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Surgical Mask

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Surgical Mask

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Preface

The standard is drafted in accordance with the rules given in GB/T 1.1-2009.

Please note that some contents of the document may involve patents. The issuing authority of the document is not responsible for identifying such patents.

Compared with YY 0469-2004, the main changes of this standard are as follows:

This standard replaces YY 0469-2004 *Technical Requirements for Surgical Mask*;

- Normative References are supplemented and revised;
- Terms and definitions are editorially revised;
- Surface moisture resistance is removed;
- The technical requirements and test methods of gas exchange are modified, and only the differential pressure is reserved;
- The total number indicator of bacterial colonies in microbial cleanliness of masks is modified;
- According to GB/T 16886.10-2005, the technical requirements of "skin irritation" are revised, and the test method is defined;
- Technical requirements and test methods for delayed-type hypersensitivity and cytotoxicity are added;
- For corresponding test method for ethylene oxide residue, the gas chromatography in GB/T 14233.1-2008 replaces the original method in GB 15980-1995;
- The simulated wearing method in the bacterial filtration efficiency test method of the original standard normative Appendix B is deleted, and the schematic diagram of two-way collection device for bacterial filtration efficiency testis added;
- Signs and instructions for use are modified.

The standard is proposed by the State Food and Drug Administration.

This standard is under the administration of Beijing Center for Medical Device Quality Supervision and Testing of the State Food and Drug Administration.

The standard is drafted by Beijing Institute of Medical Device Testing.

Main drafters of the standard: Weihua Yue, Jian Su, Hong Chen, Simin Liu.

Surgical Mask

1. Scope

The standard specifies the technical requirements, test methods, marks, instructions for use, packaging, transportation and storage of surgical mask (hereinafter referred to as “mask”).

This standard is applicable to single-use masks worn by clinical medical personnel in the process of invasive operation.

2. Normative references

The following documents are indispensable for application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 14233.1-2008	Test methods for infusion, transfusion, injection equipment for medical use—Part 1: Chemical analysis methods
GB/T 14233.2-2005	Test methods for infusion, transfusion, injectionequipment for medical use—Part 2: Biological test methods
GB 15979-2002	Hygienic standard for disposable sanitary products
GB/T 16886.5-2003	Biological evaluation of medical devices—Part 5: Test for in vitro cytotoxicity
GB/T 16886.10-2005	Biological evaluation of medical devices—Part 10: Tests for irritation and delayed-type hypersensitivity

3. Terms and Definitions

The following terms and definitions apply to the document.

3.1 Surgical mask

It is used to cover the user's mouth, nose and chin, and provide a physical barrier for preventing the direct penetration of pathogens, microorganisms, body fluids, particles, etc.

3.2 Synthetic blood

It is a mixture of a red dye, surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and some other body fluids, and the color of blood.

Note: The synthetic blood in this test method does not simulate all of the characteristics of blood or body fluids, for example, polarity (wetting characteristics), coagulation, content of cell matter.

[ASTM F1862-00a, definition 3.1.9]

3.3 Particle

A granular substance that is solid, liquid, or both, such as dust, smoke, fog, and microorganisms, suspended in the air.

[GB/T 12903-2008, definition 5.1.16]

3.4 Filtration efficiency

Percentage of particulate matter removed by the filter element under specified test conditions.

[GB 2626-2006, definition 3.16]

3.5 Bacterial filtration efficiency (BFE)

The percentage of aerosolized bacteria particles that do not pass the mask material at a given flow rate.

[ASTM F2101-07, definition 3.1.4]

3.6 Flame retardation properties

The ability to prevent oneself from being ignited, flaming, and smoldering.

[GB/T 12903-2008, definition 3.12]

3.7 Sterilization

Use physical or chemical methods to kill all microorganisms on the transmission medium and make it sterile.

