



USER: GRAY, ILKA K (ixg)

FOLDER: K954828 - 114 pages (FOI:10003547)

COMPANY: GIBECK, INC. (GIBECK)

PRODUCT: FILTER, BACTERIAL,
BREATHING-CIRCUIT (CAH)

SUMMARY: Product: ISO-GARD HEPA FILTER-HME,
ISO-ARD HEPA FILTER-HME W/PORT

DATE REQUESTED: Thu Oct 21 24:00:00 2010

DATE PRINTED: Thu Oct 21 12:41:07 2010

Note: Releasable Version

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MAY -2 1996

K954828

Subject: 510(k) Summary of Safety and Effectiveness

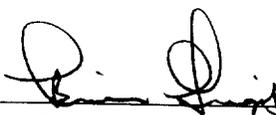
Product: Gibeck Iso-Gard® HEPA Filter-HME and
Iso-Gard® HEPA Filter-HME with Port

Summary:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port are combination products, i.e. bacterial/viral filters and heat and moisture exchangers, and are substantially equivalent to the Humid-Vent Filter. The bacterial filtration efficiency has been demonstrated to be >99.99 for a mean particle size of 3.0 microns. The viral filtration efficiency has been demonstrated to be >99.99 for a mean particle size of 3.1 microns. The moisture output has been demonstrated to be 26.6 mg H₂O/l air at 300 ml tidal volume and 22.2 mg H₂O/l air at 600 ml tidal volume.

The principal differences between the Iso-Gard HEPA Filter-HME, the Iso-Gard HEPA Filter-HME with Port and the Humid-Vent Filter are the design of the housing and the filtration/HME media utilized. These differences are not considered to be critical to the intended therapeutic, diagnostic, prosthetic or surgical use of the device nor should these differences significantly affect the safety or effectiveness of the device when used as labeled.



Submitter/Contact Person

2/9/96

Date

Gibeck, Inc.
10640 East 59th Street • P.O. Box 36430 • Indianapolis, IN 46236
Telephone: (317) 823-6866 • Telefax: (317) 823-1662

A Member of the Gibeck Group



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Brian Grigsby
Gibeck, Inc.
10640 East 59th Street
P.O. Box 36430
Indianapolis, Indiana 46236

Re: K954828
Iso-Gard® HEPA Filter-HME,
Iso-Gard® HEPA Filter-HME
with Port
Dated: February 9, 1996
Received: February 12, 1996
Regulatory Class: II (two)
Product Code: 73 CAH

Dear Mr. Grigsby:

MAY - 2 1996

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the act for devices under the Electronic Product ion Control provisions, or other Federal laws or regulations.

001

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director

Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) ROUTE SLIP

510(k) NUMBER K954828 PANEL AN DIVISION DCRND BRANCH ADDG
TRADE NAME ISO-GARD HEPA FILTER-HME, ISO-ARD HEPA FILTER-HME W/PORT
COMMON NAME HEAT & MOISTURE EXCHANGER
PRODUCT CODE _____

APPLICANT GIBECK, INC.
SHORT NAME GIBECK
CONTACT BRIAN GRIGSBY
DIVISION _____
ADDRESS 10640 E. 59TH ST.
P.O. BOX 36430
INDIANAPOLIS, IN 46236
PHONE NO. (____) ____-____ FAX NO. (____) ____-____
MANUFACTURER GIBECK, INC. REGISTRATION NO. 1824054

DATE ON SUBMISSION 19-OCT-95 DATE DUE TO 510(K) STAFF 03-JAN-96
DATE RECEIVED IN ODE 20-OCT-95 DATE DECISION DUE 18-JAN-96
DECISION _____ DECISION DATE _____

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
<u>S001</u>	<u>09-FEB-96</u>	<u>12-FEB-96</u>	<u>27-APR-96</u>	<u>12-MAY-96</u>	

CORRESPONDENCE	SENT	DUE BACK
<u>C001</u>	<u>26-JAN-96</u>	<u>25-FEB-96</u> <u>HOLD LETTER</u>

Is this 510(k) identified as a Class III device _____ YES _____ NO

SE
MAY 2 1996



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

Date: 5/1/96
From: Reviewer(s) - Name(s) Kevin Milne
Subject: 510(k) Number 1K954828/s'

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Is substantially equivalent to marketed devices.
- Requires premarket approval. NOT substantially equivalent to marketed devices.
- Requires more data.
- Accepted for review _____
(date)
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? YES NO
 Is this device subject to the Tracking Regulation? YES NO
 Was clinical data necessary to support the review of this 510(k)? YES NO
 Is this a prescription device? YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: Additional Product Code(s) with panel (optional):

73 CAH, II (two)

Review: Lark W. Madsen ADD6 5-1-96
(Branch Chief) (Branch Code) (Date)

Final Review: Richard Phillips 5/1/96
(Division Director) (Date)

004

◇ MEMORANDUM ◇

FILE: K954828
DATE: April 25, 1996
FROM: Kevin B. Milne, Regulatory Research Officer
OFFICE: OST/DECS/Medical Electronics Branch
DEVICE: Gibeck Iso-Gard HEPA Filter
SUBJECT: Review of additional information

LWM 5-1-96

SUBMISSION SUMMARY

The application contains Additional Information requested as a result of the initial review (1/24/96). Responses were sent to address all questions.

DEFICIENCY RESPONSE

1. Provide performance data to demonstrate filter efficiency, and associated particle levels.

Exhibit A of the application contains test reports from (b)(4), (b)(5) for bacterial and viral filtration efficiencies. It is not clear why these test reports were not included in the original application. Bacterial filtration was demonstrated at 99.99% effective on a mean particle size of 3.0 microns. Viral filtration was demonstrated at 99.99% effective on a mean particle size of 3.1 microns.

The applicant was further contacted (see phone memo) as to why the particle size for filtration was basically the same (in fact, 0.1 micron larger) for viral filtration than for bacterial, considering the fact that viruses are several orders of magnitude smaller than bacteria? This was answered satisfactorily, due to the fact that it is aerosol droplets that carry both types of particles. It was also asked during this conversation what particle sizes were tested on the predicate device, the Humid-Vent Filter, since filtering efficiencies were reported as comparison. He contacted the test facility for an answer.

2. Submit literature demonstrating microglass fiber safety.

Exhibit B contains MSDS sheets; the microglass fiber is manufactured specifically for HEPA filtering.

3. Explain how the device is in compliance with ISO 9360, as the Iso-Gard Filter has significantly less moisture output per tidal volume than the predicate device.

Exhibit C contains test methods and moisture output levels. The test results fall within known parameters. The applicant further explains that moisture output is one of the product performance characteristics left to the clinician's preference and determination. Gibeck relies on this not being an issue since filtration and flow resistance are enhanced over the predicate device.

4. Reword the 510(k) Summary or replace with a 510(k) Statement.

The 510(k) Summary is reworded to include safety and effectiveness details which were lacking in the original application.

ADDITIONAL INFORMATION NEEDED

All concerns have been addressed in the AI submission or by direct contact (see phone memo). No additional information is necessary to complete the review.

COMPANY CONTACT: Brian Grigsby, 800-428-5321, x124

ACTION: SE

Ken B. mhe 4/25/06

◇ MEMORANDUM ◇

FILE: K954828
DATE: April 19, 1996
FROM: Kevin B. Milne, Regulatory Research Officer
OFFICE: OST/DECS/Medical Electronics Branch
DEVICE: Gibeck Iso-Gard HEPA Filter
SUBJECT: Phone memo

1. Why is the particle size for filtration basically the same (and in fact 0.1 micron larger) for viral filtration than for bacterial, considering the fact that viruses are several orders of magnitude smaller than bacteria?

Mr. Grigsby contacted (b)(4), (b)(5) with this question. The actual size of the bacteria is 0.8 μ , while virus size is 0.027 μ . The size difference is not an issue, as the bacteria and viruses are transmitted by aerosol droplets, which range from 2.7 - 3.3 μ . They test filtration at around 3.0 μ to fall midrange.

2. What was the size particles for which filtration efficiency of 99.90% was reported for the predicate device, the Gibeck Humid-Vent Filter? This information is not contained in the predicate device (K881657) archived file.

Unsure, we will contact (b)(4), (b)(5) for this answer.

DATE: April 22, 1996
FROM: Kevin B. Milne, Regulatory Research Officer
SUBJECT: Phone memo

The particle size for filtration tests of the Humid-Vent Filter, also tested by (b)(4), (b)(5) (b)(4), (b)(5) is virtually the same as the current device. Bacterial filtering was demonstrated for particles of 3.3 μ , and virus particles of 3.3 μ . Again, the filtering efficiencies were determined at a size for aerosol droplets, the carrier for disease particles. A fax copy was sent for filing purposes. This information is satisfactory to address filtration concerns.

Kevin B. Milne 4/25/96
Lwm 5-1-96

007



TELEFAX MESSAGE

To: Kevin Milne (301) 443-2536
Company: FDA
Fax: (301) 443-9101

From: Brian Grigsby
Date: April 23, 1996
Pages: 1
Subject: 510(k) Premarket Notification - K954828

Dear Kevin,

In response to your earlier inquiry, I have confirmed that the mean particle size of the aerosol used to determine both the BFE and the VFE for the Humid-Vent Filter product was 3.3 microns.

Thank you for your patience and assistance!

Sincerely,

Brian Grigsby
Director, Quality and Regulatory Affairs

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 12, 1996

GIBECK, INC.
10640 E. 59TH ST.
P.O. BOX 36430
INDIANAPOLIS, IN 46236
ATTN: BRIAN GRIGSBY

510(k) Number: K954828
Product: ISO-GARD HEPA
FILTER-HME,
ISO-ARD HEPA
FILTER-HME

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

009

K954828/s1



February 9, 1996

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

FDA/CDRH/ODE/DMO

12 FEB 96 11 26

RECEIVED

Re: K954828 - 510(k) Premarket Notification - Iso-Gard® HEPA Filter-HME, Iso-Gard® HEPA Filter-HME with Port

Dear Office of Device Evaluation Reviewer:

In accordance with your letter dated January 26, 1996, I am enclosing the additional information which you requested. For your convenience, I have included your requests along with our responses immediately below:

1. Submit performance data to demonstrate filtration efficiency of the Iso-Gard HEPA Filter-HME, and at what level (particle size) which this efficiency can be achieved.

Response: Please refer to Exhibit A for test reports of the bacterial filtration efficiency (BFE) and virus filtration efficiency (VFE) of the Iso-Gard HEPA Filter-HME. The percent BFE with a mean particle size of 3.0 microns was determined to be >99.99. The percent VFE with a mean particle size of 3.1 microns was determined to be >99.99.

2. Submit data or manufacturer literature which demonstrates the safety of the microglass fiber used for filtration and HME.

Response: Please refer to Exhibit B for the manufacturer's Material Safety Data Sheet (MSDS) for the microglass paper used in the Iso-Gard HEPA Filter-HME. This paper is manufactured specifically for use as HEPA filter media

3. Submit data to support compliance with ISO 9360 moisture output levels, as the Iso-Gard Filter has significantly less moisture output per tidal volume than the predicate device.

Gibeck, Inc.
10640 East 59th Street • P.O. Box 36430 • Indianapolis, IN 46236
Telephone: (317) 823-6866 • Telefax: (317) 823-1662
A Member of the Gibeck Group

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Response: Please refer to Exhibit C for details regarding the test method and results of moisture output testing of the Iso-Gard HEPA Filter.

It is important to understand that the Iso-Gard HEPA Filter and Humid-Vent Filter are combination products which provide both bacterial/viral filtration and humidification. When a clinician selects products like these, he/she must select the most appropriate device based on a number of factors including: dead space, weight, resistance to flow, moisture output, bacterial/viral filtration efficiency, etc. This decision making process often involves prioritizing the performance requirements of available devices, i.e. a combined filter/HME versus the increased weight and dead space of separate devices, or improved filtration efficiency versus moisture output.

You are correct in pointing out that the moisture output of the Iso-Gard HEPA Filter is less than the Humid-Vent Filter. It should also be noted that the Iso-Gard HEPA Filter offers improved filtration and reduced resistance to flow compared to the Humid-Vent Filter. We feel that the prescribing clinician is best suited to determine the most appropriate balance of a product's performance characteristics based on the individual patient's needs.

4. Reword the 510(k) Summary to summarize safety and effectiveness of the device, or replace with a 510(k) Statement.

Response: Please see Exhibit D for a revised 510(k) Summary of Safety and Effectiveness.

We trust that the above information satisfactorily answers your questions and, in summary and conclusion, feel that the Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port are "substantially equivalent" to the Humid-Vent Filter for premarket notification purposes. We respectfully request your concurrence with this determination.

Sincerely,



Brian Grigsby
Director, Quality and Regulatory Affairs
(317) 823-6866, Ext. 124

Enclosures
Submitted in triplicate

011

Exhibit A

(b)(4)

(b)(4)

BACTERIAL FILTRATION EFFICIENCY (BFE) /
DIFFERENTIAL PRESSURE (ΔP)

LABORATORY NUMBER:

PROCEDURE NUMBER:

SAMPLE SOURCE:

SAMPLE IDENTIFICATION:

TEST REQUESTED:

DELTA P MANOMETER NUMBER:

DELTA P FLOWMETER NUMBER:

START DATE:

COMPLETION DATE:

REPORT DATE:

(b)(4)

(b)(4)

TEST PROCEDURE:

(b)(4)

(b)(4)

(b)(4)

(b)(4)

013

(b)(4)

(b)(4)

RESULTS:

(b)(4)

(b)(4)

Gibeck-Dryden
BFE-Delta P Test
Lab Number (b)(4)
Page 3

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

TABLE OF RESULTS

(b)(4)

(b)(4)

(b)(4)

(b)(4)

VIRAL FILTRATION EFFICIENCY

LABORATORY NUMBER:
PROCEDURE NUMBER:
SAMPLE SOURCE:
SAMPLE IDENTIFICATION:
TEST REQUESTED:

(b)(4)

(b)(4)

START DATE:
COMPLETION DATE:
REPORT DATE:

PROCEDURE:

