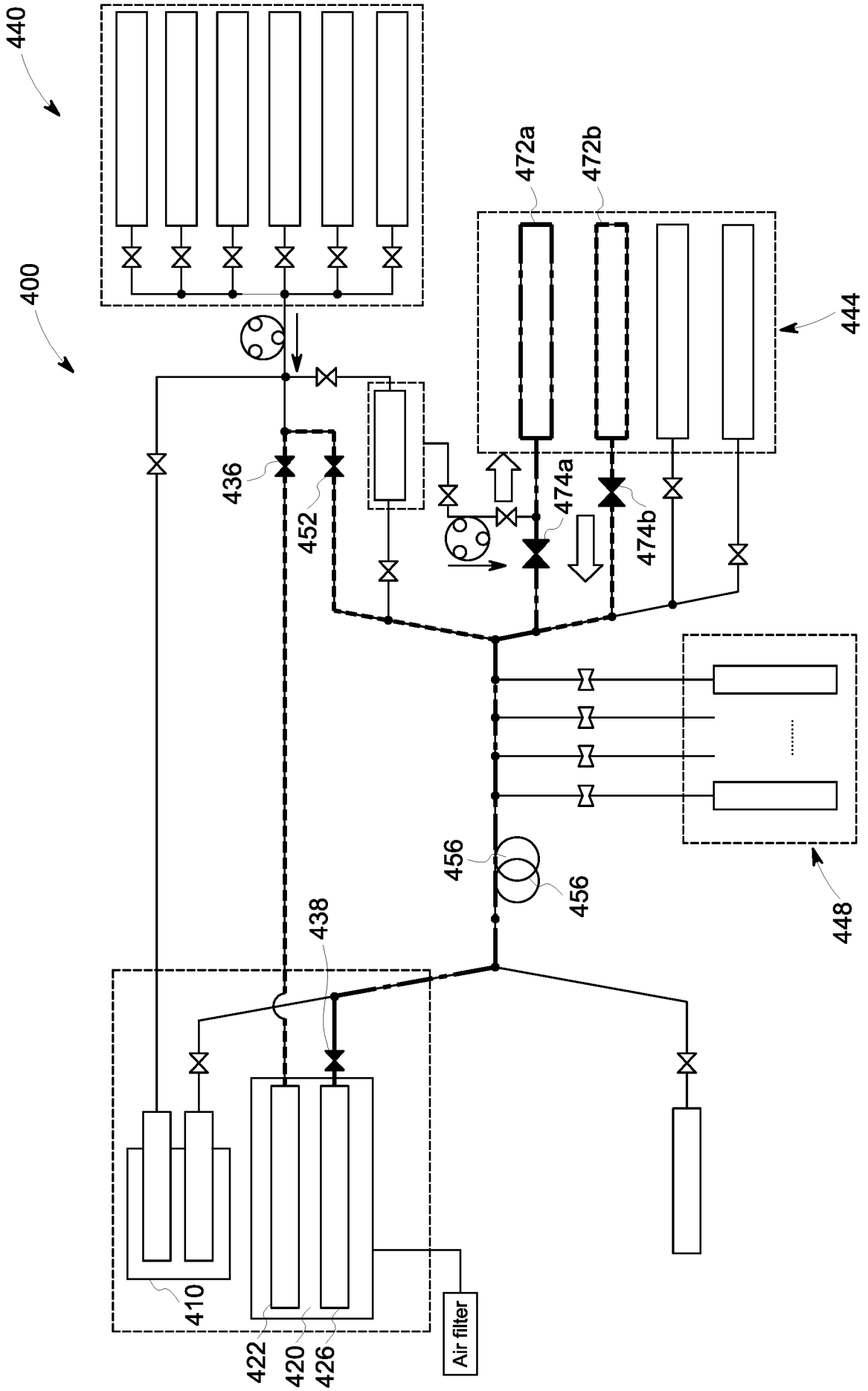

440
400
472a
472b
444
436
452
474a
474b
456
456
438
448
410
422
420
426
Air filter