[GB/T 15980-1995, definition 3.1]

3.8 Delayed-type hypersensitization

An exposure by an individual to an allergen produces a specific T cell-mediated immunological memory response, which leads to delayed-type hypersensitivity after re-exposure to the allergen.

[GB/T 16886.10-2005, definition 3.5]

3.9 Irritation

A local nonspecific inflammation caused by one, more or continuous contact with a material.

[GB/T 16886.10-2005, definition 3.11]

4. Technical (Performance) requirements

4.1 Appearance

Appearance of a mask is clean and intact, and surface shall not be damaged or stained.

4.2 Structure and size

After wearing the mask, it should be able to cover the nose, mouth and chin of the wearer. It shall conform to the design dimension and tolerance of the sign.

4.3 Nose clip (bridge)

4.3.1 The mask shall have a nose clip made of plastic material.

4.3.2 Length of nose clip shall not be less than 8.0 cm.

4.4 Mask belts(strap)

4.4.1 Mask belt shall be easy for use.

4.4.2 Breaking strength at the connection point between each mask belt and mask body shall not be less than 10N.

4.5 Synthetic blood penetration

When 2 mL synthetic blood is squirted to the outer side of the mask at 16.0 kPa (120 mmHg), there should be no penetration on the inner side of the mask.

4.6 Filtration efficiency

4.6.1 Bacterial filtration efficiency (BFE)

Bacterial filtration efficiency of the mask shall not be less than 95%.

4.6.2 Particle filtration efficiency (PFE)

The filtering efficiency of mask for non oily (sodium chloride) particles shall not be less than 30%.

4.7 Differential pressure (Δp)

The differential pressure Δp between the two sides of the mask for gas exchange shall not be greater than 49Pa.

4.8 Flame retardation properties

The material of the mask shall be non combustible; the burning time of the mask after leaving the flame shall not be more than 5 seconds.

4.9 Microbial cleanliness

4.9.1 Non-sterile masks shall meet the requirements of Table 1.

Table 1 Mask Bioburden

Total number of bacterial colonies CFU/g	Coliform bacteria	*Pseudomonas aeruginosa*	*Staphylococcus aureus*	*Hemolytic streptococcus*	Fungus
≤100	No detection	No detection	No detection	No detection	No detection

4.9.2 Masks marked with the words or illustrations of "sterilization" or "asepsis" shall be sterile.

4.10 Residual ethylene oxide

For the mask sterilized by ethylene oxide, the residual amount of ethylene oxide shall not exceed 10 μg/g.

4.11 Skin irritation

The primary irritation index of mask material shall not exceed 0.4.

4.12 Cytotoxicity

Cytotoxicity of mask shall not be greater than Level 2.

4.13 Delayed-type hypersensitization

The mask material shall not have a sensitization reaction.

5. Test method

5.1 Appearance

The test shall be conducted with 3 samples, and they shall meet the requirements of 4.1 by visual inspection.

5.2 Structure and size

The test shall be conducted with 3 samples, and they shall meet the requirements of 4.2 by actual wearing and measurement with common or special measuring tools.

5.3 Nose clip (bridge)

5.3.1 The test shall be conducted with 3 samples, and they shall meet the requirements of 4.3.1 by visual inspection and actual wearing.

5.3.2 The test shall be conducted with 3 samples and they shall meet the requirements of 4.3.2 by measuring with general or special measuring tools.

5.4 Mask belts(strap)

5.3.2 The test shall be conducted with 3 samples and they shall meet the requirements of 4.4.1 by actual wearing for adjustment inspection.

5.4.2 The test shall be conducted with 3 samples. Test with 10 N static tensile strength for 5 s and the result shall meet the requirements of the 4.4.2.