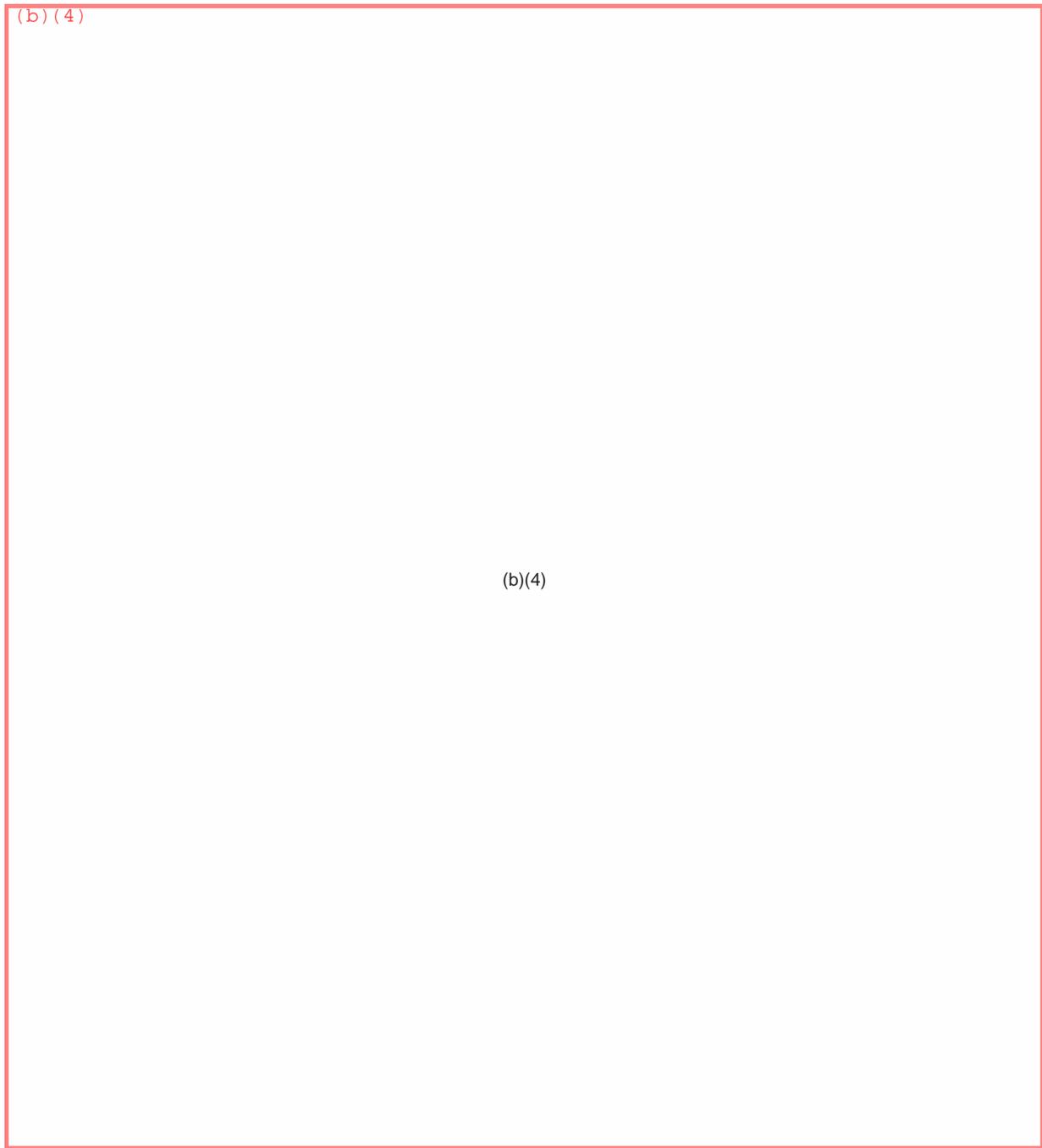
(b)(4)

(b)(4)

(b)(4)

(b)(4)

Gibeck-Dryden
Viral Filtration Efficiency
Lab Number (b)(4)
Page 2



(b)(4)

(b)(4)

(b)(4)

(b)(4)

TABLE 1. VFE Controls

(b)(4)

(b)(4)

TABLE 2. Results

(b)(4)

(b)(4)

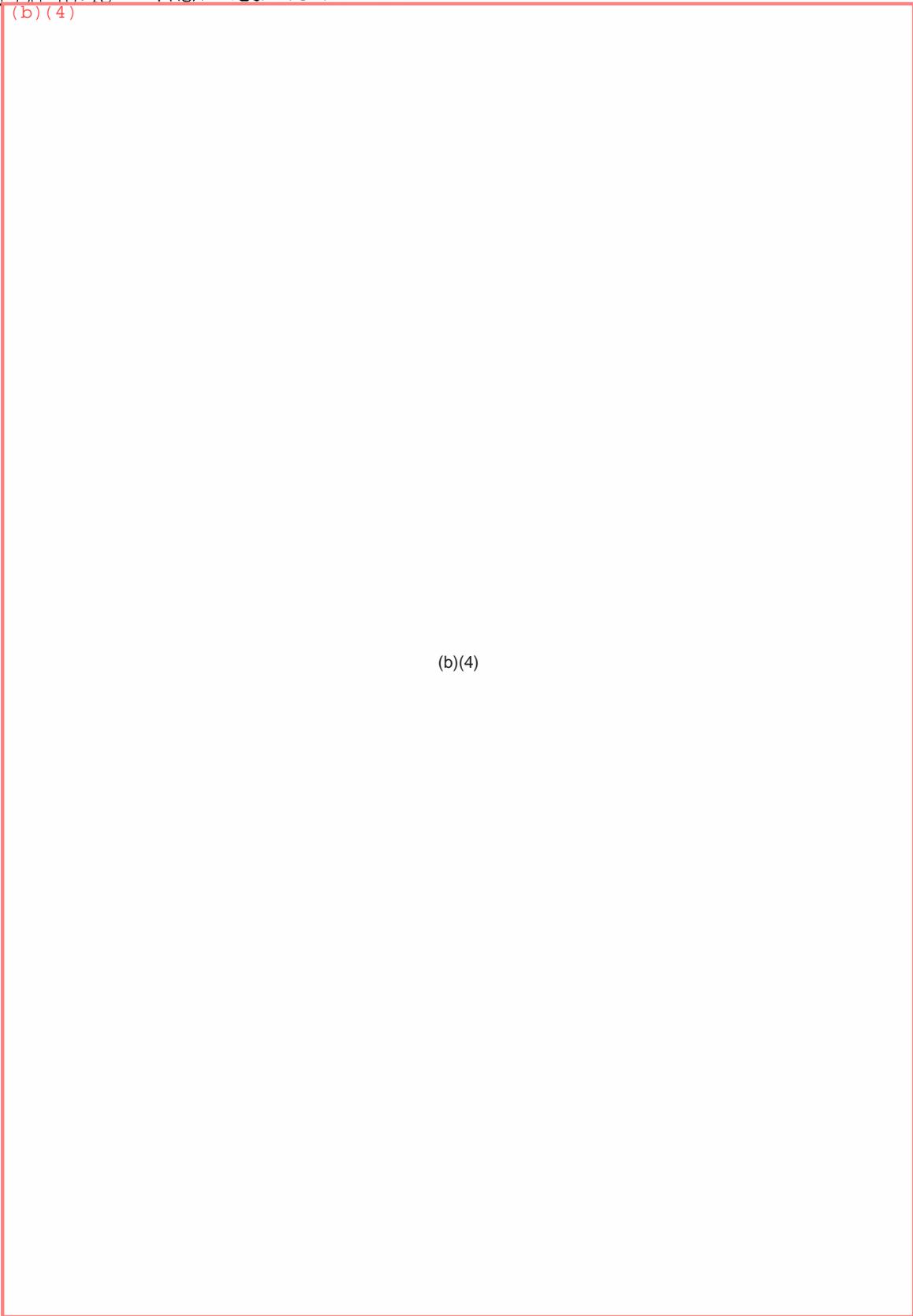
Exhibit B

MATERIAL SAFETY DATA SHEET

(b) (4)

(b)(4)

(b)(4)



(b)(4)



Exhibit C

Moisture Output of Iso-Gard HEPA Filter

The test method used to determine the moisture output of the Iso-Gard HEPA filter is per ISO 9360 Anaesthetic and respiratory equipment - Heat and moisture exchangers for use in humidifying respired gases in humans. This method (b) (4) (b)(4)

(b) (4)

(b)(4)

Exhibit D



Subject: 510(k) Summary of Safety and Effectiveness

Product: Gibeck Iso-Gard[®] HEPA Filter-HME and
Iso-Gard[®] HEPA Filter-HME with Port

Summary:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port are combination products, i.e. bacterial/viral filters and heat and moisture exchangers, and are substantially equivalent to the Humid-Vent Filter. The bacterial filtration efficiency has been demonstrated to be >99.99 for a mean particle size of 3.0 microns. The viral filtration efficiency has been demonstrated to be >99.99 for a mean particle size of 3.1 microns. The moisture output has been demonstrated to be 26.6 mg H₂O/l air at 300 ml tidal volume and 22.2 mg H₂O/l air at 600 ml tidal volume.

The principal differences between the Iso-Gard HEPA Filter-HME, the Iso-Gard HEPA Filter-HME with Port and the Humid-Vent Filter are the design of the housing and the filtration/HME media utilized. These differences are not considered to be critical to the intended therapeutic, diagnostic, prosthetic or surgical use of the device nor should these differences significantly affect the safety or effectiveness of the device when used as labeled.



Submitter/Contact Person

2/9/96
Date

Gibeck, Inc.
10640 East 59th Street • P.O. Box 36430 • Indianapolis, IN 46236
Telephone: (317) 823-6866 • Telefax: (317) 823-1662
A Member of the Gibeck Group

030



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 1996

Mr. Brian Grigsby
Director, Quality and Regulatory Affairs
Gibeck, Inc.
10640 East 59th Street
P.O. Box 36430
Indianapolis, Indiana 46236

Re: K954828
Iso-Gard® HEPA Filter-HME,
Iso-Gard® HEPA Filter-HME with Port
Dated: October 19, 1995
Received: October 20, 1995

Dear Mr. Grigsby:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

1. Submit performance data to demonstrate filtration efficiency of the Iso-Gard HEPA Filter-HME, and at what level (particle size) which this efficiency can be achieved.
2. Submit data or manufacturer literature which demonstrates the safety of the microglass fiber used for filtration and HME.
3. Submit data to support compliance with ISO 9360 moisture output levels, as the Iso-Gard Filter has significantly less moisture output per tidal volume than the predicate device.
4. Reword the 510(k) Summary to summarize safety and effectiveness of the device, or replace with a 510(k) Statement.

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

031

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(f) and (h), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have questions concerning the contents of this letter, please contact Kevin Milne at (301) 443-2536 ex-56. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for
Richard N. Phillips, Ph.D.

Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

JAN 26 1996

Mr. Brian Grigsby
Director, Quality and Regulatory Affairs
Gibeck, Inc.
10640 East 59th Street
P.O. Box 36430
Indianapolis, Indiana 46236

Re: K954828
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Iso-Gard® HEPA Filter-HME with Port
Dated: October 19, 1995
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3. Submit data to support compliance with ISO 9360 moisture output levels, as the Iso-Gard Filter has significantly less moisture output per tidal volume than the predicate device.
4. Reword the 510(k) Summary to summarize safety and effectiveness of the device, or replace with a 510(k) Statement.

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033

Page 2 - Mr. Brian Grigsby

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Sincerely yours,

Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices

(b)(2)Low

(b)(2)Low

Device Evaluation	Device Evaluation	Device Evaluation	Device Evaluation
for Devices and	for Devices and	for Devices and	for Devices and
ological Health	ological Health	ological Health	ological Health

U.S. GPO 1906-169 041

Pre

FILE
COPY



Memorandum

Date _____
 From REVIEWER(S) - NAME(S) Kevin Milne
 Subject 510(k) NUMBER K954828

To THE RECORD -- It is my recommendation that the subject 510(k) Notification:

- Is substantially equivalent to marketed devices.
- Requires premarket approval. NOT substantially equivalent to marketed devices.
- Requires more data. LWM 1-26-96
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? YES NO
 Is this device subject to the Tracking Regulation? YES NO
 Was clinical data necessary to support the review of this 510(k)? YES NO

This 510(k) contains: Truthful and Accurate Statement Requested Enclosed - (required for originals received 3-14-95 and after)

- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices

The submitter requests under 21 CFR 807.95: No Confidentiality
 Confidentiality for 90 days Continued Confidentiality exceeding 90 days

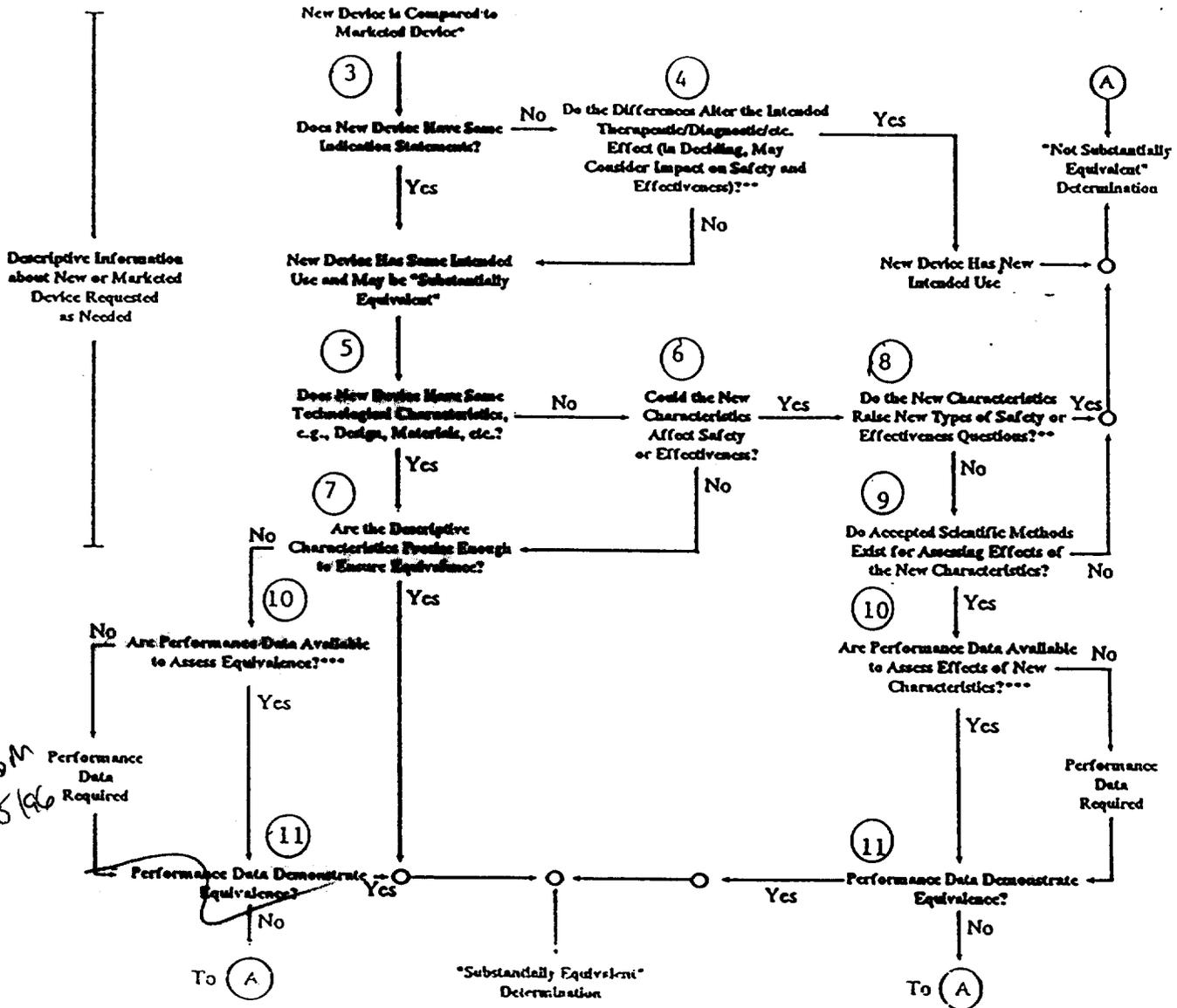
Predicate Product Code with panel and class: 73 CAH, II
 Additional Product Code(s) with panel (optional): _____

REVIEW: _____
 (BRANCH CHIEF) (BRANCH CODE) (DATE)

FINAL REVIEW: _____
 (DIVISION DIRECTOR) (DATE)

Revised 3/8/95

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



KBM
1/25/96

036

- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

K _____ Device Name _____

Division/Branch _____

Administrative Reviewer Signature _____ Date _____

Supervisory Signature _____ Date _____

Did the firm request expedited review? _____ Yes _____ No

Did we grant expedited review? _____ Yes _____ No

Truthful and accurate statement enclosed? _____ Yes _____ No

(If Not Enclosed, Must Be A Refuse To Accept Letter)

Required For Originals Received 3/14/95 And After

Is this a 510(k) for a Class III device? _____ Yes _____ No (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial equivalence until the GMP inspection process has been completed.