FIG. 60

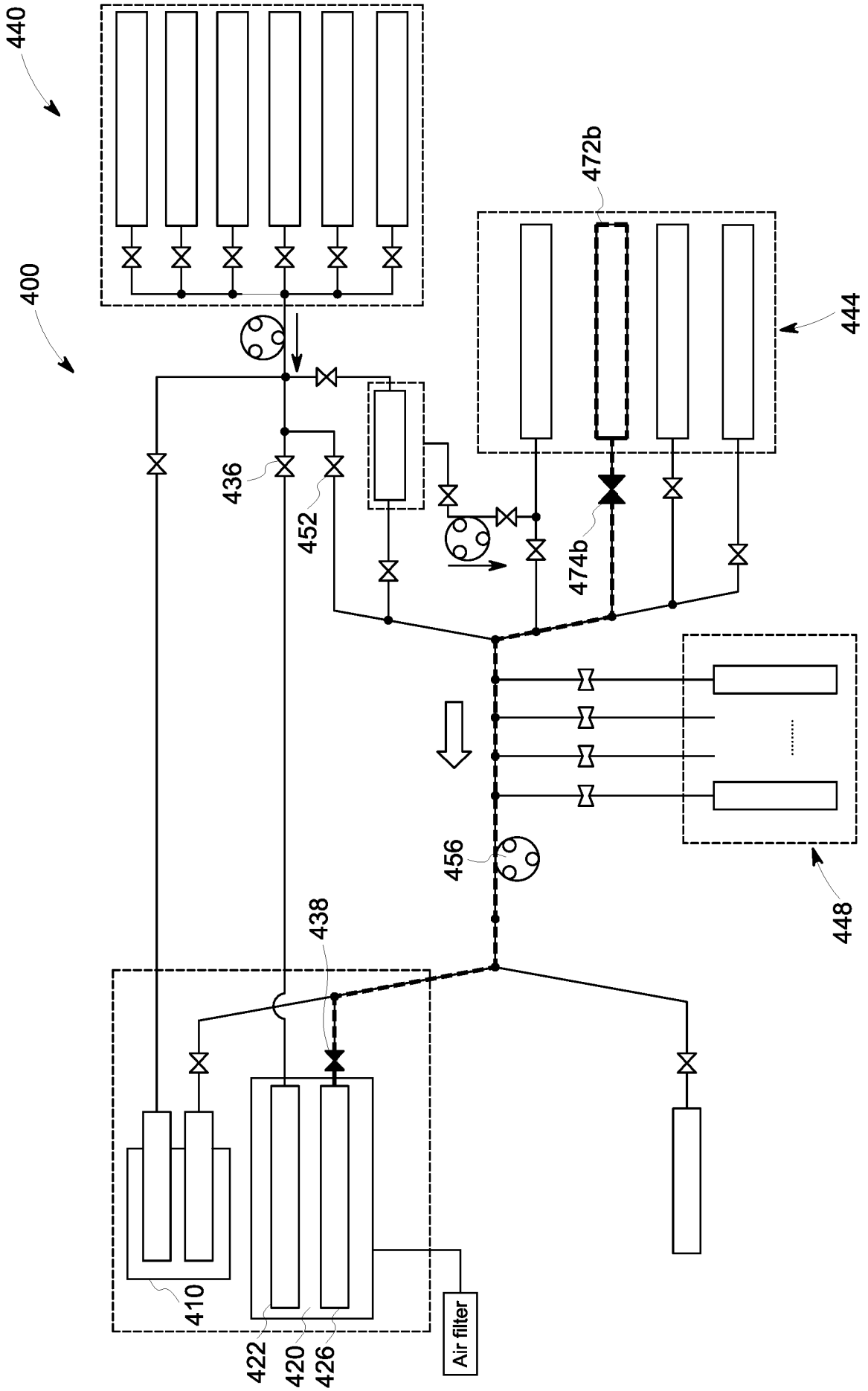

440
400
472b
444
436
452
474b
456
438
448
410
422
420
426
Air filter

FIG. 61

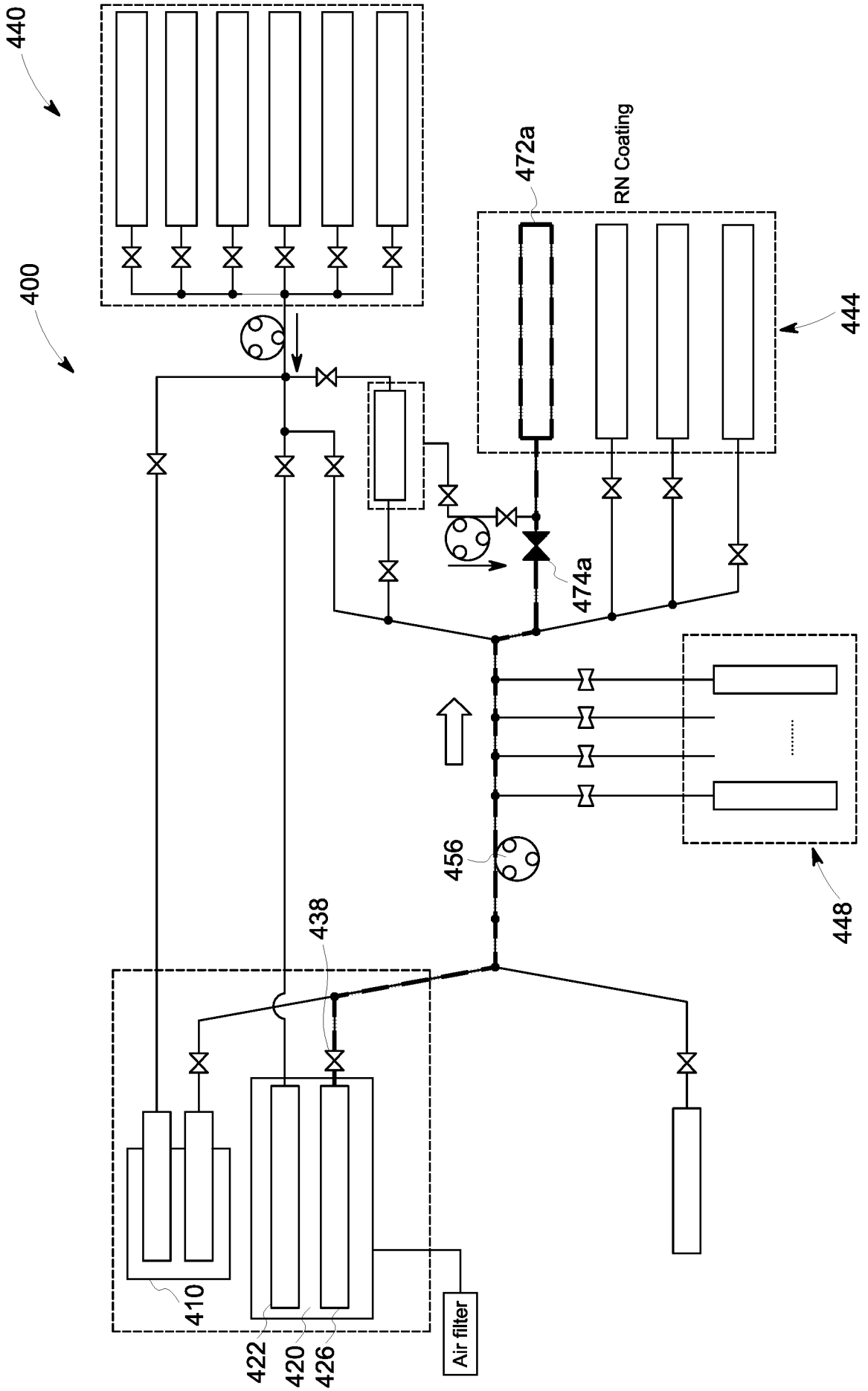

440
400
472a
RN Coating
444
474a
456
448
438
410
422
420
426
Air filter

FIG. 62

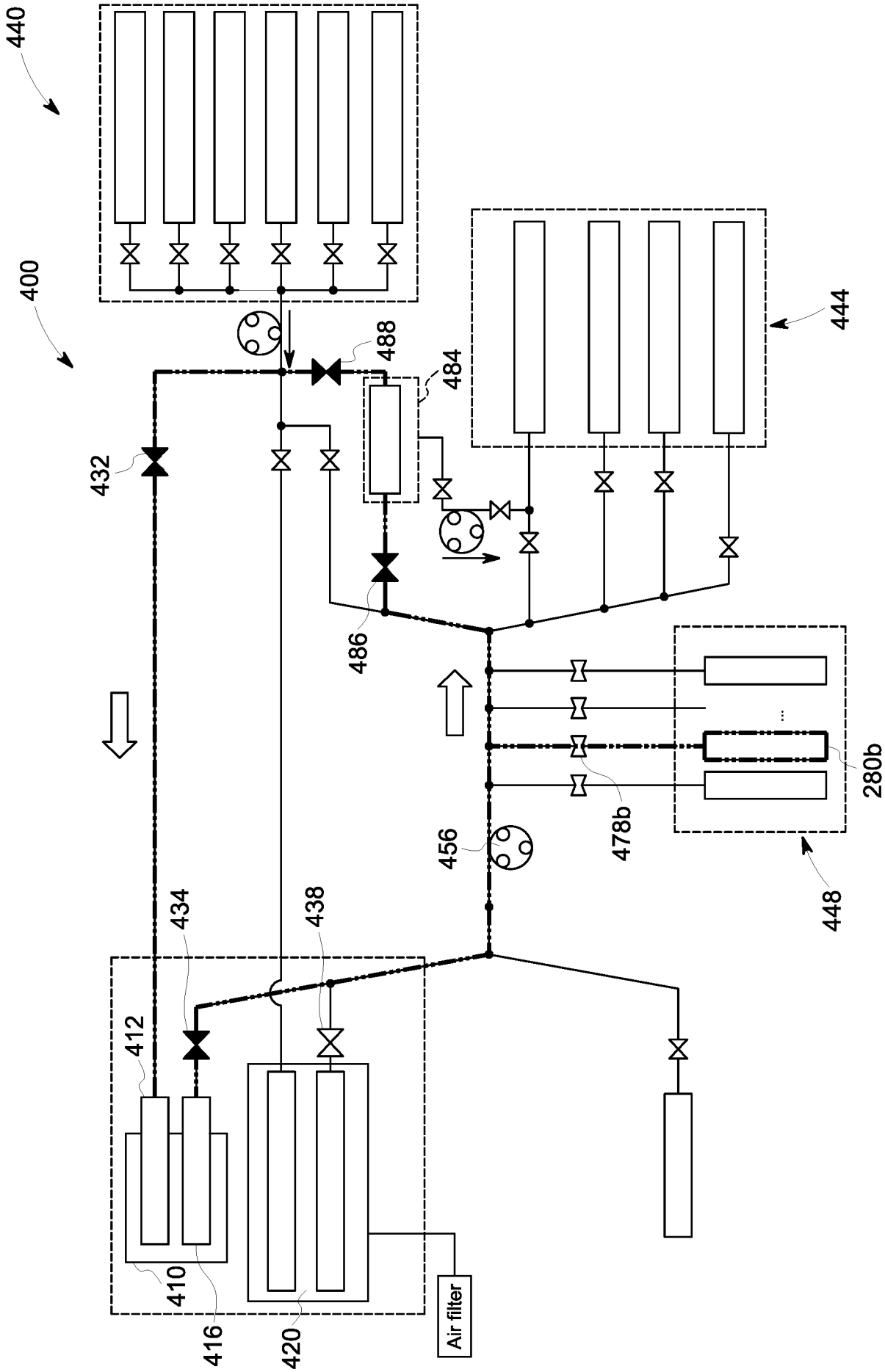

440
400
488
484
444
432