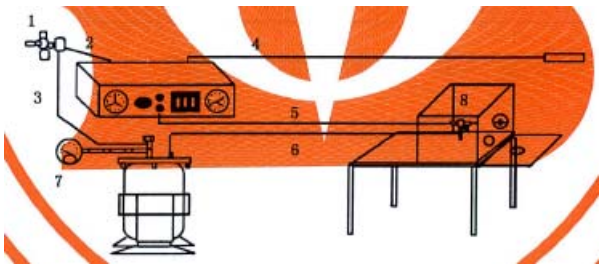
5.5 Synthetic blood penetration test

Number of samples: test with 3 samples.

Sample pretreatment: the samples shall be pretreated at the temperature of (21±5)℃ and relative humidity of (85±5)% for at least 4 h, and the test shall be conducted within one minute after they are taken out.

Test process: The samples are fixed on the sample fixture on the instrument (see Figure 1). At 30.5 cm away from the center of sample, 2 mL of synthetic blood (see Appendix A for configuration method) with surface tension of (0.042±0.002) N/m is sprayed horizontally to the target area of the tested sample, under the pressure of 16.0 kPa (120 mmHg), from the needle tube with inner diameter of 0.84 mm. And then a visual inspection is conducted within 10 seconds after being taken out.

Result treatment: Check whether there is penetration in the inner side of the sample. If the visual inspection is suspicious, daub the inside of the target area lightly with a cotton absorbent swab or similar item, and then judge whether there is synthetic blood penetration. The results should meet the requirements of 4.5.



1 - filter/regulator - air supply;

2 - air pipeline to controller (outer diameter) 12.7 mm, inner diameter 6.35 mm, pressure 1.03×10^6 Pa, length 193 cm;

3 - air pipeline (diameter 6.35 mm, length 300 cm, plastic material);

4 - wire from controller to valve switch;

5 - air line to valve (diameter 6.35 mm, length 150 cm, plastic material);

6 - liquid supply pipe to air pressure valve (diameter 6.35 mm, length 94 cm, plastic material);

7 - vessel pressure gauge;

8 - the valve screwed on the ring frame, on which is equipped with a 42 cm long needle tube.

Figure 1 Schematic diagram of synthetic blood test instrument

5.6 Filtration efficiency

5.6.1 Bacterial filtration efficiency (BFE)

The test shall be conducted with 3 samples according to the method in Appendix B, and the results shall meet the requirements of 4.6.1.

5.6.2 Particle filtration efficiency (PFE)

Number of samples: test with 3 samples.

Sample pretreatment: Before the test, the sample is taken out of the package and placed in the environment with relative humidity of (85±5)% and temperature of (38±2.5)℃ for (25±1) hours for sample pretreatment. The sample shall then be sealed in an airtight container and the test shall be completed within 10 hours after the sample pretreatment.

Test process: The test can be carried out in the environment with relative humidity of (30±10)% and temperature of (25±5)℃, using the sodium chloride aerosol or similar solid aerosol with count median diameter of particles (CMD): (0.075±0.020) μm; geometric standard deviation of particle distribution: ≤1.86; concentration: ≤200 mg/m^3. The air flow rate is set at (30±2) L/ min, and the cross-sectional area of air flow is 100 cm^2.

Note: the count median diameter of particles (CMD) is equivalent to the mass median aerodynamic diameter of (MMAD) (0.24 ± 0.06) μm.

5.7 Differential Pressure

Number of samples: test with 5 samples.

Test process: The gas flow for the test needs to be adjusted to 8 L/min, the diameter of the sample test area is 25 mm, and the test area is 4.9 cm^2. The differential pressure (△P) is calculated according to formula (1), and the result is reported as the differential pressure per square centimeter area, which shall meet the requirements of 4.7.

$$\Delta P = \frac{P_M}{4.9} \quad (1)$$

In the formula:

P_M - the average value of the differential pressure of the test sample, in Pa.

5.8 Flame retardation properties

Number of samples: test with 3 samples.

Test process: the distance between the top of burner and the lowest part of sample is set as (20±2) mm. The flame height is set as (40±4) mm and the flame temperature at (20±2) mm above the burner top is set as (800 ± 50) ℃.