Is this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If so, a new ODE review not required, please forward to POS.

_____ Yes _____ No

Accepted

Refuse To
Accept

CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	<input type="checkbox"/>	<input type="checkbox"/>
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	<input type="checkbox"/>	<input type="checkbox"/>
C. Is Device Subject To Review By CDRH?	<input type="checkbox"/>	<input type="checkbox"/>
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision? (ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation? If Yes, Consult The ODE Integrity Officer. (ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #I91-2 And Federal Register 90N-0332, September 10, 1991.)	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	<input type="checkbox"/>	<input type="checkbox"/>
1. Device Trade Or Proprietary Name	<input type="checkbox"/>	<input type="checkbox"/>
2. Device Common Or Usual Name Or Classification Name	<input type="checkbox"/>	<input type="checkbox"/>
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	<input type="checkbox"/>	<input type="checkbox"/>
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	<input type="checkbox"/>	<input type="checkbox"/>
5. Classification Panel	<input type="checkbox"/>	<input type="checkbox"/>
6. Action Taken To Comply With Section 514 Of The Act	<input type="checkbox"/>	<input type="checkbox"/>
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	<input type="checkbox"/>	<input type="checkbox"/>

8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	<input type="checkbox"/>	<input type="checkbox"/>
9. For Class III Devices Only, A Class III Certification And A Class III Summary	<input type="checkbox"/>	<input type="checkbox"/>
10. Photographs Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
11. Engineering Drawings For The Device With Dimensions And Tolerances	<input type="checkbox"/>	<input type="checkbox"/>
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
14. Data To Show Consequences And Effects Of A Modified Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
15. Truthful And Accurate Statement	<input type="checkbox"/>	<input type="checkbox"/>
II. Additional Information That <u>Is</u> Necessary Under 21 CFR 807.87(h) :	<input type="checkbox"/>	<input type="checkbox"/>
A. Submitter's Name And Address	<input type="checkbox"/>	<input type="checkbox"/>
B. Contact Person, Telephone Number And Fax Number	<input type="checkbox"/>	<input type="checkbox"/>
C. Representative/Consultant If Applicable	<input type="checkbox"/>	<input type="checkbox"/>
D. Table Of Contents With Pagination	<input type="checkbox"/>	<input type="checkbox"/>
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	<input type="checkbox"/>	<input type="checkbox"/>
III. Additional Information That <u>May Be</u> Necessary Under 21 CFR 807.87(h) :	<input type="checkbox"/>	<input type="checkbox"/>
A. Comparison Table Of The New Device To The Marketed Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
B. Action Taken To Comply With Voluntary Standards	<input type="checkbox"/>	<input type="checkbox"/>
C. Performance Data	<input type="checkbox"/>	<input type="checkbox"/>
MARKETED DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
NEW DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>

Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
D. Sterilization Information	<input type="checkbox"/>	<input type="checkbox"/>
Software Information	<input type="checkbox"/>	<input type="checkbox"/>
F. Hardware Information	<input type="checkbox"/>	<input type="checkbox"/>
G. If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	<input type="checkbox"/>	<input type="checkbox"/>
H. Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	<input type="checkbox"/>	<input type="checkbox"/>
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	<input type="checkbox"/>	<input type="checkbox"/>
I. Other (Specify)	<input type="checkbox"/>	<input type="checkbox"/>

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 954828

Reviewer: Kevin Milne

Division/Branch: OST / DECS / MEB

Device Name: Cubeck Iso-Gard HEPA Filter-HME

Product To Which Compared (510(K) Number If Known): Humid - vent Filter, K881657

	YES	NO	
1. Is Product A Device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Stop
2. Is Device Subject To 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Stop
3. Same Indication Statement?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Stop NE
5. Same Technological Characteristics?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Stop NE
9. Accepted Scientific Methods Exist?	<input type="checkbox"/>	<input type="checkbox"/>	If NO = Stop NE
10. Performance Data Available?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	If NO = Request Data
11. Data Demonstrate Equivalence?	<input type="checkbox"/>	<input type="checkbox"/>	Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
Filtration efficiency is claimed, but not substantiated.
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed: *To demonstrate effectiveness and adequately compare to predicate*
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

DCRND Screening Checklist for Premarket Notification 510(k)

Device: <u>Two-Card HEPA Filter-HME, Two-Card HEPA Filter-HME w/Port</u>	K <u>954828</u>	
Submitter: <u>Orbeck, Inc.</u>		
Items which should be Included (circle missing & needed information)	✓ Yes	No ✓ if Item Needed & MISSING
1. General information: a) trade name, b) common name, c) establishment registration #, d) address of manufacturer, e) device class, f) new or modification, g) predicate device identified, h) 513/514 compliance (none yet available), i) Truth and Accuracy Statement	✓	
2. SMDA requirements: 510(k) summary or statement (any Class device)	✓	
Class III Certification & Summary (if Class III)	N/A	
3. Proposed Labeling: a) package labels, b) statement of intended use, c) advertisements or promotional materials, d) MRI compatibility (if claimed)	✓	
4. Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals	✓	
5. Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include: a) labeling, b) intended use, c) physical characteristics, d) anatomical sites, f) performance (bench, animal, clinical, testing), g) safety characteristics		✓
6. Biocompatibility data for all patient-contacting materials, OR, certification of identical material/formulation: a) component & material, b) identify patient-contacting materials, c) biocompatibility of final sterilized product	N/A	
7. Sterilization and expiration dating information: a) sterilization method, b) SAL, c) packaging, d) specify pyrogen free, e) ETO residues, f) radiation dose	N/A	
8. Software validation & verification: a) hazard analysis, b) level of concern, c) development documentation, d) certification	N/A	
9. Meets current DCRND guidelines and applicable standards for this device: a) specify guidance, b) comply with content	✓	

Items shaded under "No" are necessary for all submissions.

Any checks in the last (Needed & MISSING) column requires resubmission.

Passed Screening Yes No Reviewer: Senad Smilund Date: 10/24/95

043

For DCRND Use Only

**DCRND Classification Checklist
for Premarket Notification 510(k)**

Device: <i>100-Grad HEPA Filter - NMS, ISO-Grad HEPA Filter - NMS w/Prot</i>		K <i>954828</i>	
Submitter: <i>Carbeck, Inc.</i>			
Date received: Original 510(k): <i>20-OCT-95</i> This submission: <i>20-OCT-95</i>		Review cycle 1	
Review Tier (circle one): I , II, III <i>(for Tier I, complete items 1-5 on the Screening Checklist)</i>			
Question		Yes	No
A. Is the product a device?		X	
B. Is the device exempt from 510(k) by regulation or policy?			X
C. Expedited Review Status: Requested by sponsor			X
Identified by DCRND			X
Granted by DCRND			
D. Has this device has been the subject of a previous NSE decision?			
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?			
E. Has the sponsor been the subject of an integrity investigation?			
If yes, has the ODE Integrity Officer given permission to proceed with the review?			

Administrative Reviewer Signature: *Senora L. Smallwood* Date: *10/24/95*
Senora Smallwood

MEMORANDUM

510(K) REVIEW FOR DCRND/ADRB

File: K954828

From: Kevin Milne
Date: January 24, 1996
Office: OST/DECS/MEB

Device: Iso-Gard HEPA Filter-HME, Iso-Gard HEPA Filter-HME with Port
Company: Gibeck
Contact: Brian Gigsby, (317) 823-6866,x124

Classification name: Heat and moisture exchanger (HME)
Product Code: 73 CAH
Class: II
Imposed Standards: None
Voluntary Standards: ISO 5356-1, conical connectors
ISO 9360, HME humidifying respired gases in humans
Predicate Device: Gibeck Humid-Vent Filter, K881657

Submission Summary

Gibeck intends to market the application device, the Iso-Gard HEPA Filter-HME, with and without Port, as substantially equivalent to their own predicate device. The Gibeck Humid-Vent Filter, K881657, was approved 6/24/88. The Iso-Gard Filter varies in design of the housing and in the filtration media from the Humid-Vent Filter.

Intended Use

The device is a single-use heat and moisture exchanger with a bacterial/viral filter for humidification of the airway during anesthesia and ventilation.

Device Description

The Iso-Gard Filter is used in conjunction with a tracheotomy or tracheal tube, to warm and humidify gases breathed in by the patient. The Port feature allows for gas sampling. The device can be used for bacterial/viral filtration and/or humidification. The Iso-Gard uses a microglass fiber paper media for filtration and HME.

Performance Evaluation

There is no performance data included in the submission to demonstrate filtration efficiency of the Iso-Gard HEPA Filter-HME, and at what level (particle size) this filtering claim is intended. There is simply a claim of 99.99% efficiency, with no substantiation of the claim. This data is required for a complete review. Similarly, the moisture output levels claimed for the device are significantly less than those of the predicate device. No data is submitted to support compliance with the ISO 9360 standard referenced in the file.

Substantial Equivalence

The Iso-Gard varies from the predicate device, the Humid-Vent Filter, by a housing design change and filtration media. The Iso-Gard has a micro-glass fiber for both filtration and HME, while the Humid-Vent used a polypropylene fiber for filtration and a microwell paper for HME. They are both single-use devices, requiring cleanliness, but not sterility. There is no comparative data submitted, simply comparative description. The Iso-Gard claims slightly less resistance to air flow, better filtration (though not substantiated), and less moisture output.

Required Statements

A 510(k) Summary of Safety and Effectiveness is included, but is only a restatement of the device classification without any safety or effectiveness summary. It should be reworded or a 510(k) Statement substituted. A Truthful and Accurate Statement is included and satisfactory.

Recommendations

Additional information is required for a complete review of the application, as stated above.

1. Submit performance data to demonstrate filtration efficiency of the Iso-Gard HEPA Filter-HME, and at what level (particle size) which this efficiency can be achieved.
2. Submit data or manufacturer literature which demonstrates the safety of the micro-glass fiber used for filtration and HME.
3. Submit data to support compliance with ISO 9360 moisture output levels, as the Iso-Gard Filter has significantly less moisture output per tidal volume than the predicate device.
4. Reword the 510(k) Summary to summarize safety and effectiveness of the device, or replace with a 510(k) Statement.

ACTION: AI

Kevin B. White 1/25/96
Louise V. Madoo 1-28-96

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

October 23, 1995

GIBECK, INC.
10640 E. 59TH ST.
P.O. BOX 36430
INDIANAPOLIS, IN 46236
ATTN: BRIAN GRIGSBY

510(k) Number: K954828
Received: 20-OCT-95
Product: ISO-GARD HEPA
FILTER-HME, ISO-ARD
HEPA FILTER-HME
W/PORT

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

On December 14, 1994, FDA published a regulation entitled "Medical Devices; Substantial Equivalence; 510(k) Summaries and 510(k) Statements; Class III Summaries; Confidentiality of Information." The regulation took effect March 14, 1995. Please note that this regulation includes a requirement that all submitters provide a statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance at the number below for more information.

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

If you have procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or call me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

047

K954828



October 19, 1995

Document Mail Center (HFZ-401)
Office of Device Evaluation
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RECEIVED
20 OCT 95 13 15
FDA/CDRH/ODE/DNC

RE: 510(k) Premarket Notification

Dear Office of Device Evaluation Reviewer:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, Gibeck, Inc. hereby notifies the Food and Drug Administration of the devices described below. For your convenience, I have prepared a 510(k) Premarket Notification Checklist that you may wish to use. Please see Exhibit A.

- a. **Classification Name:** Heat and Moisture Exchanger (Artificial Nose)
Common/Usual Name: Heat and Moisture Exchanger (HME)
Proprietary Name: Iso-Gard® HEPA Filter-HME, Iso-Gard® HEPA Filter-HME with Port
- b. **Establishment Registration Number:** Product will be manufactured by Gibeck, Inc., 10640 E. 59th Street, P.O. Box 36430, Indianapolis, IN 46236 - Establishment Registration Number: 1824054.
- c. **Classification:** The anesthesiology devices panel of the Food and Drug Administration has classified heat and moisture exchangers as Class II devices (21 CFR 868.5375).
- d. **Performance Standards:** No performance standards for heat and moisture exchangers have been established by the Food and Drug Administration. The Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port comply with the following voluntary standards:

Gibeck, Inc.
10640 East 59th Street • P.O. Box 36430 • Indianapolis, IN 46236
Telephone: (317) 823-6866 • Telefax: (317) 823-1662
A Member of the Gibeck Group

AN II

<u>Feature</u>	<u>Standard</u>
15/22 mm Connectors	ISO 5356-1 Anaesthetic and respiratory equipment - Conical connectors - Part 1 - Paragraph 6.2 (See Exhibit B).
Moisture Output	ISO 9360 Anaesthetic and respiratory equipment - Heat and moisture exchangers for use in humidifying respired gases in humans - Paragraph 6.3 (See Exhibit C).

- e. **Labeling:** Draft promotional materials and package label containing instructions for use, specifications, warnings and cautions are attached as Exhibit D.
- f. **Substantial Equivalence:** The Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port heat and moisture exchangers are substantially equivalent to the Gibeck Humid-Vent Filter heat and moisture exchanger, a legally marketed predicate device which has been granted marketing clearance via 510(k) K881657 (See Exhibit E). See Exhibit F for a detailed comparison table.
- g. **Description:** According to 21 CFR 868.5375, a heat and moisture exchanger (artificial nose) is a device intended to be positioned over a tracheotomy (a surgically created opening in the throat) or tracheal tube (a tube inserted into the trachea) to warm and humidify gases breathed in by a patient. As the patient's exhaled breath enters the heat and moisture exchanger, it is warm. This warm breath condenses, with the heat and water vapor being retained by the media (paper) of the heat and moisture exchanger. As the patient inhales, the heat and water vapor are transferred from the paper and returned to the patient. The Humid-Vent Filter is a combination product which provides bacterial/viral filtration in addition to humidification. See Exhibit G for engineering drawings illustrating the Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port.

The Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port can be used for either bacterial/viral filtration, humidification or both. The Iso-Gard HEPA Filter-HME with Port also allows for gas sampling. The main differences between the Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port and the Humid-Vent Filter are the design of the housing and the filtration/HME media used. The Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port utilize a microglass fiber paper

media for both filtration and heat and moisture exchange. The Humid-Vent Filter utilizes a polypropylene fiber media for filtration and a microwell paper media for heat and moisture exchange.

The Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port will be labeled for single use only.