486
280b
478b
456
448
434
438
412
410
416
420
Air filter

FIG. 63

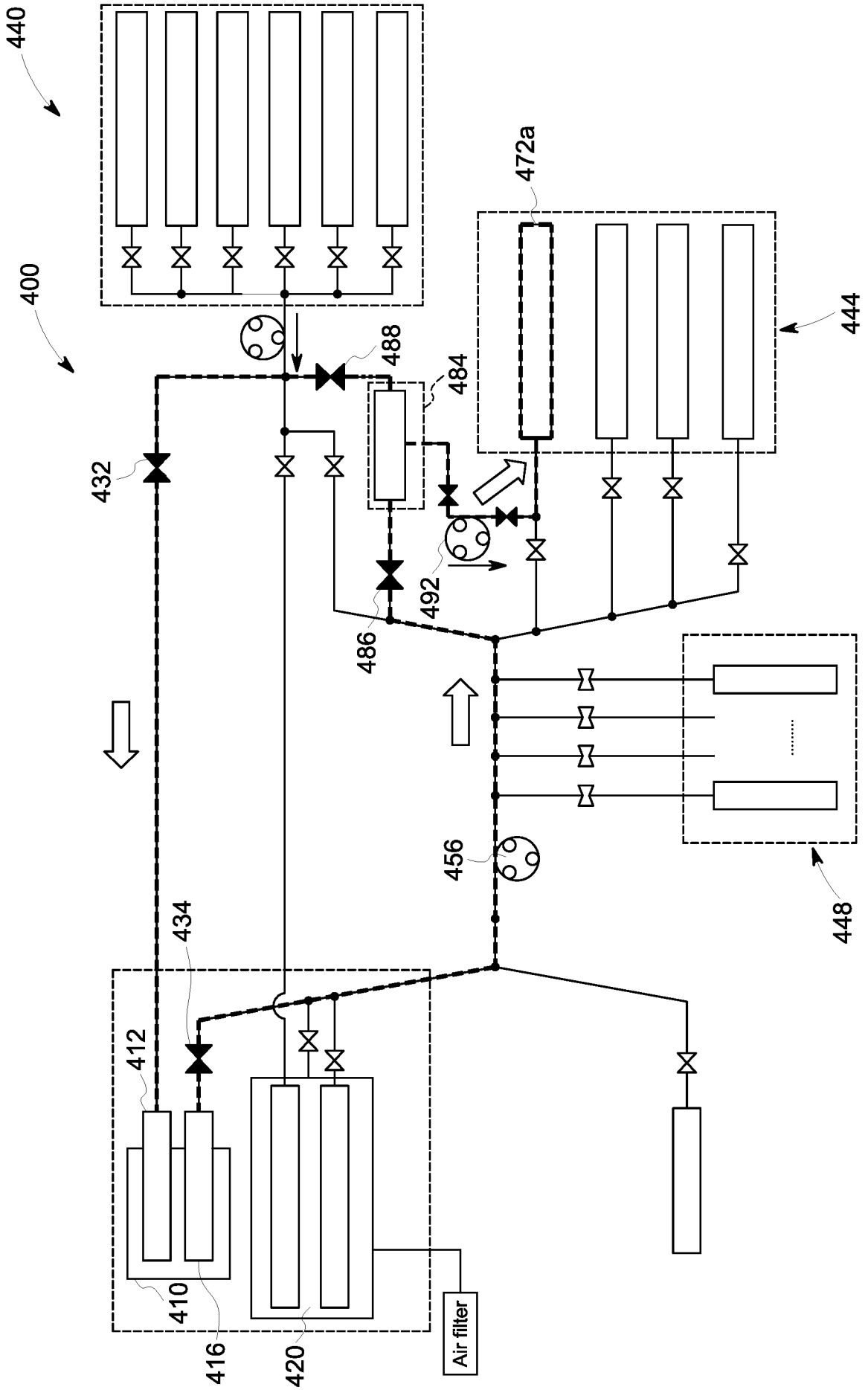

440
400
472a
444
488
484
432
492
486
456
448
434
412
410
416
420
Air filter

FIG. 64

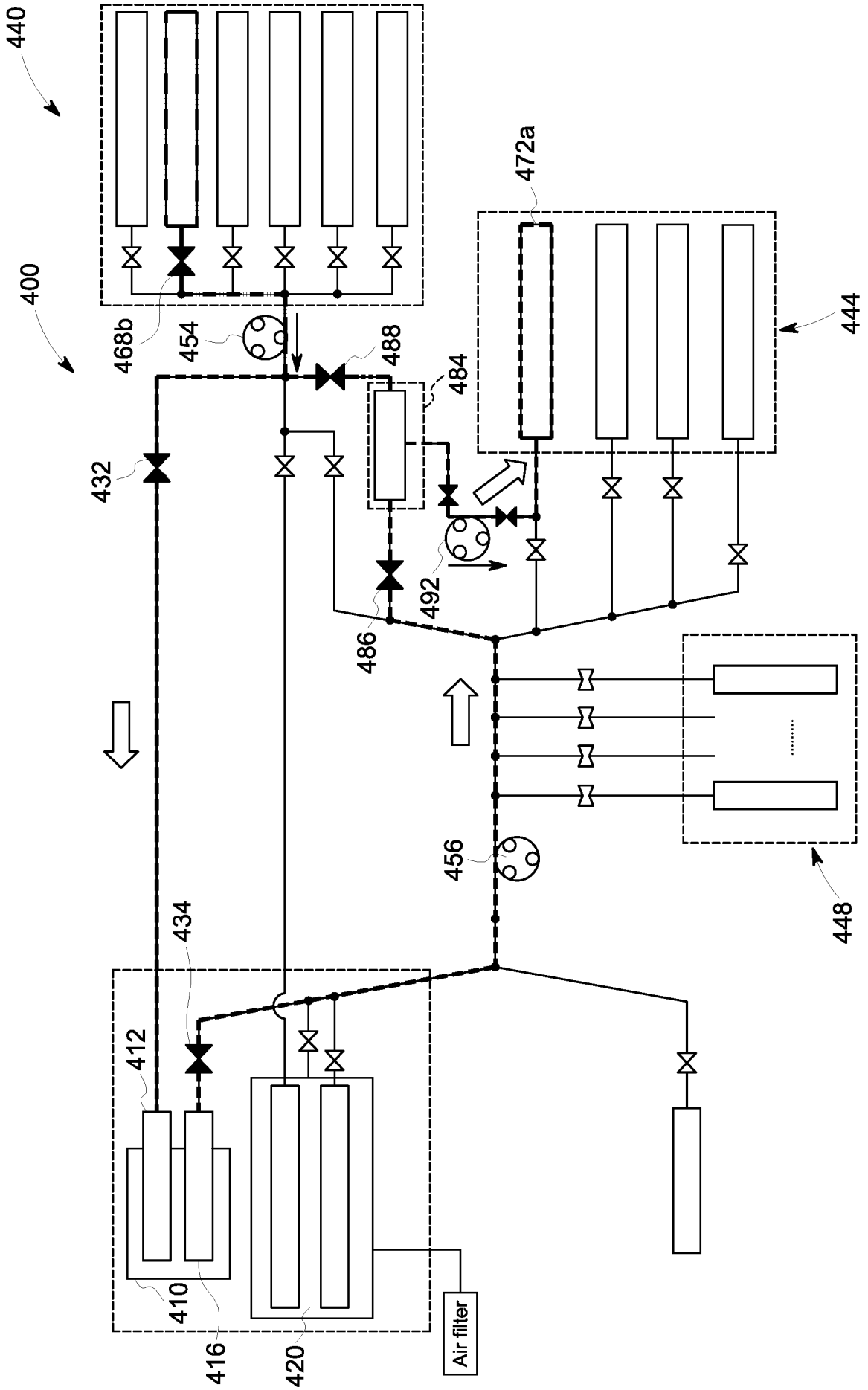

440
400
468b
454
488
484
472a
444
432
492
486
456
448
434
412
410
416
420
Air filter