The sample is worn on the dummy head, the linear velocity of the dummy head at the tip of nose is set as (60±5) mm/s, the change is recorded after the sample passing through the flame once, and the sum of burning time and flame-retardant time is reported.

5.9 Microbial cleanliness

According to the property of the sample, the following tests shall be carried out:

b) Test shall be carried out according to the method specified in Appendix B of GB/T 15979-2002, and the results shall meet the requirements of 4.9.1.

b) Sterility test shall be carried out according to the method specified in Chapter 2 of GB/T 14233.2-2005, and the results shall meet the requirements of 4.9.2.

5.10 Residual ethylene oxide

The test shall be carried out according to the gas chromatography method specified in GB/T 14233.1-2008, and the results shall meet the requirements of 4.10.

5.11 Skin irritation

The test shall be carried out according to the method specified in section 6.3 of GB/T 16886.10-2005. The result shall meet the requirements of the 4.11

5.12 Cytotoxicity

The test shall be carried out according to the method specified in section 8.2 of GB/T 16886.5-2003. The result shall meet the requirements of the 4.12

5.13 Delayed-type hypersensitization

The test shall be carried out according to the method specified in section 7.5 of GB/T 16886.10-2005. The result shall meet the requirements of the 4.13

6. Mark

The minimum package of mask shall have clear Chinese mark. If the package is transparent, the mark shall be seen through the package. The mark shall at least include:

a) Product name;

b) Production date and/or batch number;

c) Manufacturer's name and contact information;

d) Executive standard number;

e) Product registration certificate number;

f) Instructions for use

g) Storage conditions;

h) The word or symbol "Single-use";

i) If the product is sterilized, there shall be corresponding sterilization mark, and the sterilization method used and sterilization valid period shall be indicated;

j) Specification, dimension and tolerance;

k) Product use.

7 Packaging, transportation and storage

7.1 Packaging

7.1.1 Packaging of mask shall be able to prevent physical damage and pollution before use.

7.1.2 The masks are packed according to the quantity.

7.2 Transportation

According to the conditions stipulated in the contract.

7.3 Storage

Follow the instructions.

Appendix A

(normative appendix)

Preparation of synthetic blood

A. 1 Reagents

Composition of synthetic blood:

Sodium carboxymethylcellulose (CMC, medium viscosity)	2 g
Tween 20	0.06 g
Sodium chloride (analytical pure)	4.5 g
Methylisothiazolinone (MIT)	0.5 g
Amaranth dye	1.0 g
Distilled water	Add to 1L

A.2 Preparation method

The sodium carboxymethylcellulose is dissolved in 0.5L water, and mixed for 60 min with a magnetic stirrer. Tween 20 is weighed in a small beaker, and mixed with water.

Tween 20 solution is added to the above solution of sodium carboxymethylcellulose. The beaker is washed with distilled water for several times and then added to the mixture.

Sodium chloride is dissolved in the solution, followed by MIT and amaranth dye. And the solution is diluted to 1000 g with water.

The pH of synthetic blood is adjusted to 7.3±0.1 with 2.5 mol/L sodium hydroxide solution.

The surface tension of synthetic blood is measured with a surface tensiometer. The result should be (0.042±0.002) N/m. if it is beyond this range, it cannot be used.

Appendix B

(normative appendix)

Test method for bacterial filtration efficiency (BFE)

B. 1. Test instruments and materials

B. 1.1 Test instruments

See Figure B.1 for the schematic diagram of test instrument.