- h. **Performance:** The resistance to flow for the Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port compared to the Humid-Vent Filter is shown below:

Resistance to Flow

<u>Flow Rate</u>	<u>Iso-Gard HEPA Filter-HME, Iso-Gard HEPA Filter-HME with Port</u>	<u>Humid-Vent Filter</u>
30 l/min	0.5 cm H ₂ O	0.8 cm H ₂ O
60 l/min	1.0 "	1.6 "
90 l/min	1.5 "	2.9 "

The moisture output for the Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port compared to the Humid-Vent Filter is shown below:

Moisture Output

<u>Tidal Volume</u>	<u>Iso-Gard HEPA Filter-HME, Iso-Gard HEPA Filter-HME with Port</u>	<u>Humid-Vent Filter</u>
300 ml	26.6 mg H ₂ O/l air	31.0 mg H ₂ O/l air
600 ml	22.2 "	30.0 "

The bacterial/viral filtration efficiency for the Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port compared to the Humid-Vent Filter is shown below:

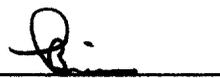
Filtration Efficiency

<u>Testing</u>	<u>Iso-Gard HEPA Filter-HME, Iso-Gard HEPA Filter-HME with Port</u>	<u>Humid-Vent Filter</u>
Bacterial filtration	99.99%	99.90%
Viral filtration	99.99%	99.94%

- i. **Sterility:** The Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port will be supplied clean in a poly film or poly film/paper package.
The Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port will not be labeled as non-pyrogenic.
- j. **510(k) Summary:** A summary of 510(k) safety and effectiveness is attached as Exhibit H.
- k. **Truthful and Accurate Statement:** A truthful and accurate statement is attached as Exhibit I.

In summary and conclusion, the Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port are "substantially equivalent" to the Humid-Vent Filter for premarket notification purposes. We respectfully request your concurrence with this determination.

Sincerely,



Brian Grigsby
Director, Quality and Regulatory Affairs
(317) 823-6866, Ext. 124

Enclosures
Submitted in triplicate

Exhibit A

510(k) Premarket Notification Checklist

K _____ Date Received _____
Device Trade Name: Iso-Gard HEPA Filter-HME, Iso-Gard HEPA Filter-HME with Port
Reason for 510(k): New submission
Division/Branch: Anesthesia/Respiratory
Administrative Reviewer Signature: _____ Date: _____
Supervisory Signature: _____ Date: _____
Did the firm request expedited review? No
Accepted _____ Refuse to accept _____

I. Critical Elements

- A. Is the product a device? Yes (Ref. 21 CFR 868.5375).
- B. Is the device exempt from 510(k) by regulation or policy? No.
- C. Is device subject to review by CDRH? Yes.
- D. (i) Are you aware that this device has been the subject of a previous NSE decision? No.
- E. (i) Are you aware of the submitter being the subject of an integrity investigation? No.
- F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:
1. Device trade or proprietary name - Iso-Gard HEPA Filter-HME, Iso-Gard HEPA Filter-HME with Port.
 2. Device common or usual name or classification name - Heat and moisture exchanger (artificial nose).
 3. Establishment registration number - 1824054.
 4. Class into which the device is classified - Class II.
 5. Classification Panel - Anesthesiology.
 6. Action taken to comply with Section 514 of the Act - No performance standards for heat and moisture exchangers have been established by the Food and Drug Administration. Product has been tested for compliance with ISO 5356-1 (15 mm connector) and ISO 9360 (moisture output). See Exhibits B & C.
 7. Proposed labels, labeling and advertisements (if applicable) that describe the device, its intended use, and directions for use - Draft promotional materials and package label containing instructions for use, specifications, warnings and cautions are attached as Exhibit D.
 8. A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request - A summary of 510(k) safety and effectiveness is attached as Exhibit H.

9. For Class III devices only, a Class III certification and a Class III summary - Not applicable.
10. Photographs of the device - Engineering drawings are attached as Exhibit G.
11. Engineering drawings for the device with dimensions and tolerances - Engineering drawings are attached as Exhibit G.
12. The marketed device(s) to which equivalence is claimed including labeling and description of the device - The Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port are substantially equivalent to the Humid-Vent Filter. A copy of 510(k) K881657 describing the Humid-Vent Filter is attached as Exhibit E.
13. Statement of similarities and/or differences with the marketed device(s) - An Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port/Humid-Vent Filter Comparison Table is attached as Exhibit F. See paragraph g. for additional details and discussion of differences.
14. Data to show consequences and effects of a modified device(s) - See paragraph h. for a discussion of the performance of the Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port.

II. Additional Information that is necessary under 21 CFR 807.87(h):

- A. Submitter's name and address - Brian Grigsby, Gibeck, Inc., 10640 East 59th Street, P.O. Box 36430, Indianapolis, IN 46236.
- B. Contact person, telephone and fax number - Brian Grigsby, phone (317) 823-6866, ext. 124; fax (317) 823-1662.
- C. Representative / Consultant if applicable - Not applicable.
- D. Table of Contents with pagination - Contents include 510(k) submission letter (4 pages) followed by Exhibits A-I.
- E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s) - Manufactured by Gibeck, Inc., 10640 E. 59th Street, P.O. Box 36430, Indianapolis, IN 46236.

III. Additional Information that may be necessary under 21 CFR 807.87 (h):

- A. Comparison table of the new device to the marketed device(s) - A Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port/Humid-Vent Filter Comparison Table is attached as Exhibit F. See paragraph g. for additional details and discussion of differences.
- B. Action taken to comply with voluntary standards - Product has been tested for compliance with ISO 5356-1 (15/22 mm connectors) and ISO 9360 (moisture output). See Exhibits B & C.
- C. Performance data - marketed device
 - bench testing - See Comparison Table, Exhibit F.
 - animal testing - Not applicable.
 - clinical testing - Not applicable.

- new device
- bench testing - See Comparison Table, Exhibit F.
- animal testing - Not applicable.
- clinical testing - Not applicable.

- D. Sterilization information - Not applicable.
- E. Software information - Not applicable.
- F. Hardware information - Not applicable.
- G. If this 510(k) is for a kit, has the kit certification statement been provided? - Not applicable.
- H. Is this device subject to issues that have been addressed in specific guidance document(s)? - No.
If no, is 510(k) sufficiently complete to allow substantive review? - Yes.
- I. Other (specify) - _____

Exhibit B

INTERNATIONAL STANDARD

ISO
5356-1

First edition
1987-06-15



INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Anaesthetic and respiratory equipment — Conical connectors —

Part 1 : Cones and sockets

Matériel respiratoire et d'anesthésie — Raccords coniques —

Partie 1 : Raccords mâles et femelles

056

Reference number
ISO 5356-1 : 1987 (E)

Anaesthetic and respiratory equipment — Conical connectors —

Part 1 : Cones and sockets

0 Introduction

0.1 ISO 5356 comprises the following two parts :

Part 1 : Cones and sockets.

Part 2 : Screw-threaded weight-bearing connectors.

0.2 In clinical practice several breathing attachments may have to be joined together to provide a suitable breathing system. Items of medical equipment, such as a humidifier or a spirometer, are often incorporated into the breathing system which may also be connected to an anaesthetic gas scavenging system. Connections for these purposes are usually, though not invariably, cone and socket joints and a lack of standardization of these connections has given rise to problems of interchangeability when connecting equipment made by different manufacturers.

This part of ISO 5356 gives requirements for five sizes of conical connector of which only the 15 mm and 22 mm sizes are intended for general use in breathing systems. The 23 mm size is intended for use with vaporizers which are unsuitable for use in the breathing system (see ISO 5358); usually because they impose a high resistance to gas flow. The 19 mm and 30 mm sizes are intended for the connection of a breathing system to an anaesthetic gas scavenging system.¹⁾

An important consideration is that conical connections are secure but are nevertheless disconnectable by the user. The use of connectors meeting the requirements of this part of ISO 5356 will not necessarily prevent their being disconnected accidentally, although accessory devices for this purpose may be incorporated.

It should be noted that compliance with this part of ISO 5356 does not preclude the possibility that some flow direction sensitive components may be mis-connected and it is stressed that the avoidance of this hazard has to remain the responsibility of the user.

0.3 Requirements for the application of conical connectors are not included in this part of ISO 5356 but are given in the

relevant International Standards for devices and items of equipment (see clause 9).

0.4 Figures 1 to 5 detailing the dimensions and tolerances of metal conical connectors have been prepared in accordance with the principles given in ISO 3040.

Annex A gives recommendations for materials and is not an integral part of the standard.

Annex B includes figures detailing plug and ring gauges that may be used to check the sizes of metal conical connectors and is not an integral part of the standard.

1 Scope and field of application

This part of ISO 5356 specifies basic dimensional and gauging requirements for cones and sockets intended for use in breathing systems, anaesthetic gas scavenging systems and vaporizers.

NOTE — Requirements for screw-threaded weight-bearing conical connectors are specified in ISO 5356-2.

2 References

ISO 2878, *Rubber, vulcanized — Antistatic and conductive products — Determination of electrical resistance.*

ISO 2882, *Rubber, vulcanized — Antistatic and conductive products for hospital use — Electrical resistance limits.*

3 Definitions

For the purposes of this part of ISO 5356, the following definitions apply.

NOTE — Definitions have been taken from ISO 4135.

3.1 breathing attachments: Components intended to make up or complete a breathing system.

¹⁾ An International Standard on anaesthetic gas scavenging systems is currently being prepared.

3.2 breathing system: Those gas pathways continuously or intermittently in communication with the patient's respiratory tract during any form of ventilation.

NOTES

- 1 In practice a breathing system usually extends from
 - a) the point of supply¹⁾ of a controlled gas mixture, for example the common gas outlet of an anaesthetic machine, or
 - b) the fresh-gas inlet of a circle system, lung ventilator, T-piece, etc., or
 - c) the fresh-gas inlet of a manually-operated resuscitator.
- 2 It usually extends to the point at which gas mixture escapes to atmosphere or a gas scavenging system, for example from an APL valve, the open end of a T-piece, etc.
- 3 Gas pathways exclusively concerned with gas scavenging systems are not regarded as a part of the breathing system.

4 Materials

If components are made of anti-static materials, they shall comply with the requirements given in ISO 2882 when tested by the methods described in ISO 2878.

5 Conical connectors made of metal

NOTES

- 1 Metal connectors include those of composite materials where the mating surfaces are metal.
- 2 Conical connectors of 19 mm, 23 mm and 30 mm size are not breathing system components.
- 3 See annex 8 for dimensions of plug and ring gauges.

5.1 Conical connectors of 15 mm size

The dimensions of conical connectors of 15 mm size made of metal shall be as shown in figure 1.

5.2 Conical connectors of 19 mm size

The dimensions of conical connectors of 19 mm size made of metal shall be as shown in figure 2.

5.3 Conical connectors of 22 mm size

5.3.1 The dimensions of conical connectors of 22 mm size made of metal, with or without a recess in the male component, shall be as shown in figure 3a) or 3b), as appropriate.

5.3.2 Male conical connectors of 22 mm size, with the exception of those intended for connection with a face mask, shall incorporate the recess as shown in figure 3a).

NOTE — The recess is to accommodate the end of a female connector made of elastomeric material²⁾ or to permit the fitting of other devices

to improve the security of the attachment of the socket to the male conical connector.

5.3.3 All male conical connectors to which it is intended to attach a face mask shall incorporate a shoulder or equivalent construction as shown in figure 3b).

If a circumferential groove or grooves are incorporated in the surface of a male conical connector, the total width of the groove or grooves at the surface shall not exceed 8 mm.

NOTE — The design may permit the fitting of a device to ensure the secure attachment of tracheal (or tracheostomy) tube connectors.

5.4 Conical connectors of 23 mm size

The dimensions of conical connectors of 23 mm size made of metal shall be as shown in figure 4.

5.5 Conical connectors of 30 mm size

The dimensions of conical connectors of 30 mm size made of metal shall be as shown in figure 5.

6 Conical connectors made of materials other than metal

6.1 The axial length of conical connectors of 15 mm and 22 mm sizes made of materials other than metal, for example of polyamide, polyacetal, polycarbonate, polysulfone, etc., shall be as shown in figures 1 and 3, respectively. Other dimensions may be varied from those shown in figures 1 and 3 provided that both 15 mm and 22 mm connectors comply with the requirement laid down in 6.2 and that 22 mm connectors comply with the requirement laid down in 5.3.2.

6.2 Conical connectors of 15 mm and 22 mm sizes made of materials other than metal shall comply with the requirements laid down in 6.3 when they are type tested with gauges having dimensions as shown in figures 6 and 7, respectively.

NOTE — Since connectors made from plastics materials may vary enormously in their physical characteristics, it is not considered practicable to specify their dimensions; for this reason, gauging requirements have been included. It is also considered impracticable to generalize on matters such as cold flow and thermal instability as well as possible changes in physical characteristics, contact with solvents, etc. It is, therefore, the responsibility of the manufacturer to ensure that adequate tests have been carried out to prove as far as possible that the particular materials are suitable. Attention is drawn to the fact that some connectors will be used at elevated temperatures, for example those on heated humidifiers, and extra care will be required when selecting suitable materials.

¹⁾ In some situations, particularly in lung ventilators, this point may be inside a piece of equipment and should not be confused with a connection port fitted elsewhere, for example on the casing of a ventilator.

²⁾ The term "elastomeric material" includes soft rubber (natural or synthetic) and some soft plastics materials, for example polyvinyl chloride and polyisobutylene.

6.3 When the connector is engaged in the appropriate plug or ring gauge, shown in figures 6 and 7, by applying an axial force of 35 ± 3.5 N for 15 mm connectors and 50 ± 5 N for 22 mm connectors, and, while maintaining the same force, rotating the connector up to 20° , its leading edge shall lie between the minimum and maximum diameter steps of the gauge. The connectors and gauges shall be maintained at a temperature of 20 ± 3 °C during this test.

NOTE — A disengagement test for conical connectors made of materials other than metal is currently being prepared. Requirements in this respect will be added in a future revision of this part of ISO 5356.

7 Sockets made of elastomeric material¹⁾

Sockets made of elastomeric material shall mate with the appropriate male connector complying with the requirements laid down in clause 5 or 6.

8 Information to be supplied by the manufacturer

Except for components that are designated for single use, the manufacturer shall state the methods of cleaning and either disinfection or sterilization of the connectors.