FIG. 65

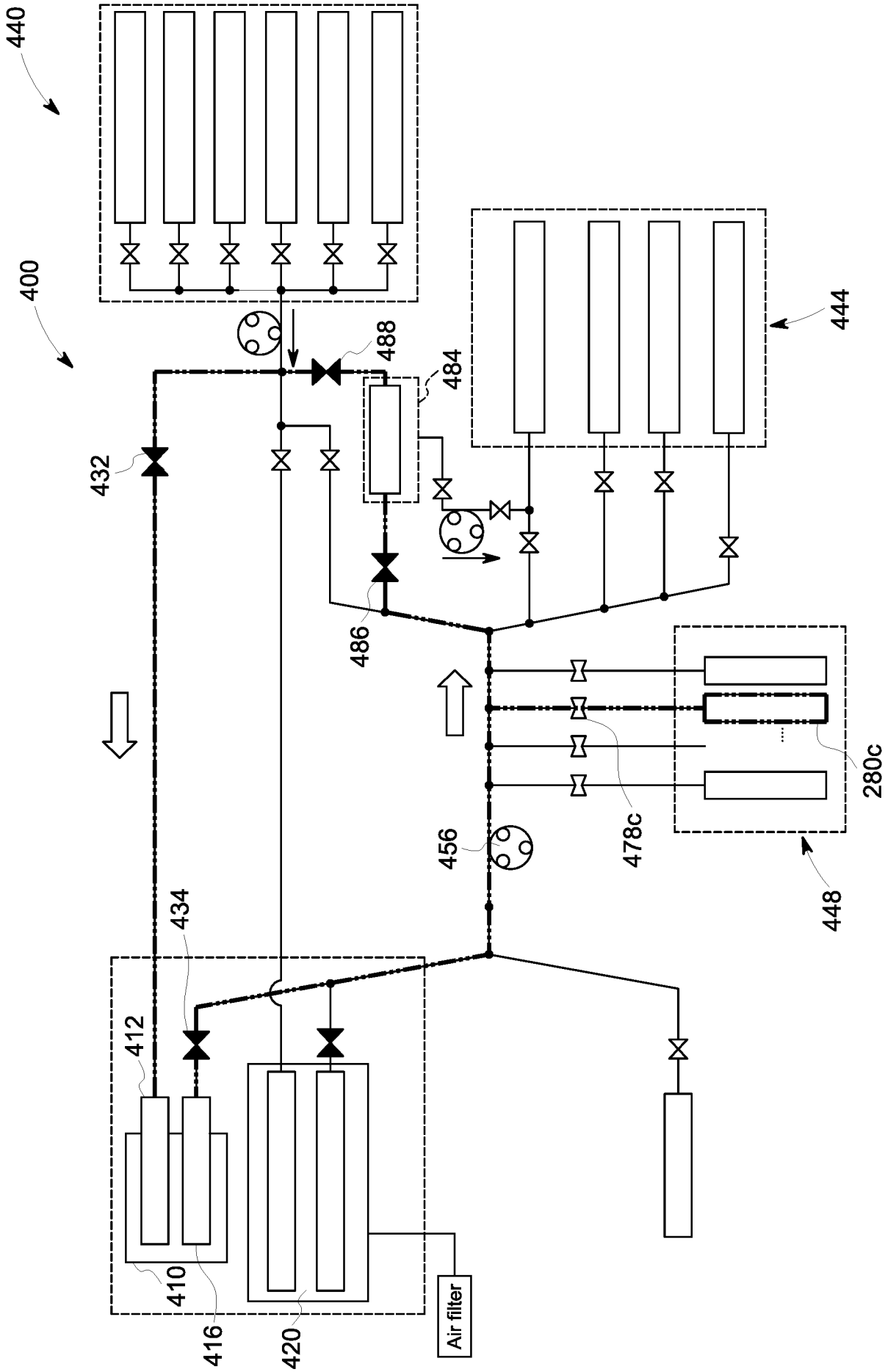

440
400
488
484
444
432
486
280c
478c
456
448
434
412
410
416
420
Air filter

FIG. 66

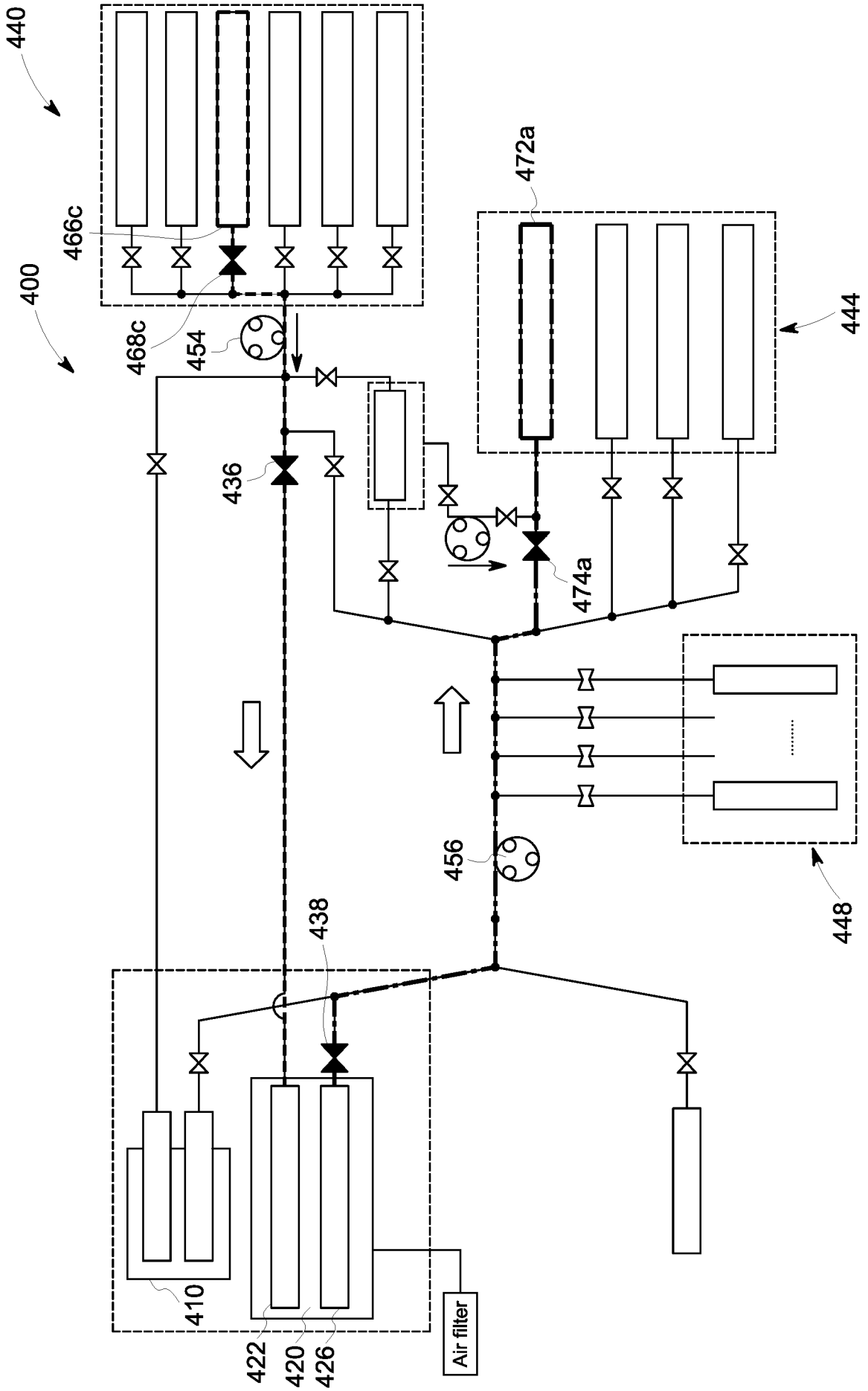

440
400
466c
468c
454
436
472a
444
474a
456
448
438
410
422
420
426
Air filter

FIG. 67

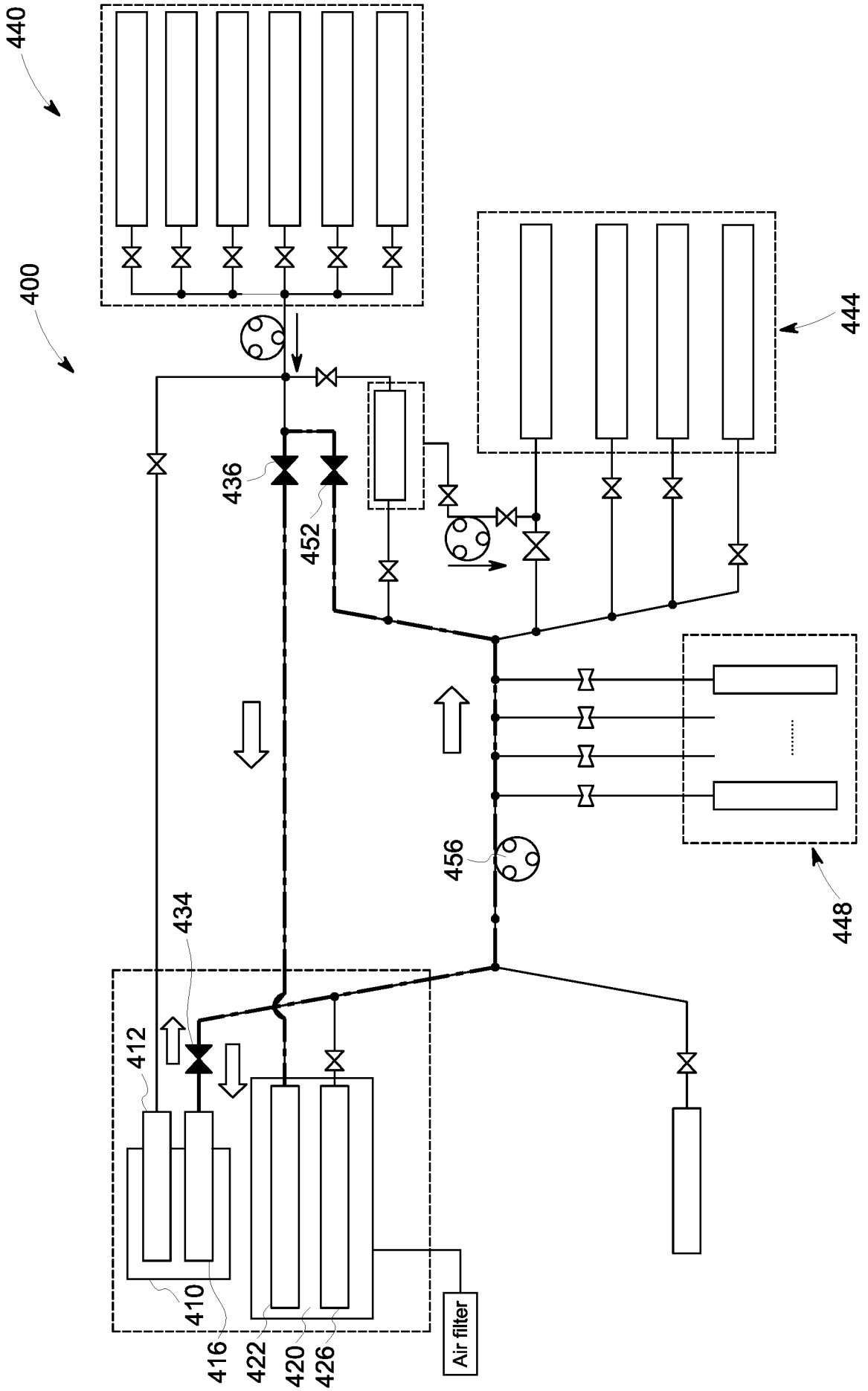