High pressure steam sterilizer (constant temperature 121℃ ~ 123℃); incubator (constant temperature 37℃±2℃); analytical balance (weighing 0.001g); Swirling mixer (which can accommodate 16 mm × 150 mm test tube); orbital oscillator (speed 100 r/min~250 r/min); refrigerator (2℃ ~ 8℃); six-stage aerosol sampler; vacuum pump (57 L/m); air pump/pressure pump (at least 103 kPa); peristaltic pump (flow rate 0.01mL/min); nebulizer; glass aerosol chamber (60 cm × 8 cm diameter glass tube); colony counter (which can count 400 colonies/plate); stopwatch (accuracy 0.1s); pipette (1.0 mL±0.05 mL); flowmeter; aerosol condenser; pressure gauge (accurate to 35 kPa±1 kPa); air conditioner.

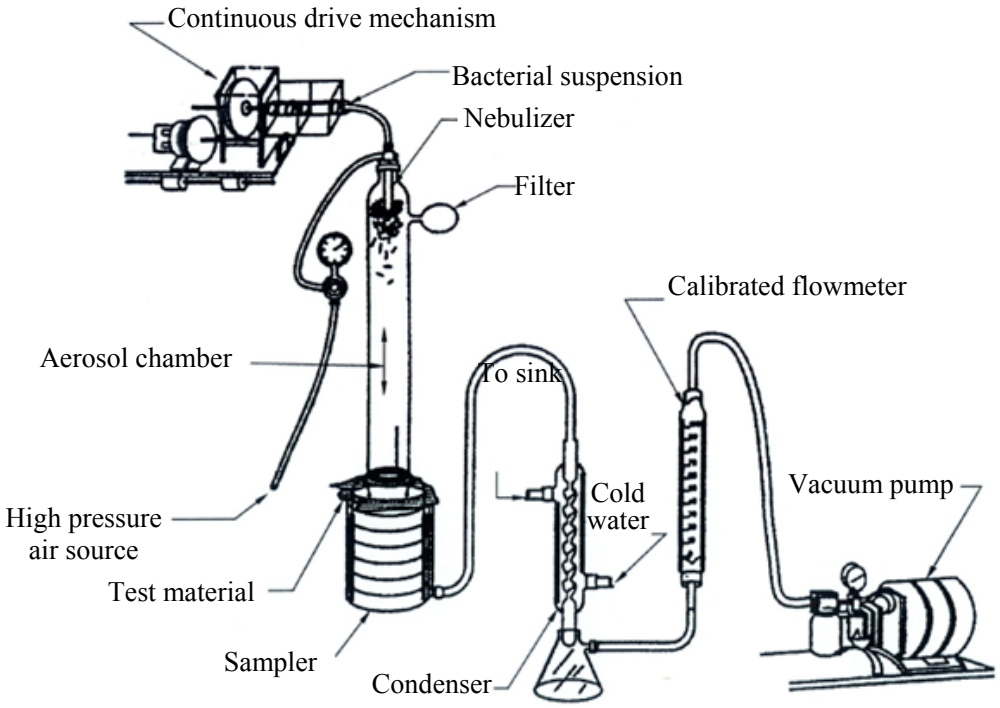


Figure B.1 Schematic diagram of bacterial filtration efficiency test instrument

B. 1.2 Materials

Conical flask (250 mL ~ 500 mL); plate; pipette (1 mL, 5 mL, 10 mL); stainless steel test tube rack; sterile glass bottle (100 mL ~ 500 mL); inoculation ring; bottle stopper; test tube (16 mm × 150 mm).

B.1.3 Reagent

Tryptic Soy agar (TSA); Tryptic Soy broth (TSB); peptone water; *Staphylococcus aureus* ATCC 6538.

B.2 Sample pretreatment

Before the test, the sample shall be placed in the environment with temperature of (21±5)℃ and relative humidity of (85±5)% for pretreatment for at least 4 hours.

B. 3. Preparation of bacterial suspension for test

Staphylococcus aureus ATCC 6538 is propagated in a proper volume of TSB with shaking at (37±2) ℃ for (24±2) hours. The culture above is then diluted with 1.5% peptone solution to a concentration of approximately 5×10^5 CFU/mL.