9 Bibliography

The following International Standards were used as reference documents in the development of this part of ISO 5356 :

ISO 3040, *Technical drawings — Dimensioning and tolerancing cones.*

ISO 4135, *Anaesthesiology — Vocabulary.*

The following International Standards for devices and items of equipment should be consulted for requirements pertaining to the application of conical connectors :

ISO 5358, *Continuous flow inhalational anaesthetic apparatus (anaesthetic machines) for use with humans.*

ISO 5366-1, *Tracheostomy tubes — Part 1 : Connectors.*

ISO 5367, *Breathing tubes used with anaesthetic apparatus and ventilators.*

ISO 5369, *Breathing machines for medical use — Lung ventilators.*

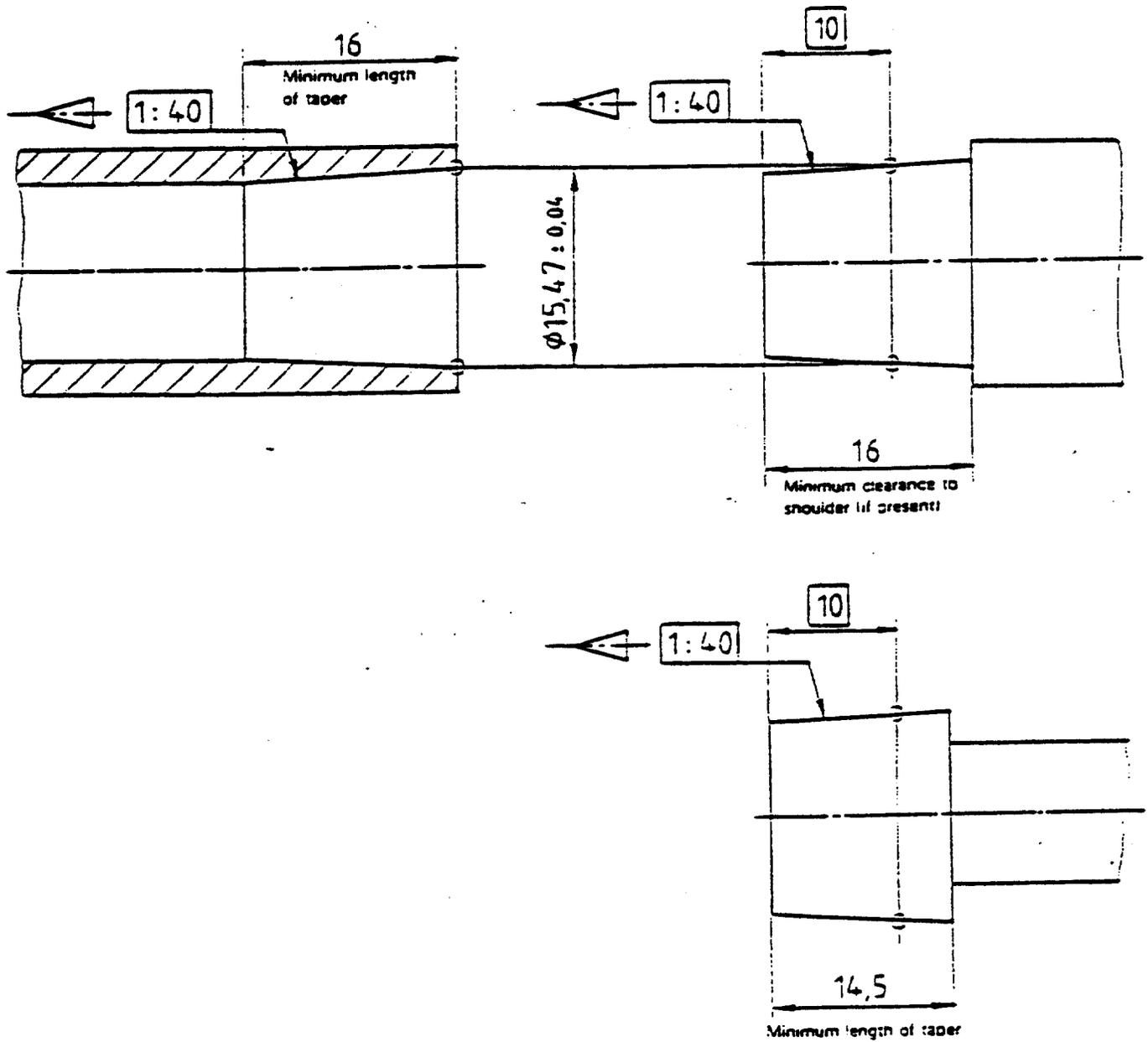
ISO 7228, *Tracheal tube connectors.*

ISO 8185, *Humidifiers for medical use — Safety requirements.*

International Standards on breathing systems and anaesthetic gas scavenging systems are currently being prepared.

1) The term "elastomeric material" includes soft rubber (natural or synthetic) and some soft plastics materials, for example polyvinyl chloride and low density polyethylene.

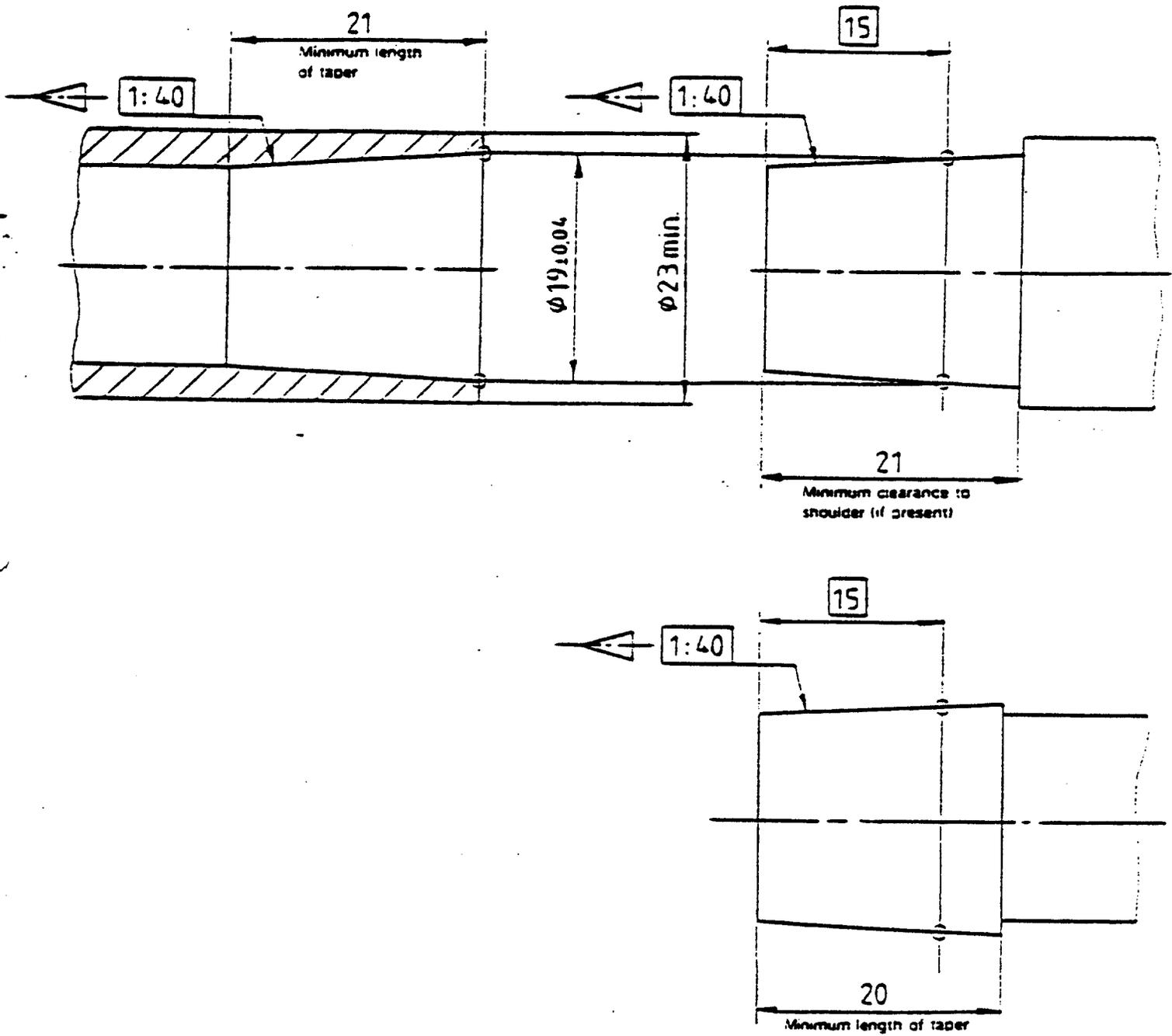
Dimensions in millimetres



NOTE — Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0.5 mm.

Figure 1 — Conical connectors of 15 mm size made of metal

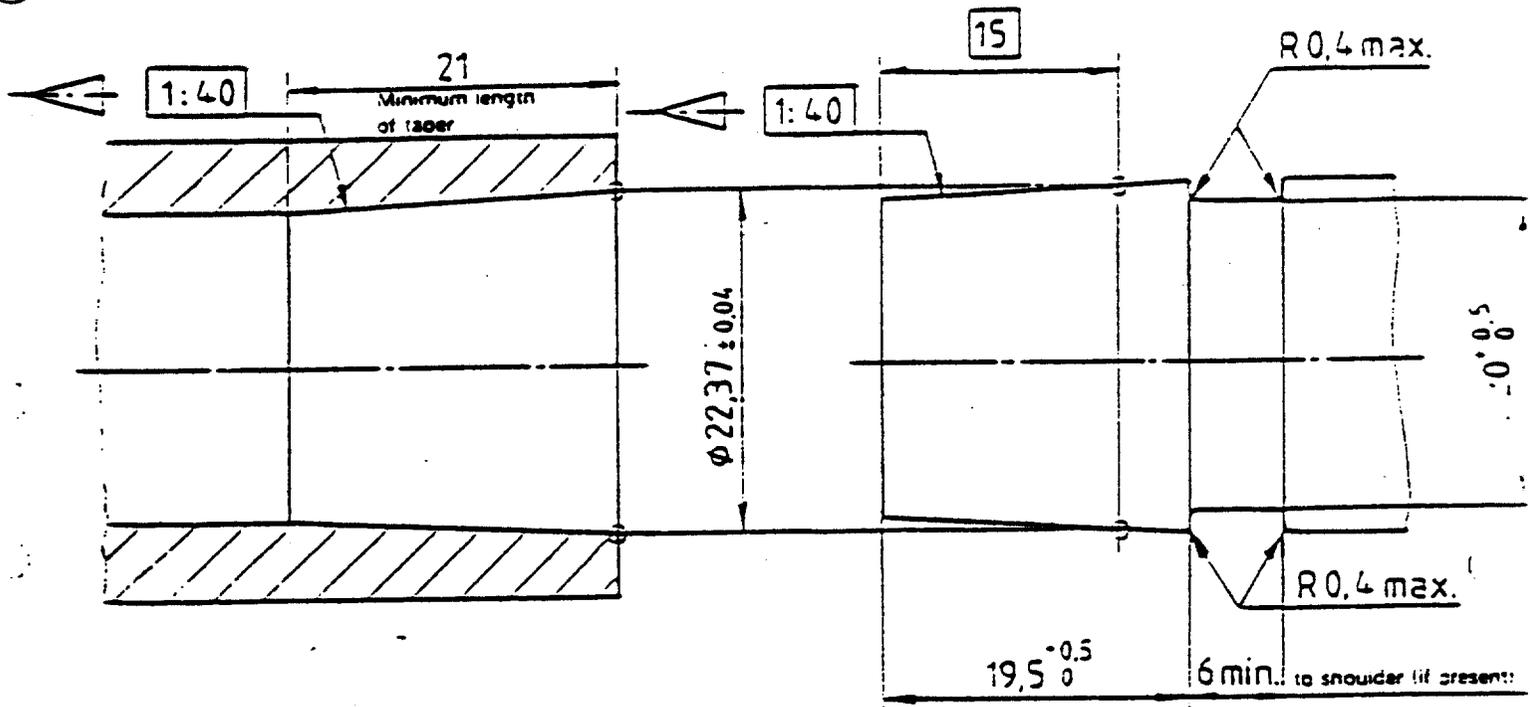
Dimensions in millimetres



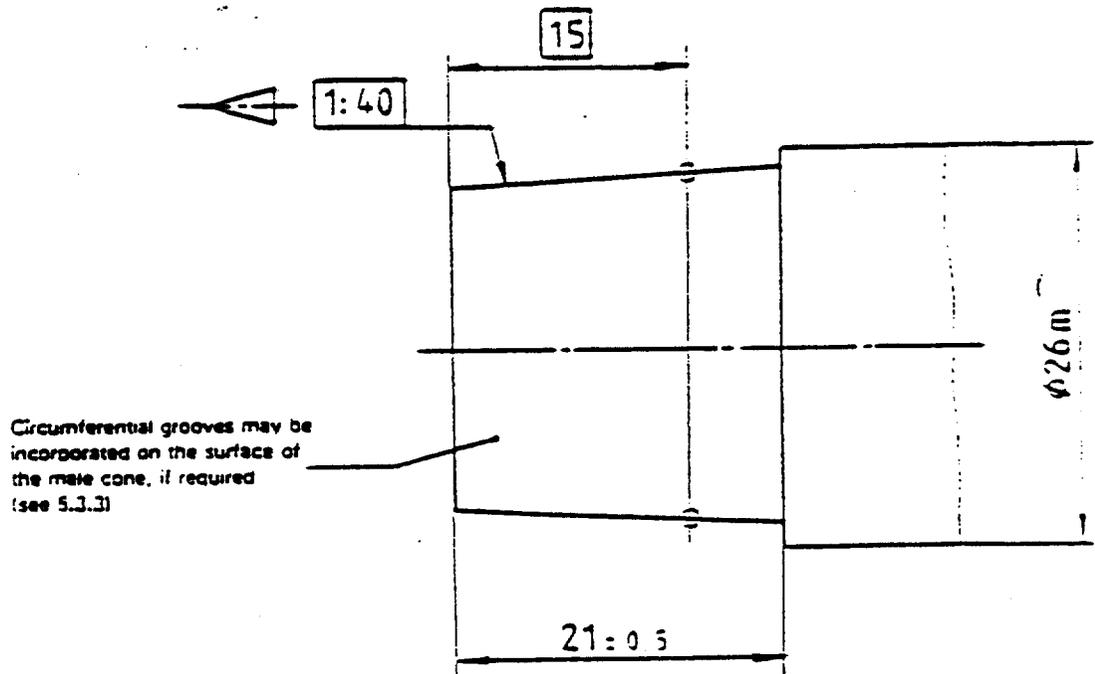
NOTE — Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0.5 mm.

Figure 2 — Conical connectors of 19 mm size made of metal

Dimensions in millimetres



a) Connector intended for breathing attachment (with recess)

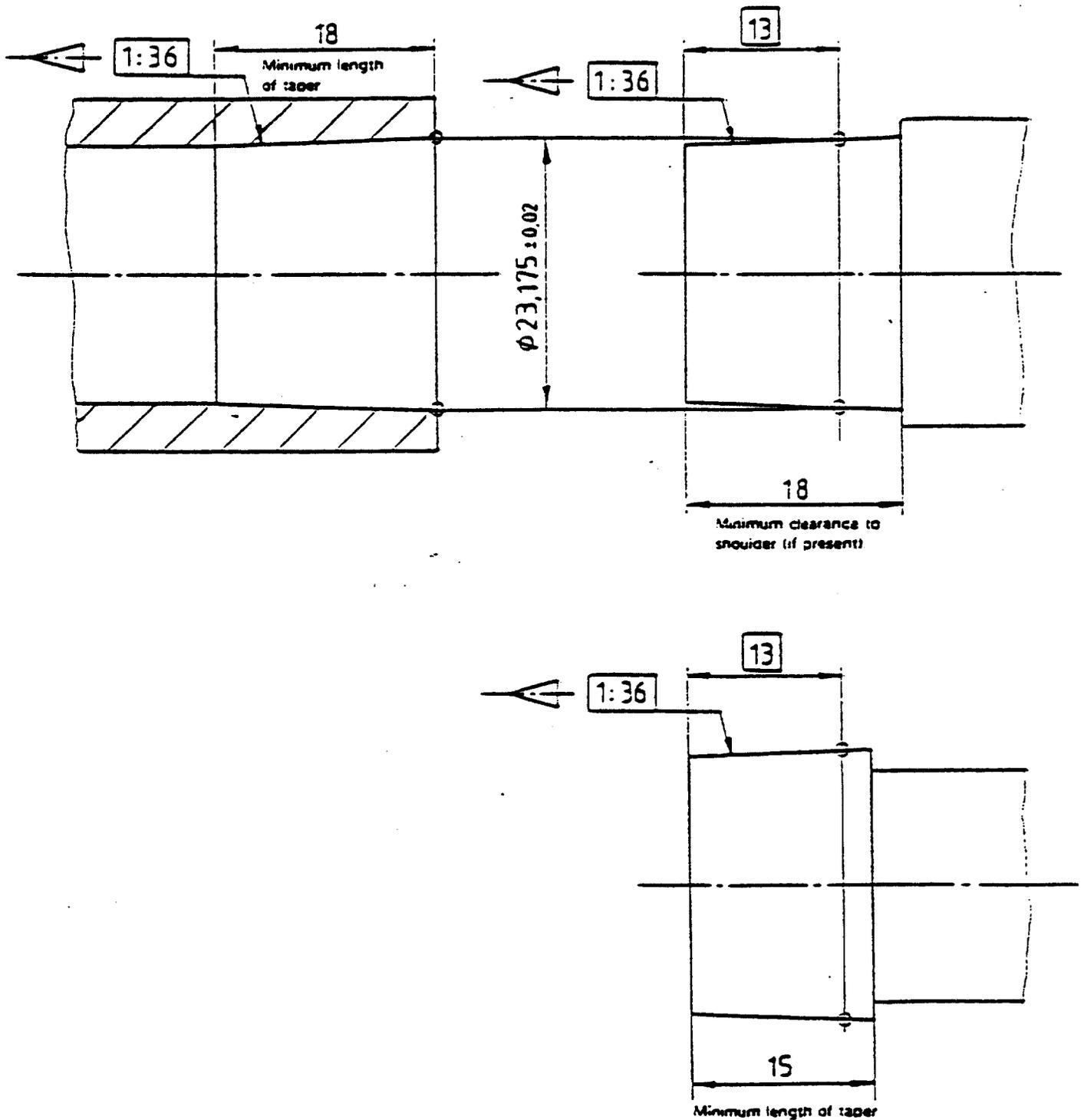


b) Connector intended for face mask (with shoulder)

NOTE - Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0.5 mm.