440
400
444
436
452
456
448
434
412
410
416
422
420
426
Air filter

FIG. 68

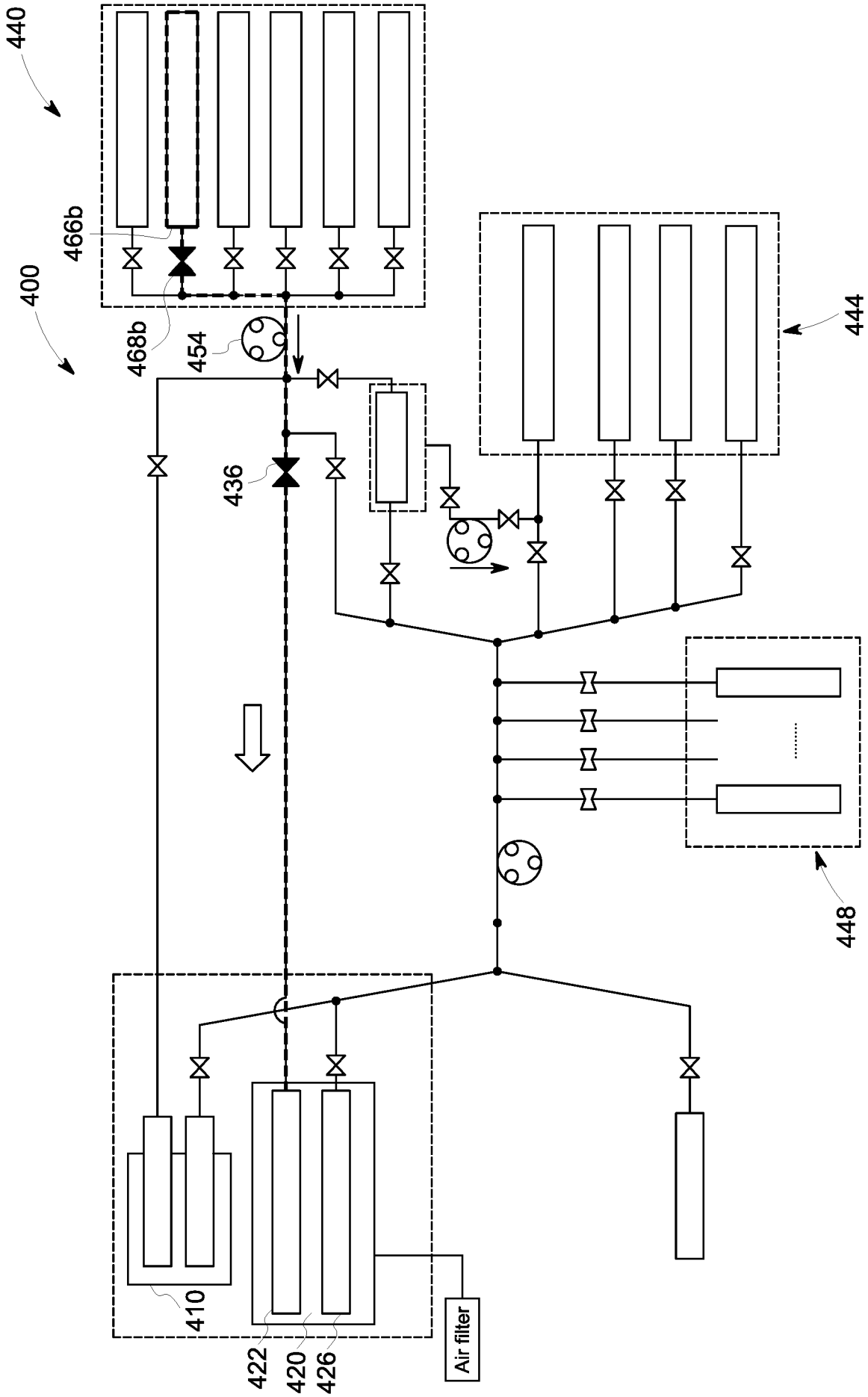


FIG. 69

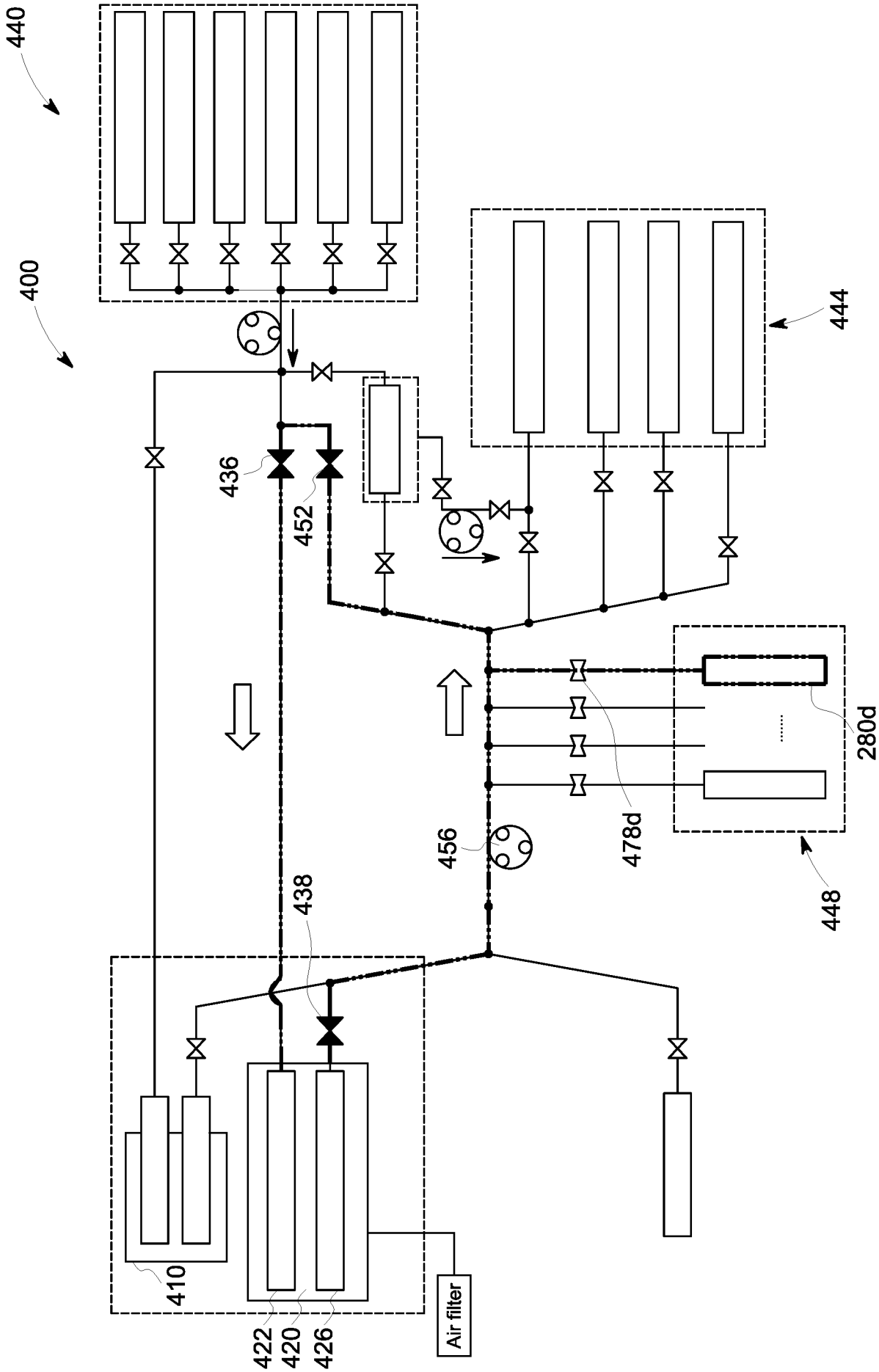

440
400
444
436
452
280d
478d
456
448
438
410
422
420
426
Air filter

FIG. 70

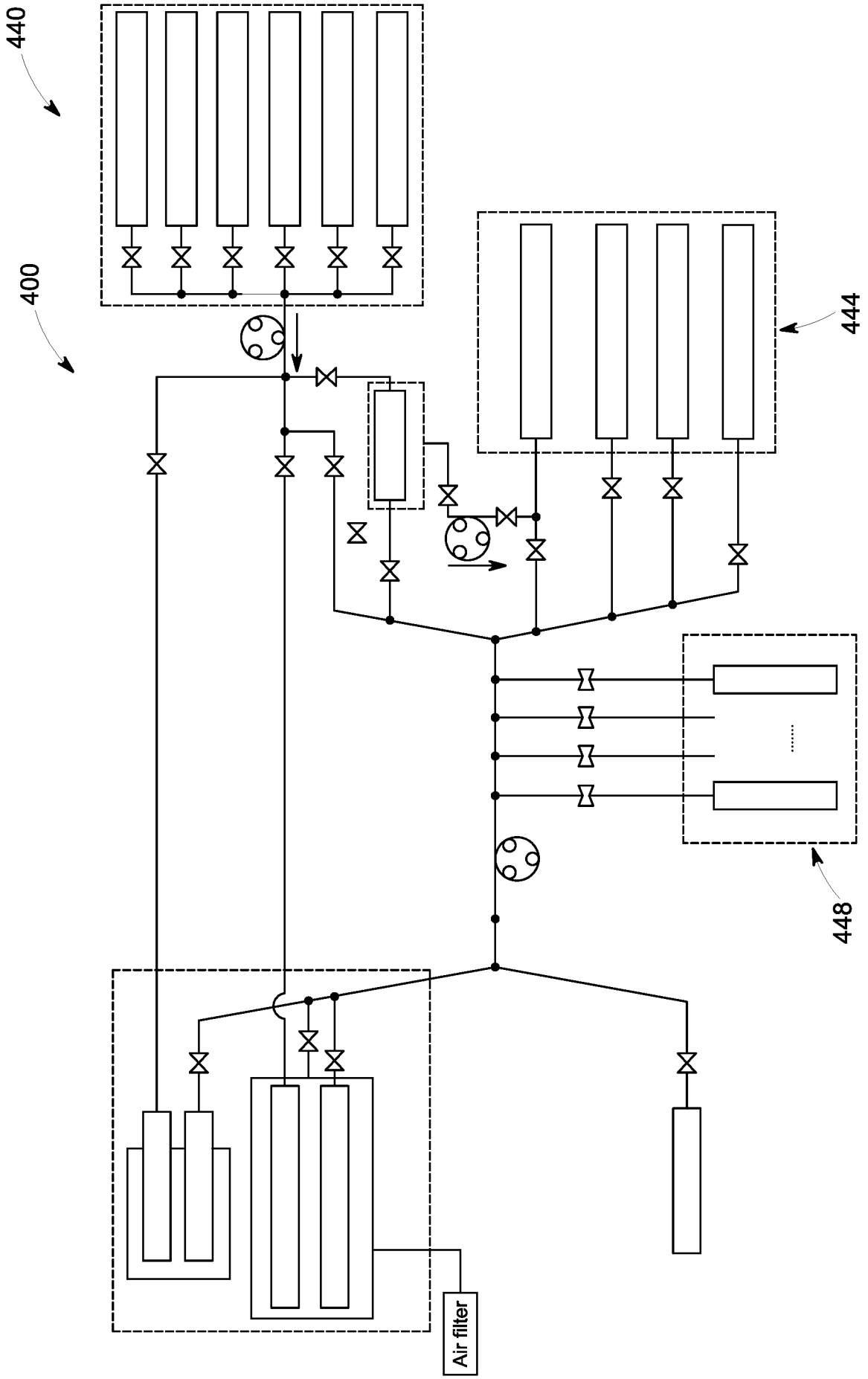


FIG. 71