B. 4. Test procedure

The air flow rate of the sampler is controlled at 28.3L/min before the test sample was fixed. Deliver the bacteria suspension to the nebulizer for 1 min, and maintain the airflow through the sampler for 2 min. The bacterial aerosol is collected on TSA plates as a positive control which should be maintained at (2200 ± 500) CFU per test, otherwise the concentration of the bacteria suspension needs to be adjusted accordingly. The mean particle diameter (MPS) of the bacteria aerosol is calculated which should be maintained at (3.0±0.3) μm, and the geometric standard deviation should be less than 1.5.

After the positive quality control test is completed, the agar plates are removed and marked with stage number. Then fresh agar plates are placed, and the test sample is fixed with the inside toward the aerosol challenge. Sampling is carried out according to the procedure mentioned above.

After a batch of test samples are tested, a further positive run is performed. After that a negative control test was performed during which the bacteria suspension should not be transported to the nebulizer.

The test system (as shown in figure B.2) that can be used to collect the positive control and the sample simultaneously can also be used.

The agar plates are cultured for (48±4) hours at (37±2) ℃, and then the colonies (positive holes) formed by bacteria aerosol particles are counted, and the counts are converted to the number of probably impacted particles using the conversion table (Table B.1). The converted value is used to determine the average level of bacteria particles delivered to the test sample.

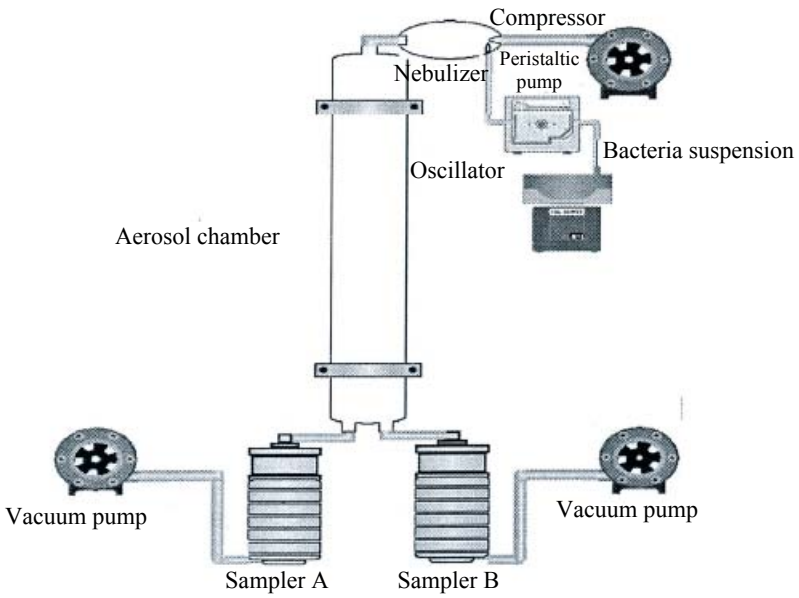


Figure B.2 Schematic diagram of two-way collection test instrument for bacterial filtration efficiency

B.5 Calculation of result

The test result is calculated according to the formula (B.1):

$$BFE = \frac{c - T}{c} \times 100\% \qquad \text{(B.1)}$$

In the formula:

c - average value of positive controls;

T - total plate count for the test sample.

Table B.1 positive pore conversion table, positive pore count value *(r)* and corresponding corrected particle count value *(P)*

r	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*
1	1	11	11	21	22	31	32	41	43	51	55	61	66	71	78	81	91	91	103
2	2	12	12	22	23	32	33	42	44	52	56	62	67	72	79	82	92	92	105
3	3	13	13	23	24	33	34	43	45	53	57	63	69	73	81	83	93	93	106
4	4	14	14	24	25	34	36	44	47	54	58	64	70	74	82	84	94	94	107
5	5	15	15	25	26	35	37	45	48	55	59	65	71	75	83	85	96	95	108
6	6	16	16	26	27	36	38	46	49	56	60	66	72	76	84	86	97	96	110
7	7	17	17	27	28	37	39	47	50	57	61	67	73	77	86	87	98	97	111
8	8	18	18	28	29	38	40	48	51	58	63	68	75	78	87	88	99	98	112
9	9	19	19	29	30	39	41	49	52	59	64	69	76	79	88	89	101	99	114
10	10	20	21	30	31	40	42	50	53	60	65	70	77	80	89	90	102	100	115