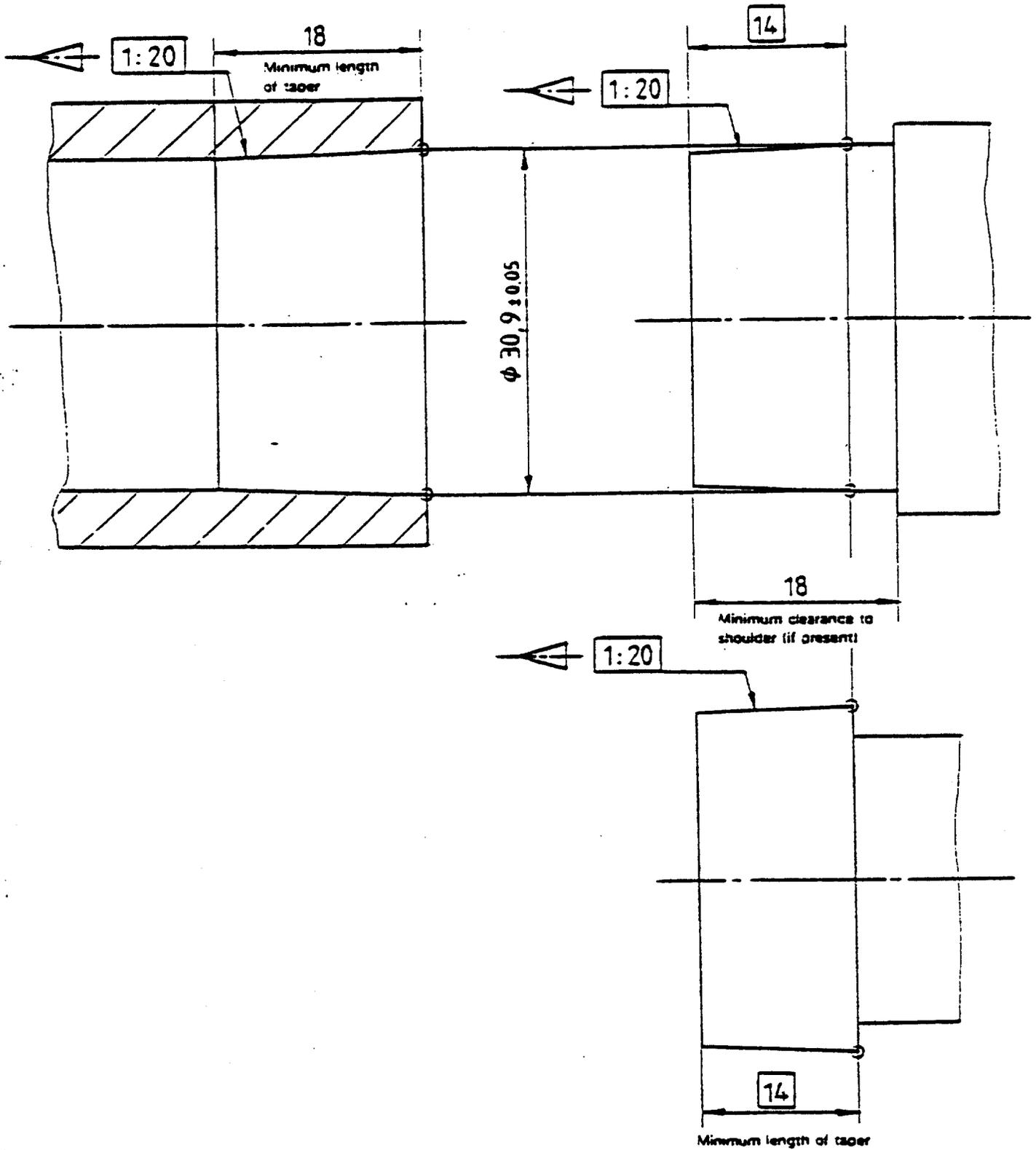
Figure 3 - Conical connectors of 22 mm size (with or without recess) made of metal

Dimensions in millimetres



NOTE - Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0,5 mm.

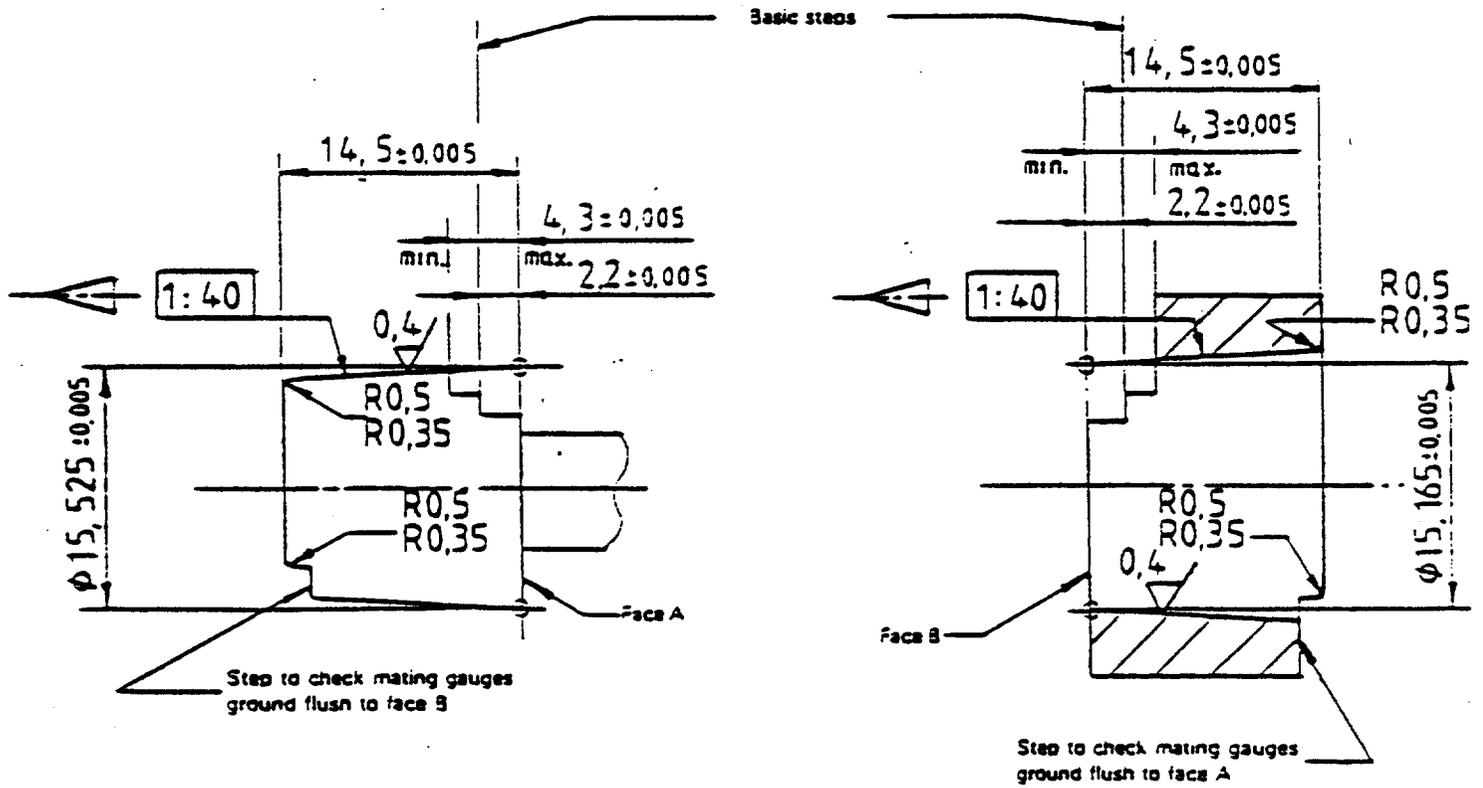
Figure 4 - Conical connectors of 23 mm size made of metal



NOTE - Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0.5 mm.

Figure 5 - Conical connectors of 30 mm size made of metal

Dimensions in millimetres; surface roughness values in micrometres

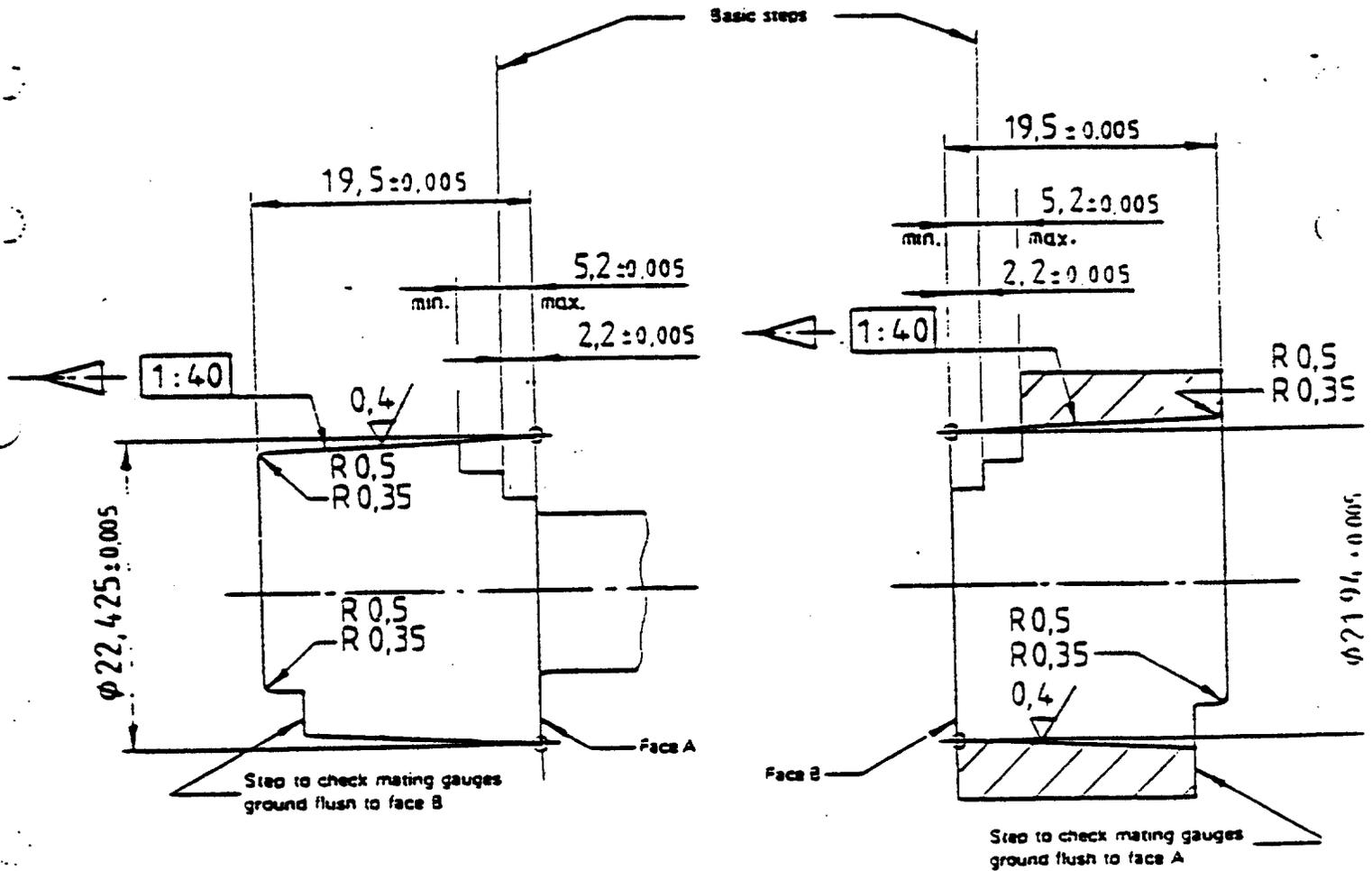


NOTES

- 1 Basic and mating gauge steps are optional.
- 2 Taper per unit of length on diameter : $0.025 = 0.0002$ units

Figure 6 — Plug and ring test gauges for conical connectors of 15 mm size made of materials other than metal

Dimensions in millimetres; surface roughness values in micrometre.



NOTES

- 1 Basic and mating gauge steps are optional.
- 2 Taper per unit of length on diameter : $0,025 \pm 0,000 2$ units

Figure 7 — Plug and ring test gauges for conical connectors of 22 mm size made of materials other than metal

Annex A

Recommendations for materials

(This annex does not form an integral part of the standard.)

A.1 General

A.1.1 Except for those connectors intended and labelled only for single use, connectors should withstand accepted methods of steam sterilization.

A.1.2 Male conical connectors should not be made of an elastomeric material¹⁾.

A.2 Freedom from cold welding characteristics

It is essential that conical connectors can be readily disconnected when required. Certain materials have been shown to exhibit the phenomenon of "cold welding" and their use should be avoided.

A.3 Resistance to deformation and to wear

Conical connectors should be resistant to wear in relation to their intended purpose and should be of adequate strength to withstand permanent deformation under conditions of normal use.

A.4 Corrosion resistance

Conical connectors should be resistant to corrosion or other deleterious effects caused by anaesthetic vapours and gases, disinfectants and other agents likely to be employed under conditions of normal use. Resistance to carbon dioxide absorbents, for example soda-lime, is important in the case of absorber canister and related connectors.

A.5 Freedom from risk of spontaneous combustion or incendive sparking

Materials liable to emit pyrophoric particles should not be used.

067

¹⁾ The term "elastomeric material" includes soft rubber (natural or synthetic) and some soft plastics materials, for example polyvinyl chloride and low-density polyethylene.