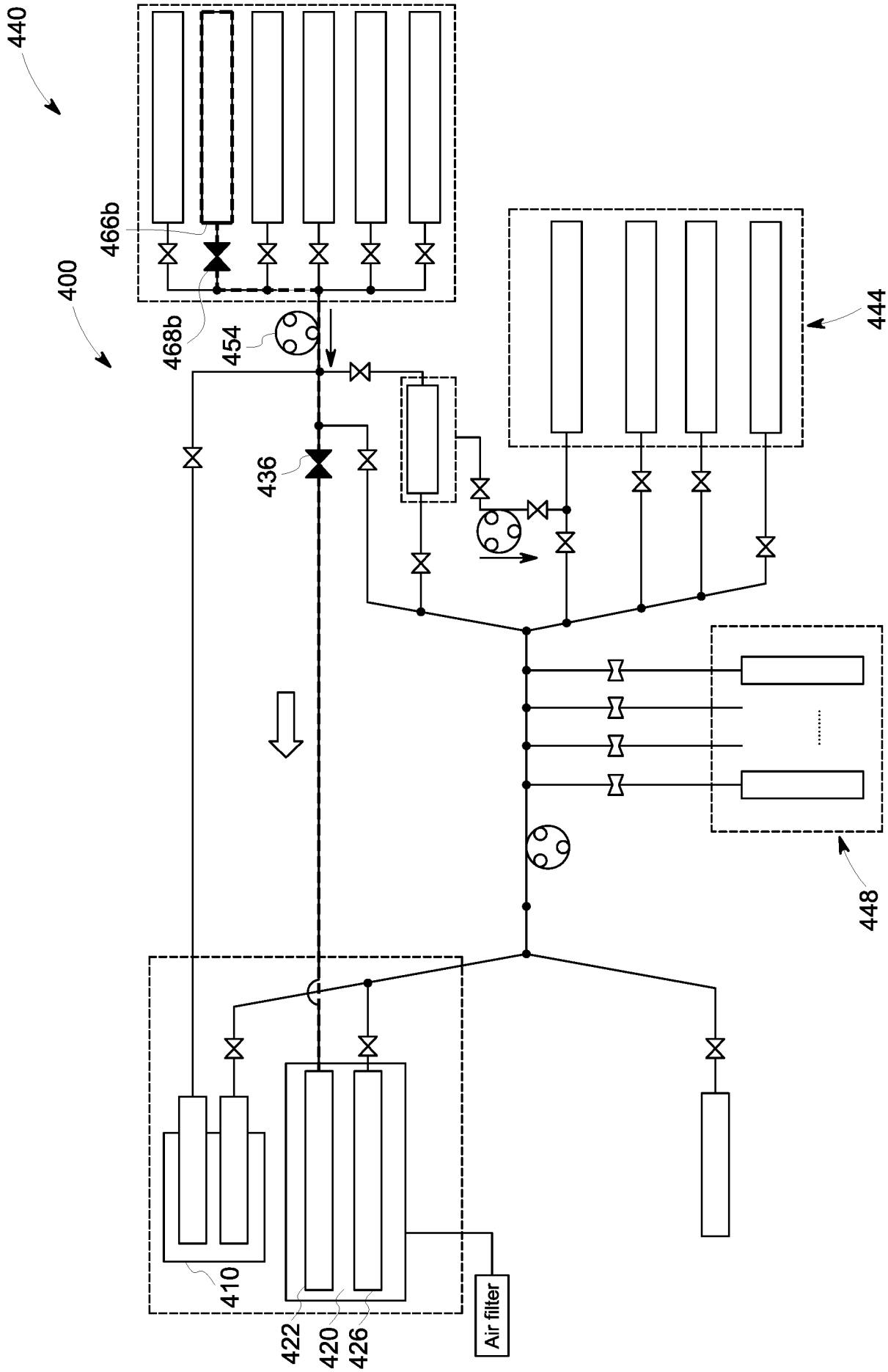


FIG. 72

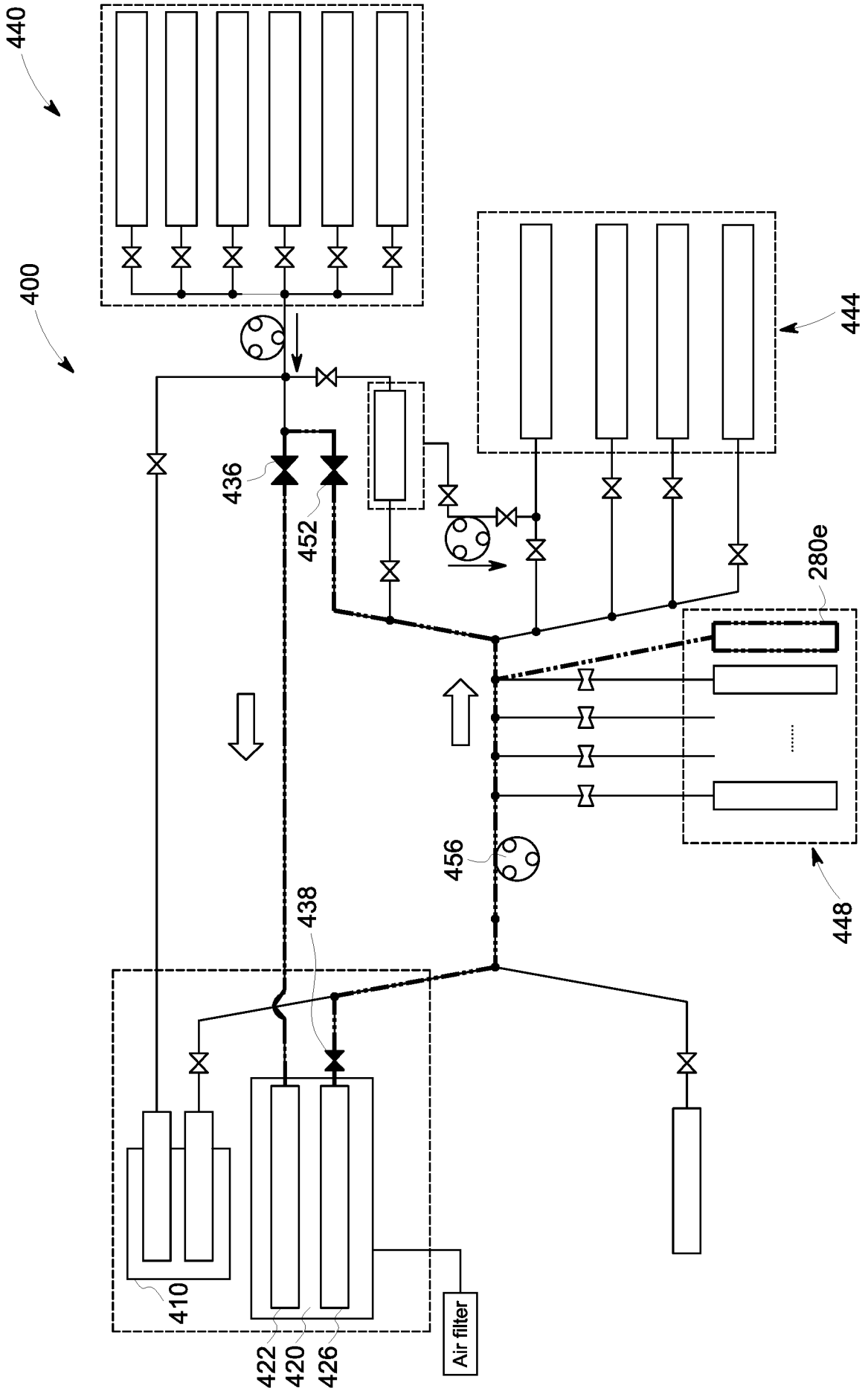


FIG. 73

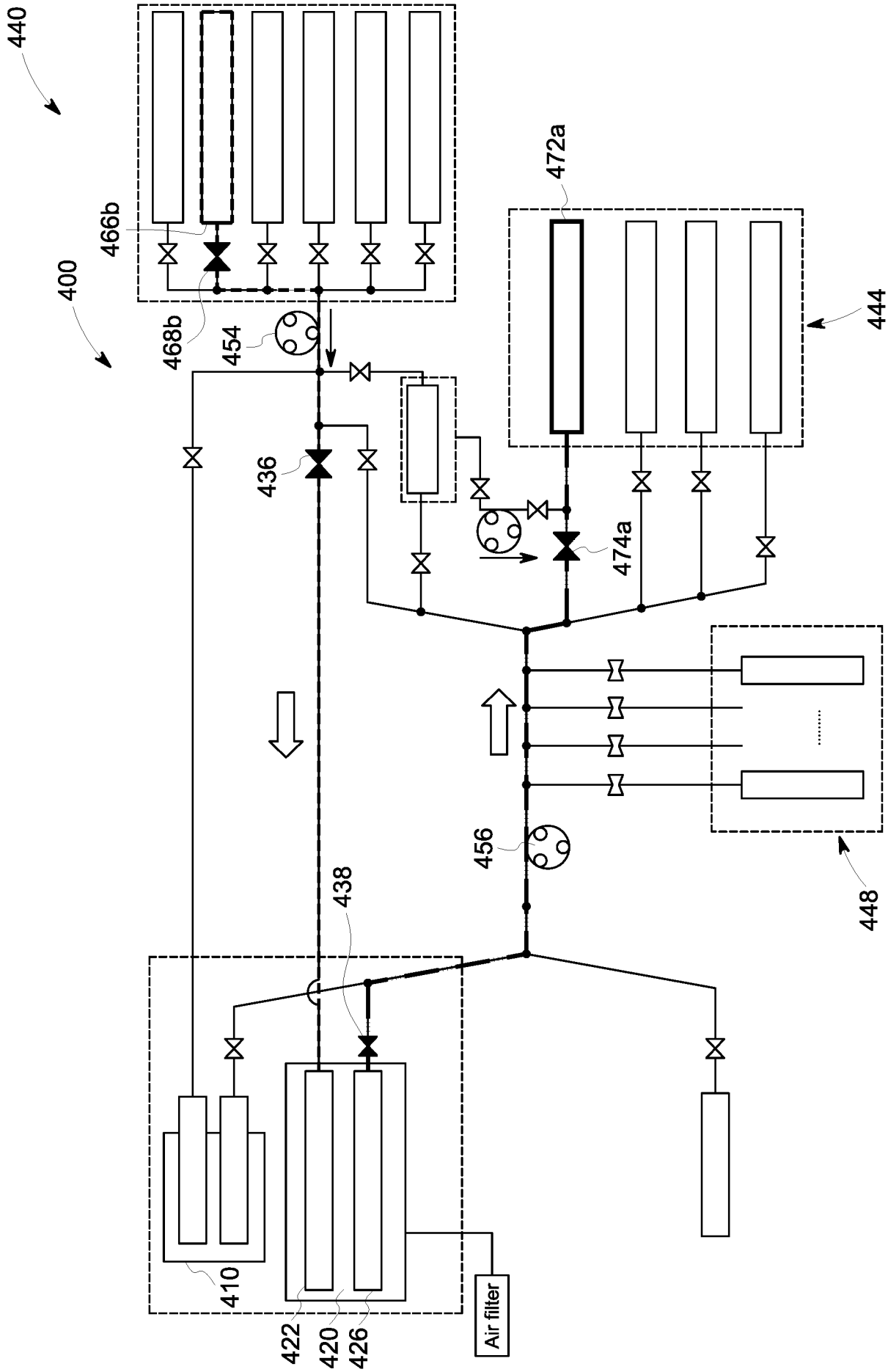

440
400
466b
468b
454
472a
444
436
474a
456
438
448
410
422
420
426
Air filter

FIG. 74

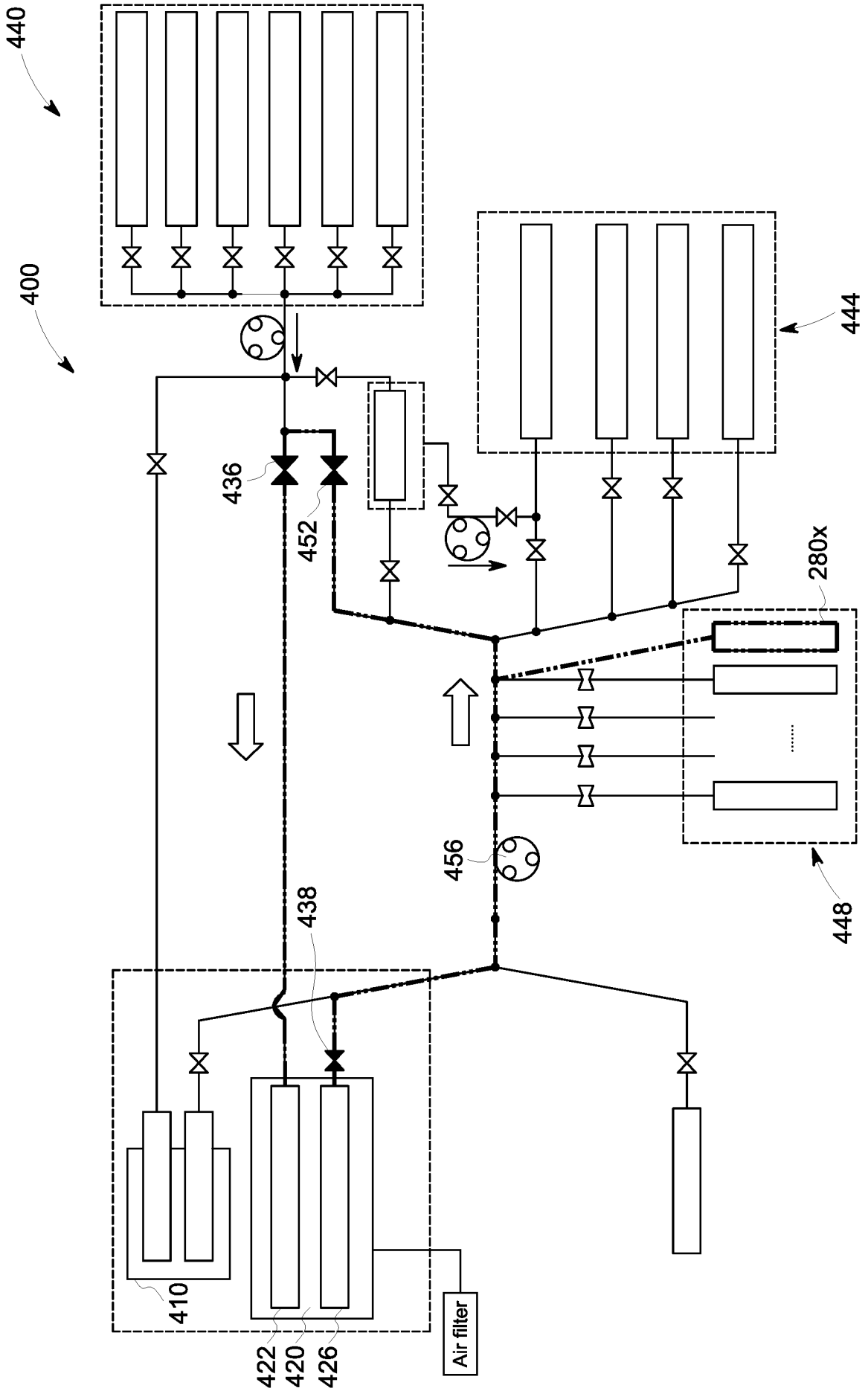


FIG. 75

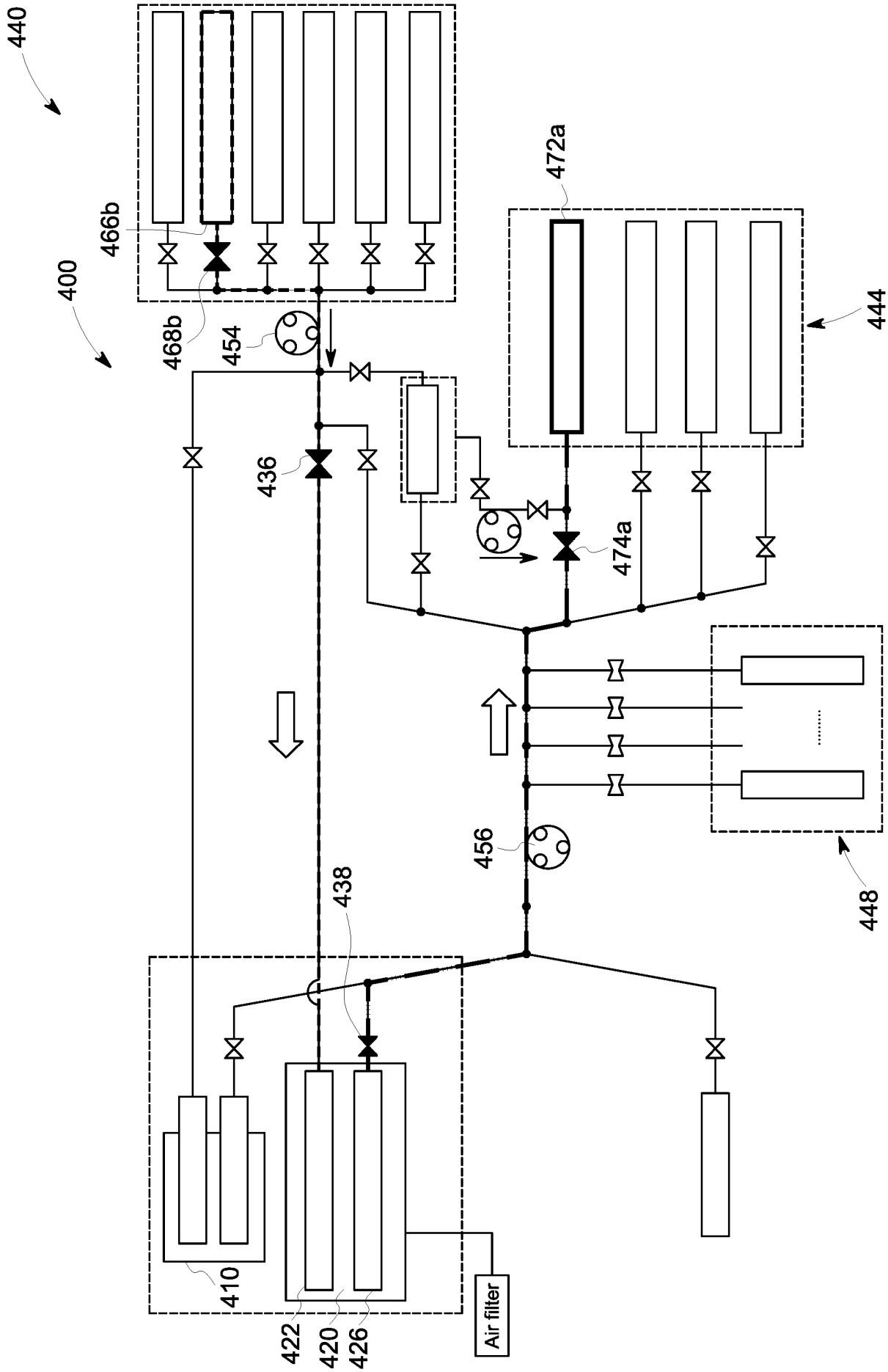