Table B.1 (Continued)

r	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*	*r*	*P*
101	116	131	159	161	206	191	260	221	322	251	395	281	485	311	601	341	766	371	1 050
102	118	132	160	162	208	192	262	222	324	252	398	282	488	312	606	342	772	372	1 064
103	119	133	162	163	209	193	263	223	326	253	400	283	492	313	610	343	779	373	1 078
104	120	134	163	164	211	194	265	224	328	254	403	284	495	314	615	344	786	374	1 093
105	122	135	165	165	213	195	267	225	331	255	406	285	499	315	620	345	793	375	1 109
106	123	136	166	166	214	196	269	226	333	256	409	286	502	316	624	346	801	376	1 125
107	125	137	168	167	216	197	271	227	335	257	411	287	506	317	629	347	808	377	1 142
108	126	138	169	168	218	198	273	228	338	258	414	288	508	318	634	348	816	378	1 160
109	127	139	171	169	220	199	275	229	340	259	417	289	513	319	639	349	824	379	1 179
110	129	140	172	170	221	200	277	230	342	260	420	290	516	320	644	350	832	380	1 198
111	130	141	174	171	223	201	279	231	345	261	423	291	520	321	649	351	840	381	1 219
112	131	142	175	172	225	202	281	232	347	262	426	292	524	322	654	352	848	382	1 241
113	133	143	177	173	227	203	283	233	349	263	429	293	527	323	659	353	857	383	1 263
114	134	144	179	174	228	204	285	234	352	264	432	294	531	324	664	354	865	384	1 288
115	136	145	180	175	230	205	287	235	354	265	434	295	535	325	670	355	874	385	1 314
116	137	146	182	176	232	206	289	236	357	266	437	296	539	326	675	356	883	386	1 341
117	138	147	183	177	234	207	292	237	359	267	440	297	543	327	680	357	892	387	1 371
118	140	148	185	178	236	208	294	238	362	268	443	298	547	328	686	358	902	388	1 408
119	141	149	186	179	237	209	296	239	364	269	447	299	551	329	692	359	911	389	1 438
120	143	150	188	180	239	210	298	240	367	270	450	300	555	330	697	360	921	390	1 476
121	144	151	190	181	241	211	300	241	369	271	453	301	559	331	703	361	934	391	1 518
122	146	152	191	182	243	212	302	242	372	272	456	302	563	332	709	362	942	392	1 565
123	147	153	193	183	245	213	304	243	374	273	459	303	567	333	715	363	952	393	1 619
124	148	154	194	184	246	214	306	244	377	274	462	304	571	334	721	364	963	394	1 681
125	150	155	196	185	248	215	308	245	379	275	465	305	575	335	727	365	974	395	1 754
126	151	156	198	186	250	216	311	246	382	276	468	306	579	336	733	366	986	396	1 844
127	153	157	199	187	252	217	313	247	384	277	472	307	584	337	739	367	998	397	1 961
128	154	158	201	188	254	218	315	248	387	278	475	308	588	338	746	368	1010	398	2 127
129	156	159	203	189	256	219	317	249	390	279	478	309	592	339	752	369	1023	399	2 427

130	157	160	204	190	258	220	319	250	392	280	482	310	597	340	759	370	1036	400	[a]

Note: it is quoted from the Andersen conversion table in Reference [1].

[a] it indicates quantitative limit of state(approx 2628 particles) is exceeded.

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