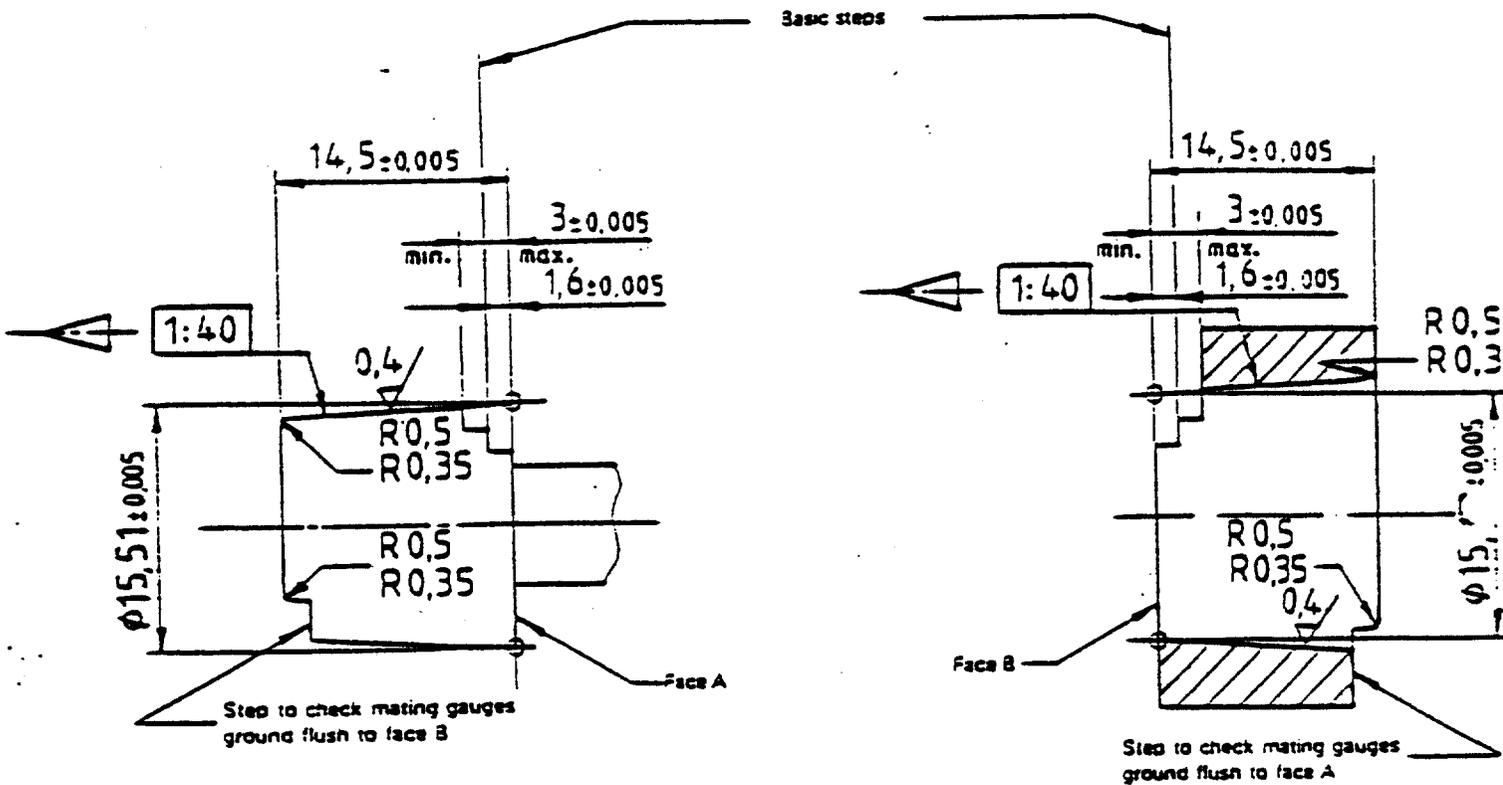
Annex B

Plug and ring gauges

(This annex does not form an integral part of the standard.)

Dimensions of plug and ring gauges that may be used to check the size of 15 mm, 19 mm, 22 mm, 23 mm and 30 mm conical connectors made of metal are given in figures 8, 9, 10, 11 and 12, respectively.

Dimensions in millimetres; surface roughness values in micrometres

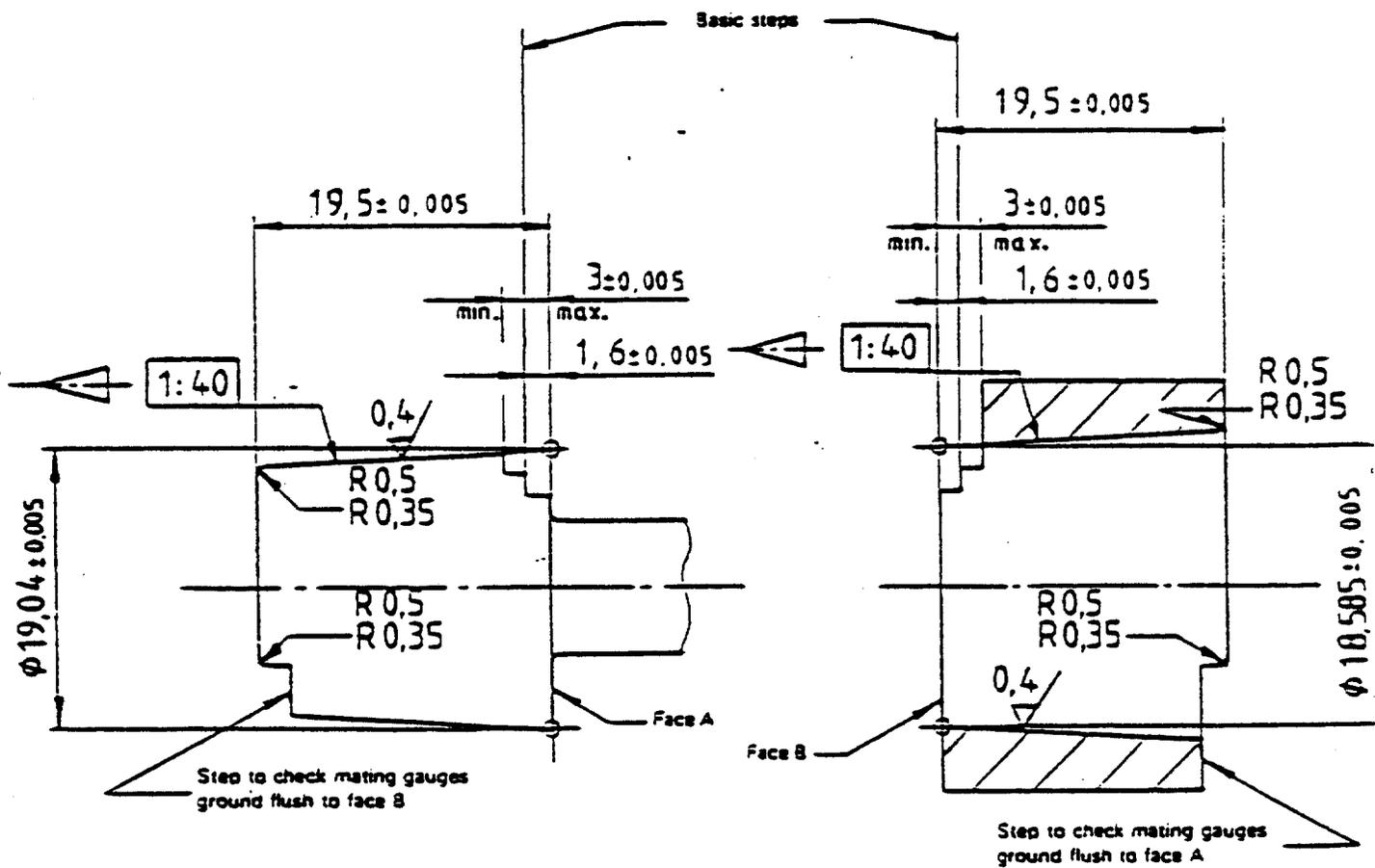


NOTES

- 1 Basic and mating gauge steps are optional.
- 2 Taper per unit of length on diameter : 0.025 ± 0.000 2 units

Figure 8 — Plug and ring test gauges for conical connectors of 15 mm size made of metal

Dimensions in millimetres; surface roughness values in micrometres

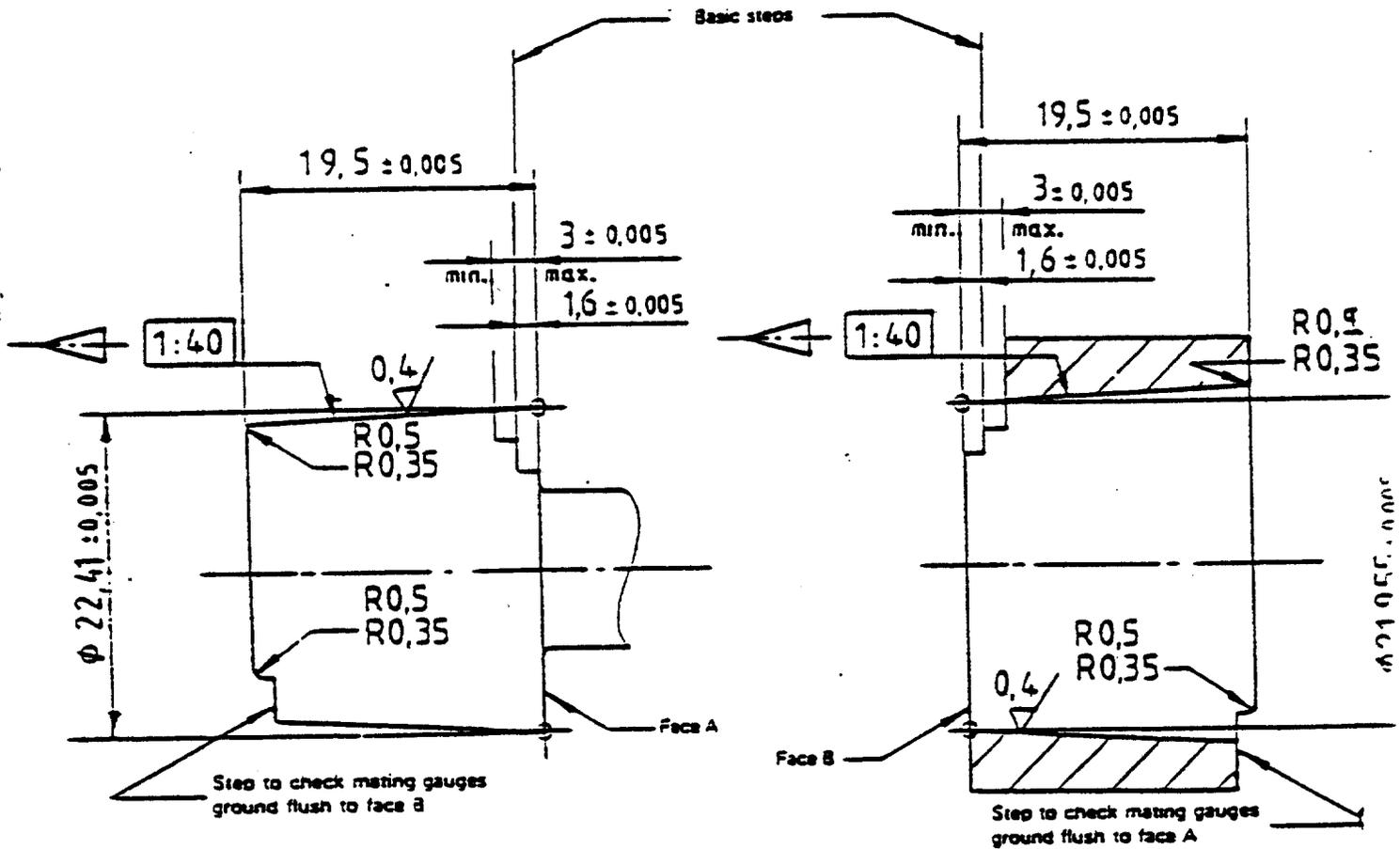


NOTES

- 1 Basic and mating gauge steps are optional.
- 2 Taper per unit of length on diameter : 0,025 = 0,000 2 units

Figure 9 — Plug and ring test gauges for conical connectors of 19 mm size made of metal

Dimensions in millimetres; surface roughness values in micrometres

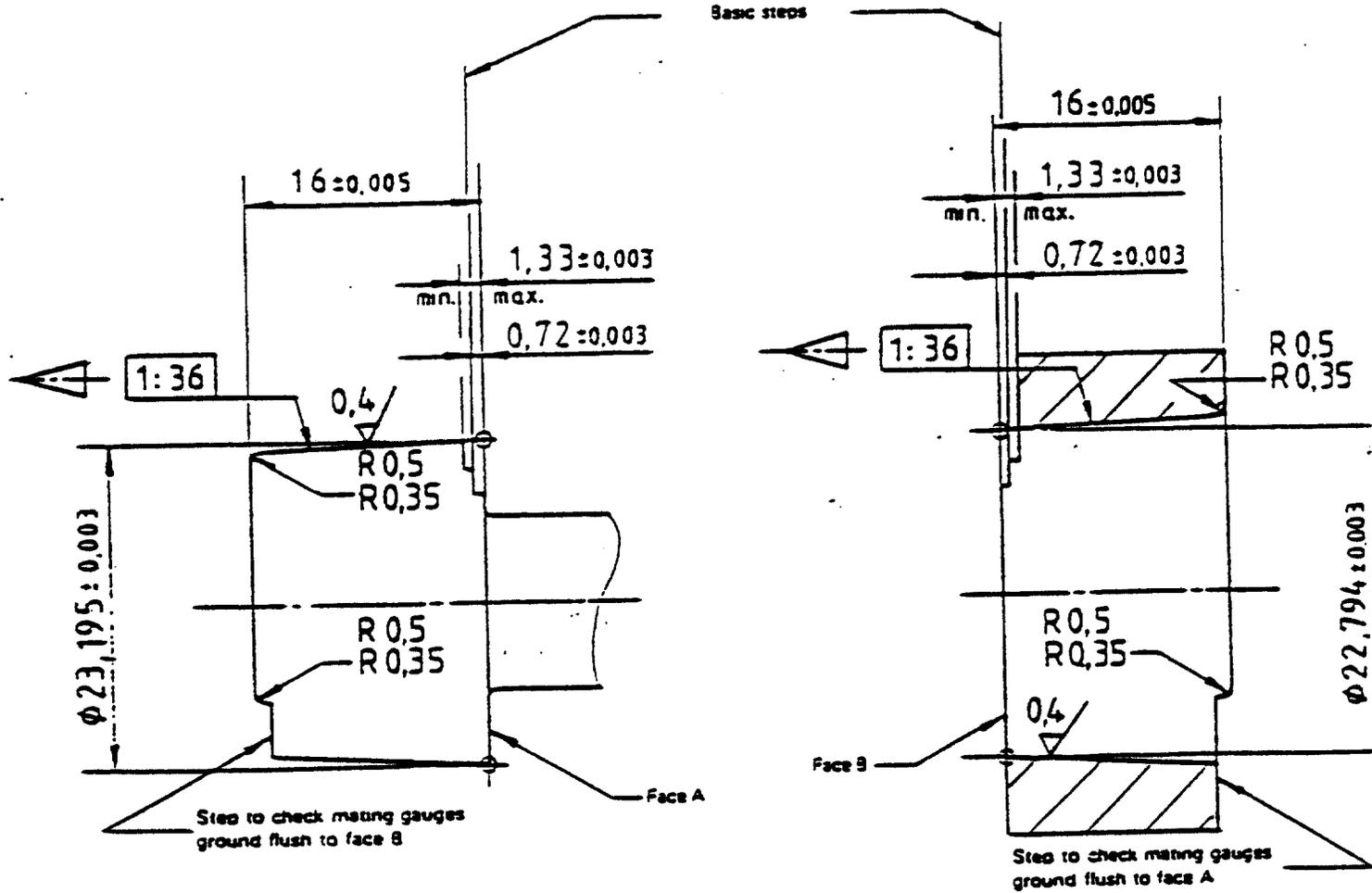


NOTES

- 1 Basic and mating gauge steps are optional.
- 2 Taper per unit of length on diameter : 0,025 ± 0,000 2 units

Figure 10 — Plug and ring test gauges for conical connectors of 22 mm size made of metal

Dimensions in millimetres; surface roughness values in micrometres



NOTES

- 1 Basic and mating gauge steps are optional.
- 2 Taper per unit of length on diameter : 0.0278 ± 0.0002 units

Figure 11 — Plug and ring test gauges for conical connectors of 23 mm size made of metal

Exhibit C

INTERNATIONAL STANDARD

ISO
9360

First edition
1992-10-01

Anaesthetic and respiratory equipment — Heat and moisture exchangers for use in humidifying respired gases in humans

*Matériel d'anesthésie et de réanimation respiratoire — Échangeurs de
chaleur et d'humidité utilisés pour humidifier les gaz respirés par les
êtres humains*



Reference number
ISO 9360:1992(E)

073

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9360 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 3, *Lung ventilators and related equipment*.