440
400
466b
468b
454
472a
444
436
474a
456
438
448
410
422
420
426
Air filter

FIG. 76

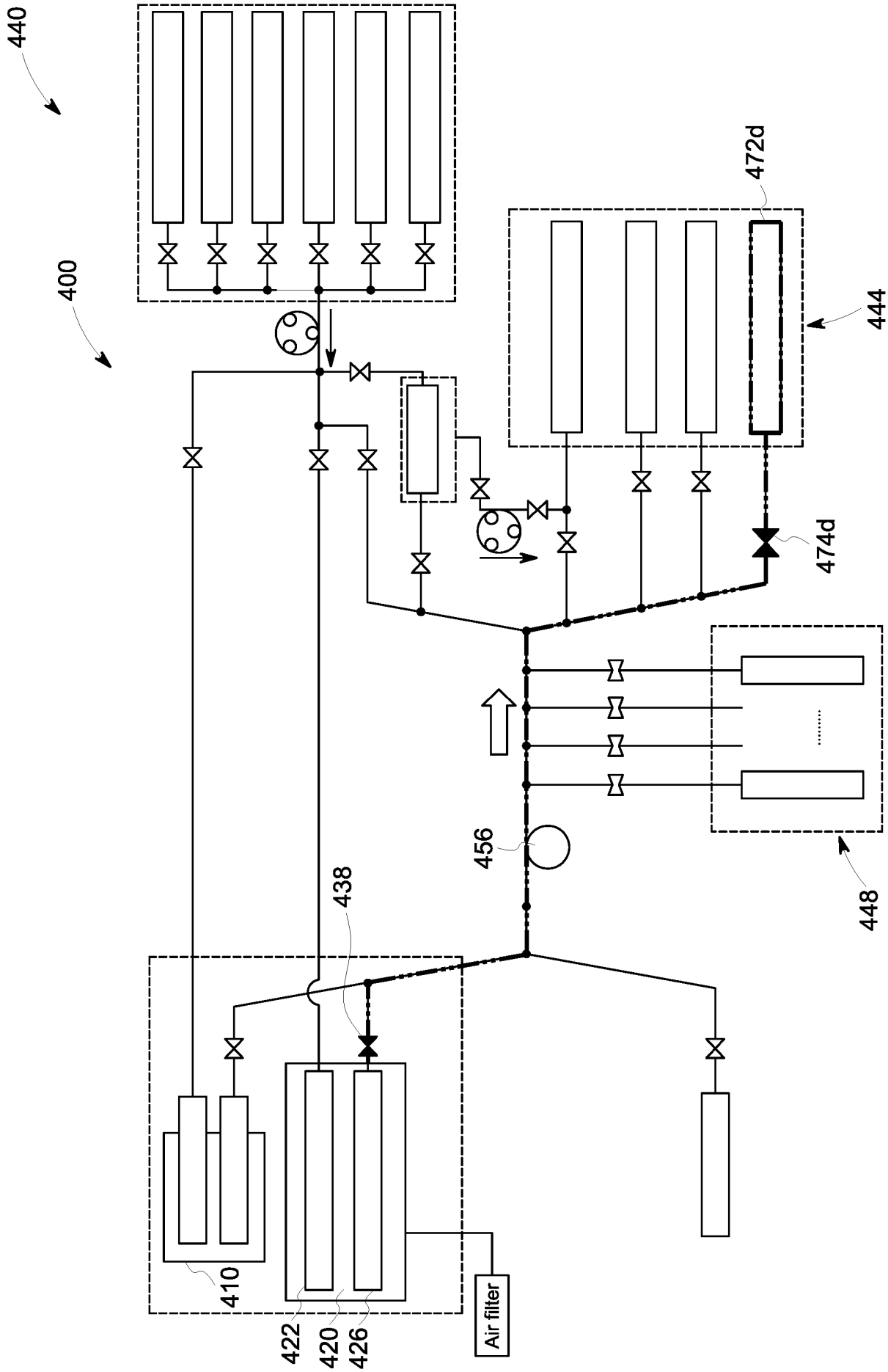


FIG. 77

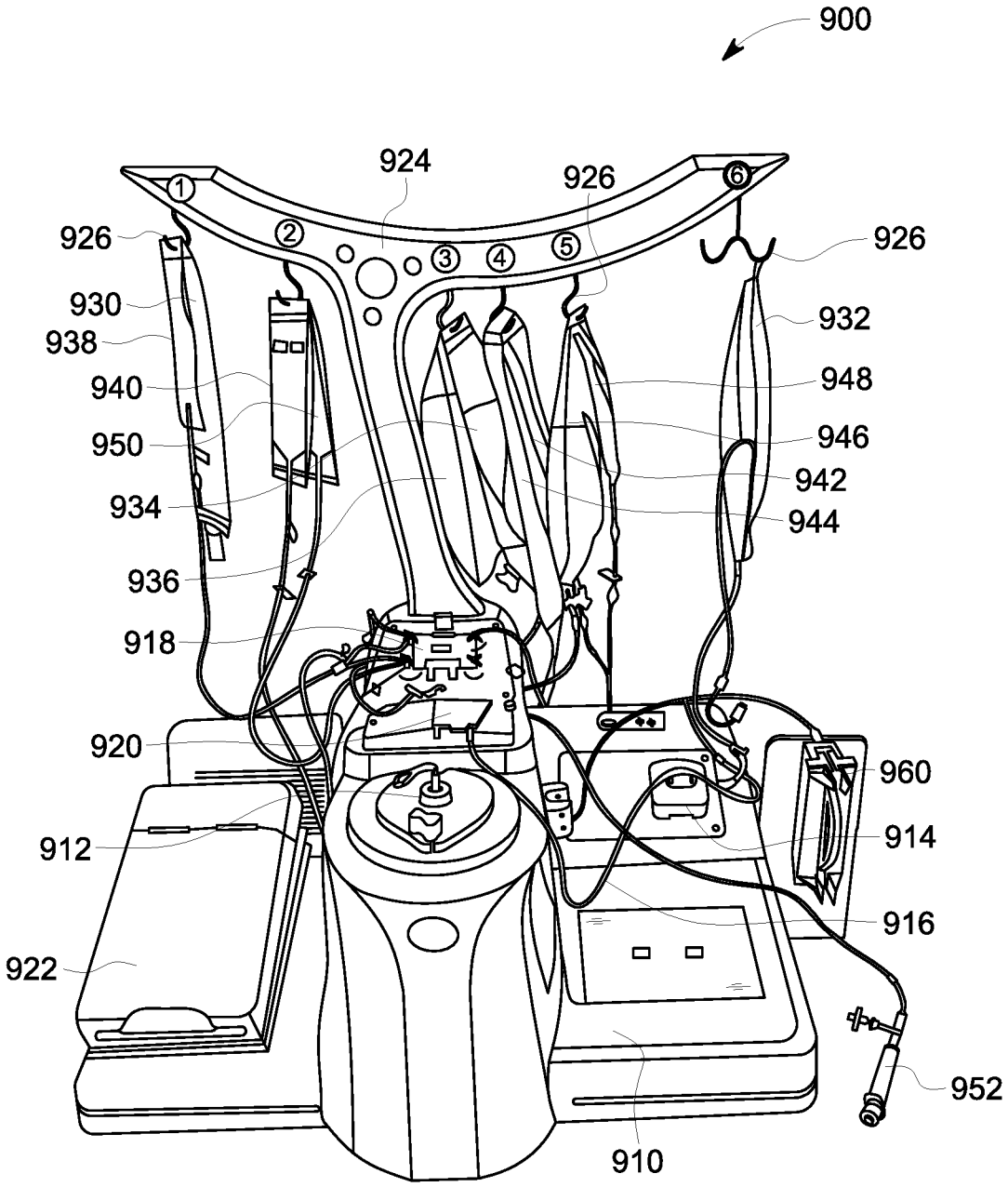

900
924
926
926
926
930
938
940
950
934
936
918
920
912
922
932
948
946
942
944
960
914
916
952
910
1
2
3
4
5
6

FIG. 78

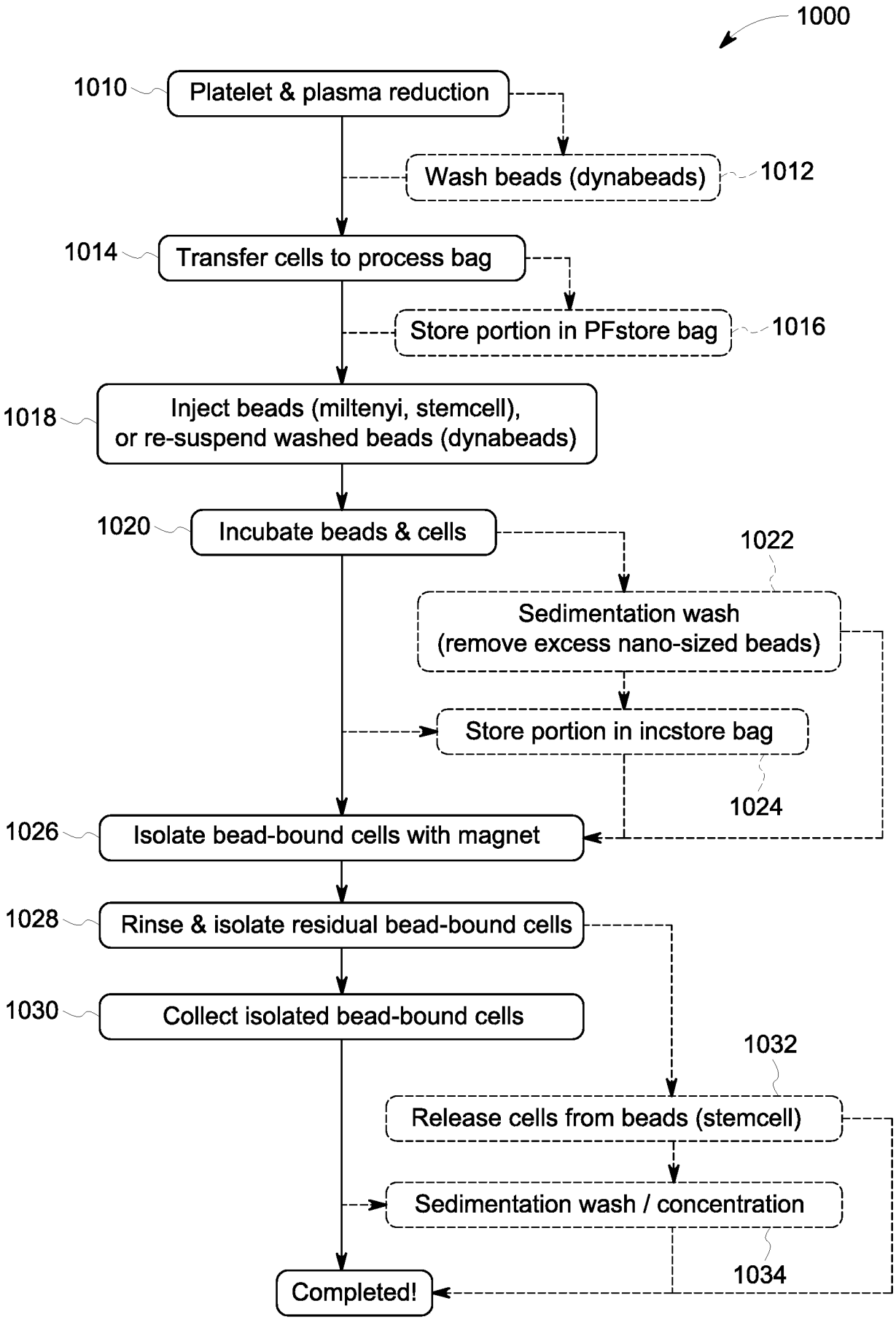

1000
1010
Platelet & plasma reduction
Wash beads (dynabeads)
1012
1014
Transfer cells to process bag
Store portion in PFstore bag
1016
1018
Inject beads (miltenyi, stemcell),
or re-suspend washed beads (dynabeads)
1020
Incubate beads & cells
1022
Sedimentation wash
(remove excess nano-sized beads)
Store portion in incstore bag
1024
1026
Isolate bead-bound cells with magnet
1028
Rinse & isolate residual bead-bound cells
1030
Collect isolated bead-bound cells
1032
Release cells from beads (stemcell)
Sedimentation wash / concentration
1034
Completed!

FIG. 79

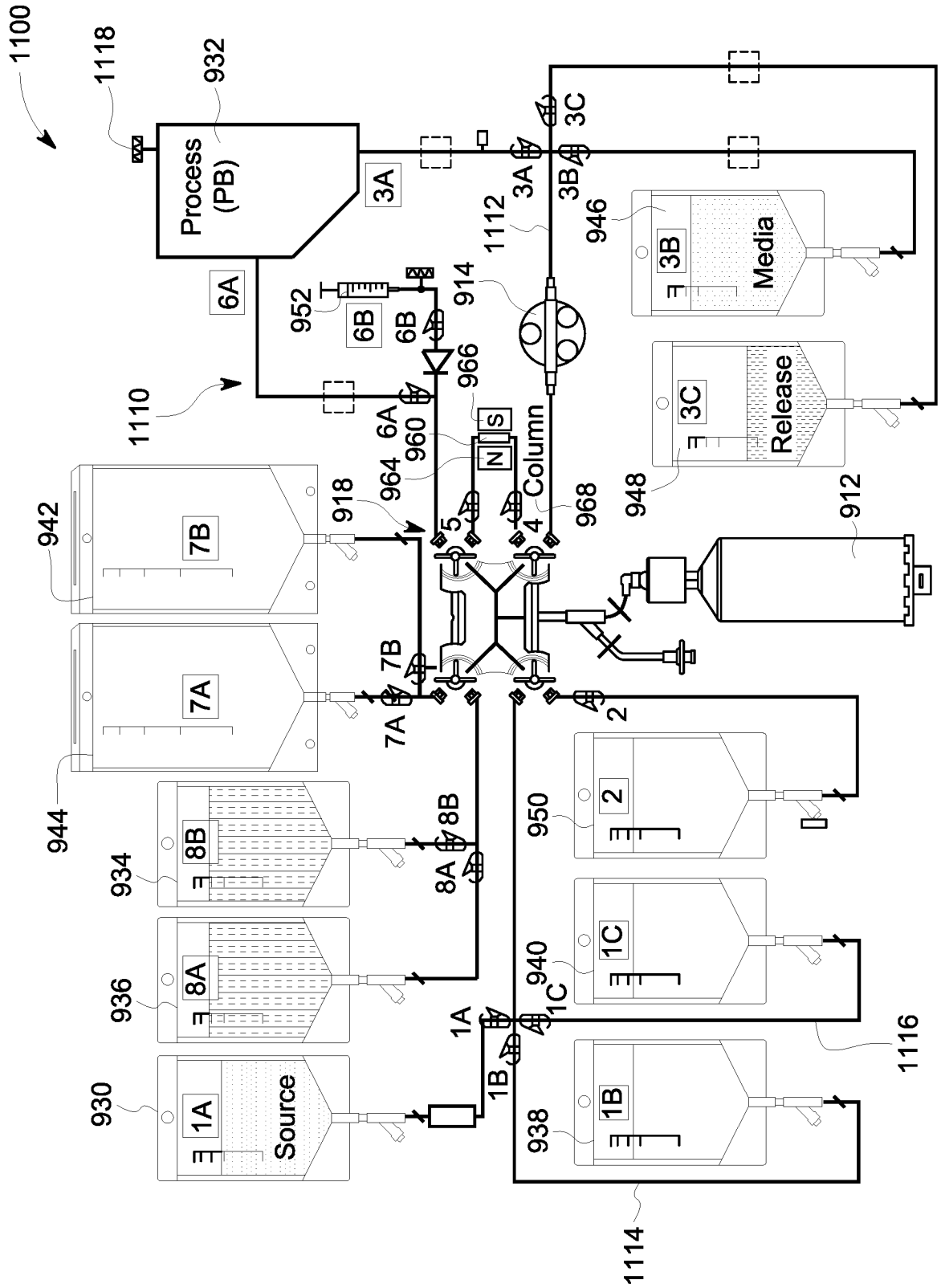

1100
1118
932
Process (PB)
3A
3C
3B
946
Media
1112
6A
952
6B
914
966
1110
960
N
S
Column
964
968
948
Release
912
942
7B
918
5
4
7A
944
2
950
8B
934
8A
936
1C
940
1A
1B
930
Source
938
1116
1114

FIG. 80

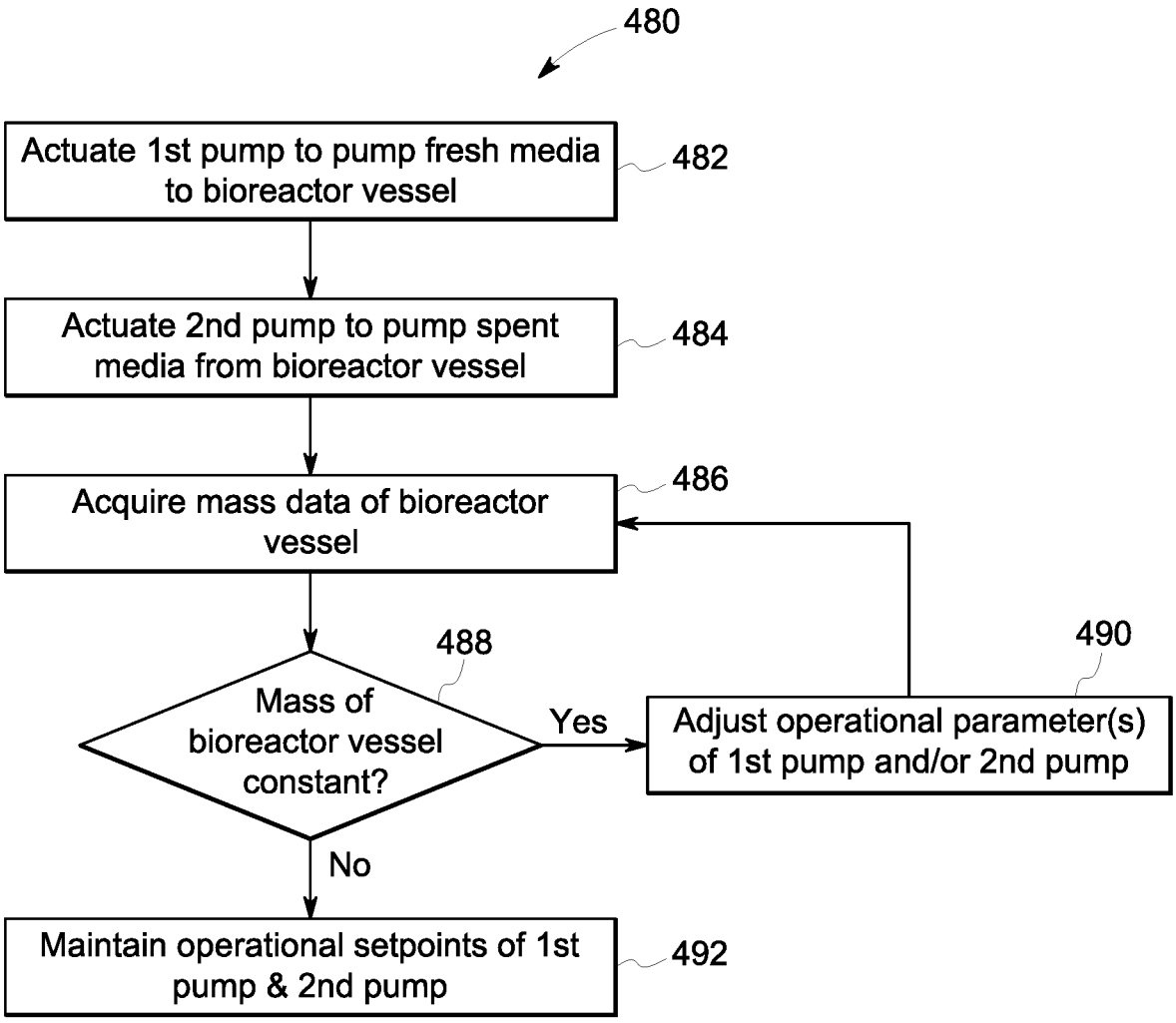

480
Actuate 1st pump to pump fresh media to bioreactor vessel
482
Actuate 2nd pump to pump spent media from bioreactor vessel
484
Acquire mass data of bioreactor vessel
486
488
Mass of bioreactor vessel constant?
Yes
490
Adjust operational parameter(s) of 1st pump and/or 2nd pump
No
Maintain operational setpoints of 1st pump & 2nd pump
492

FIG. 81