Annex A of this International Standard is for information only.

Introduction

Heat and moisture exchangers (HMEs) are used to raise the water content and the temperature of gas delivered to the respiratory tract of patients. They are primarily intended for use with tracheotomized or intubated patients, independently or as a part of a breathing system.

The gases generally available for medical use lack sufficient moisture to be physiologically acceptable to the respiratory tract. HMEs capture the exhaled heat and moisture and transfer them to the inspired gases.

Although heat and moisture exchangers have been used for many years, the introduction of HMEs utilizing primarily non-metallic components and hygroscopic additives or hydrophobic material have promoted the development of this International Standard.

Anaesthetic and respiratory equipment — Heat and moisture exchangers for use in humidifying respired gases in humans

1 Scope

This International Standard specifies minimum performance and safety requirements for heat and moisture exchangers (HMEs) intended for humidification of respired gases in humans, and describes test methods for their evaluation.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 4135:1979, *Anaesthesiology — Vocabulary*.

ISO 5356-1:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*.

ISO 5356-2:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*.

ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis*.

IEC 801-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 4135 and the following definitions apply.

3.1 Identification mark; identification number: Symbols, numbers or lettering marked on a device from which the manufacturer/user derives information concerning its production (such as material batch or date of manufacture).

3.2 HME: Device intended to retain a portion of the expired moisture and heat, and return it to the patient's respiratory tract during inspiration.

3.3 HME patient port: That part of the HME which is connected to the patient's respiratory tract.

3.4 HME machine; atmospheric end port: That part of the HME which is connected to the patient connection part of a breathing system or is open to ambient air.

3.5 HME moisture output: Total amount of water, in milligrams per litre, of inspired gas leaving the HME patient port, under specified test conditions.

4 Symbols and abbreviations

The principal symbols and abbreviations used in this International Standard are given in table 1. Additional symbols are explained in the relevant context.

5 General requirements and recommendations

5.1 Patient port connector

The connector at the patient port shall be a 15 mm female conical connector as specified in ISO 5356-1:1987.

The connector at the patient port may also have a 22 mm male conical connector as specified in ISO 5356-1:1987.

The HME incorporates an accessory port, that port shall not accept the 15 mm or 22 mm connectors specified in ISO 5356-1:1987 or ISO 5356-2:1987.

Other ports intended to accept breathing attachments, if present, shall be 15 mm male and/or 22 mm female conical connectors as specified in ISO 5356-1:1987.

The HME incorporates a gas-scavenging port, that port shall be either a 19 mm or 30 mm male conical connector as specified in ISO 5356-1:1987.

5.2 Gas leakage

When tested according to 6.6, the leakage from HMEs intended to be used at elevated intermittent or continuous pressures shall not exceed 25 ml/m

at a pressure of 30 hPa (30 cm H₂O). (See also annex A.)

5.3 Pressure drop

When tested according to 6.7, the pressure drop across the HME shall not exceed 5 hPa (5 cm H₂O). (See also annex A.)

5.4 Packaging

5.4.1 HMEs supplied sterile and intended for single use shall be individually packaged.

5.4.2 The type of container used shall be such as to ensure that once opened, the container cannot be easily resealed, and that it shall be obvious that the container has been opened.

Each HME should be packed in a single container, the materials of which should not have detrimental effects on the contents. The material and design of this container should be such as to ensure

- minimal risk of contamination of the contents from opening and removal from the container;
- adequate protection of the contents during normal handling, transit and storage.

6 Test methods

The apparatus and test methods specified in 6.1 to 6.7.5 are not intended to exclude the use of other measuring devices or methods yielding results of an accuracy equal to or greater than those specified. In case of dispute, the methods given in this International Standard shall be the reference methods.

Table 1 — Symbols and abbreviations

Symbol	Definition	Unit
HME	Heat and moisture exchanger	
V_{H_2O}	HME moisture output	mg/l
m_1	Initial mass of the patient model before testing with the HME	g or mg
m_2	Final mass of the patient model after testing with the HME	g or mg
m_3	Initial mass of the patient model before testing without the HME	g or mg
m_4	Final mass of the patient model after testing without the HME	g or mg
f	Frequency	
bpm	breaths per minute	
C	Compliance	ml/hPa
R	Resistance	hPa/l/s
I:E ratio	Inspiratory: expiratory ratio	
r.h.	Relative humidity	per cent
V_t	Tidal volume	ml

6.1 Temperatures and pressures (see also annex A)

6.1.1 The ambient temperatures (defined as temperature t_a in figure 1 zone 1) for the duration of the test shall be $23\text{ }^\circ\text{C} \pm 2\text{ }^\circ\text{C}$. Barometric pressure shall be stated, as shall the temperature at which the measurements were taken.

6.1.2 Temperature t_2 in figure 1, zone 3, shall be high enough to eliminate condensation in rubber bags, valves and tubing.

A suggested temperature is $37\text{ }^\circ\text{C} \pm 3\text{ }^\circ\text{C}$.

6.1.3 The water-bath temperature, t_0 , in figure 1 shall be regulated to give a maximum temperature t_0 measured at the HME patient port of $34\text{ }^\circ\text{C} \pm 1\text{ }^\circ\text{C}$ when averaged over 20 exspirations

6.1.4 The temperature in the inspiratory flow, t_i , in figure 1 shall be $23\text{ }^\circ\text{C} \pm 2\text{ }^\circ\text{C}$.

6.1.5 The response time for probes measuring t_a , t_0 and t_i in figure 1 shall be 10 s or less for 50 % of the actual value. The response time in flowing air at points E and F shall be 0.1 s or less for 50% of the temperature cycle

6.2 Test gas and apparatus

6.2.1 The test gas shall be air having a humidity not exceeding 0.88 mg/l, equivalent to a dew point of $-20\text{ }^\circ\text{C}$ at atmospheric pressure.

6.2.2 Gas flow measuring equipment shall be calibrated to an accuracy of $\pm 5\%$ of the reading in the range 1 l/min to 100 l/min.

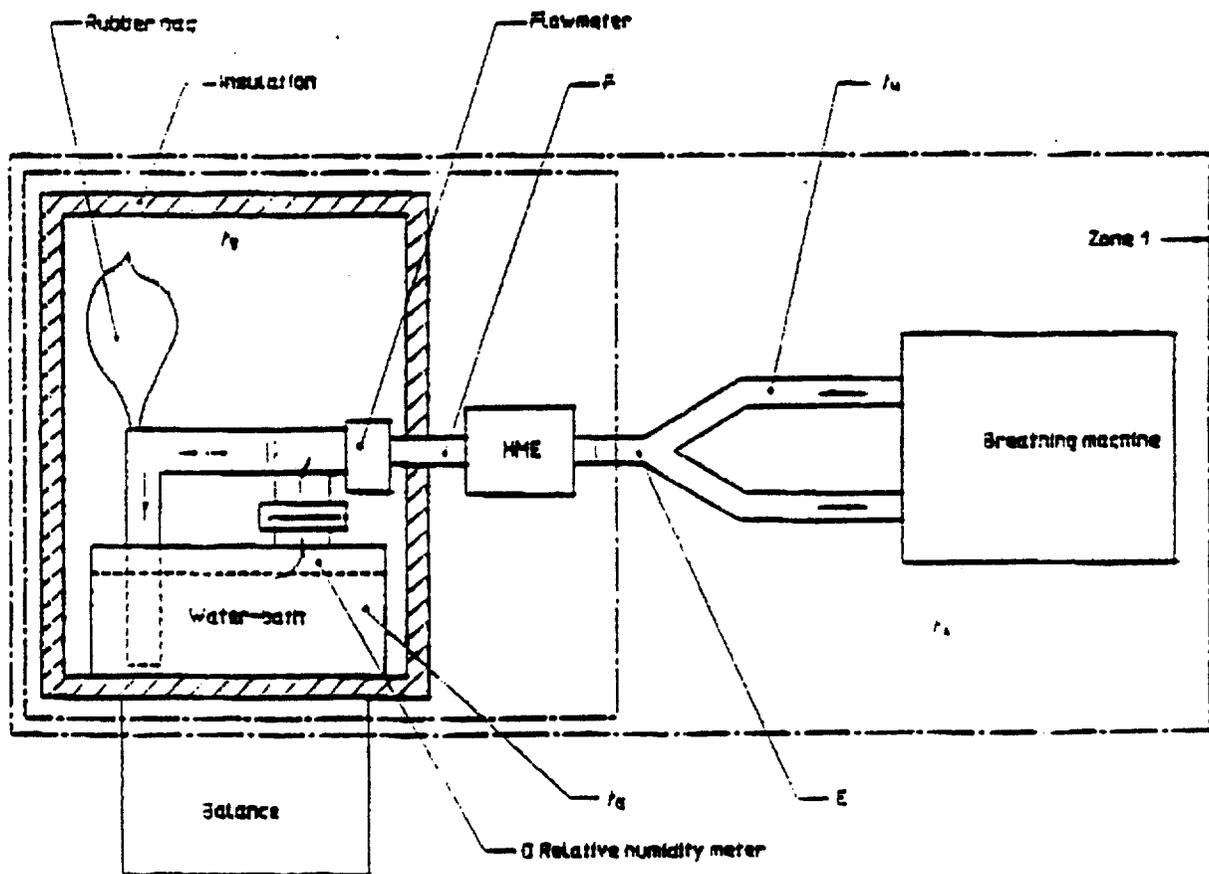


Figure 1 - Test set-up

6.2.3 Test apparatus consisting of a temperature-controlled water-bath with a means of providing compliance and resistance values as specified in table 2 shall be used (see figure 1). The inspiratory and expiratory flows shall be directed via one-way valves into separate pathways. Provision shall be made to measure the flow through the HME. Temperature probes shall be mounted at points A, B, E, F, G and H (where these letters refer also to subscripts of points at which temperature-measuring probes are inserted). The temperatures at these points shall be recorded. The temperature probe at point F shall be connected to a control system in order to regulate the water-bath temperature. Temperature probes at points E and F shall be mounted within 10 mm of the HME patient port. The length of tubing between the HME and the ventilator shall not exceed 1 m, and the length of tubing between the HME and the point of separation of the inspiratory and expiratory gas flow pathways shall not exceed 10 cm. The inspiratory and expiratory limbs shall be isolated by a uni-directional valve. A relative humidity probe shall be mounted at point O. A flowmeter shall be connected at point P. The capacity of the bag shall be greater than the tidal volumes given in table 2.

6.2.4 The HME shall be connected to the test apparatus and a ventilator.

For HMEs intended only for use during spontaneous breathing, a suitable adaptor with minimal dead space should be used.

6.2.5 The ventilator shall deliver the minute volumes at the frequencies shown in table 2. The flow profile of the ventilator during the measurements shall be stated in the test report.

NOTE 1 It is recognized that the flow profile may influence the efficiency of the HME; it is therefore assumed that the ventilator used in the test apparatus, as shown in figure 1, is capable of delivering as constant a flow as possible during inspiration.

6.2.6 The weighing equipment used shall have an accuracy of ± 0.1 g or better in the range of mass to be measured.

6.2.7 Pressure drop measuring equipment shall consist of a differential pressure gauge with an accuracy equal to or better than ± 10 kPa (0.1 cm H₂O) for the test as shown in figure 2.

6.3 Measurement of HME moisture output

6.3.1 Principle

The test apparatus, comprising the patient model and the HME under test, is connected to a flow gen-

erator for example a ventilator. After it has operated for approximately 60 min, a steady state is achieved in the test system. During inspiration, the dry gas at ambient temperature passes through the HME, thereby absorbing accumulated heat and moisture. During expiration, the expired gas, which now is assumed to be saturated with water vapour, passes through the HME, in the reverse direction, so that heat and moisture are retained in the HME.

6.3.2 Procedure

6.3.2.1 Connect the HME to the patient model and the ventilator.

6.3.2.2 Record temperatures t_A , t_B and t_C .

6.3.2.3 Adjust the ventilator to give one of the test conditions in the combinations listed in table 2 within the HME's operating range as specified by the manufacturer.

6.3.2.4 Adjust the water-bath temperature to give a maximum temperature at point F of $34^\circ\text{C} \pm 1^\circ\text{C}$ during expiration.

6.3.2.5 Verify that the relative humidity at point O is 100 % during the entire breathing cycle.

Care should be taken to choose a humidity-measuring instrument suitable for measurements in the region of 100 % r.h. at the test temperatures.

6.3.2.6 Verify that the humidity at point H is less than 0.88 mg/l (equivalent to a dew point of -20°C).

6.3.2.7 Let the equipment run for $60 \text{ min} \pm 5 \text{ min}$ to precondition the HME and stabilize the test system.

6.3.2.8 Disconnect the HME, seal the ports, and weigh the patient model.

6.3.2.9 Connect the HME and operate the test apparatus for 1 h. Record the temperatures at points E and F continuously.

NOTE 2 This temperature will vary, and typical variations are shown in figure 3.

6.3.2.10 Disconnect the HME such that any condensation that has occurred is retained *in situ* within the patient model and then weigh the patient model.

Table 2 — Test conditions

Intended for V_c of	Test conditions	V_c ml	f bpm	Minimum volume l/m	I:E ratio	C	R
> 500 ml	1	1 000	20	20	1:2	50	3
	2	1 000	10	10	1:2	50	5
	3	500	20	20	1:2	50	5
51 ml to 500 ml	1	500	20	10	1:2	50	5
	2	250	20	3	1:2	10	20
< 50 ml	1	50	40	2	1:1	10	20
	2	25	40	1	1:1	10	20

Dimensions in millimetres

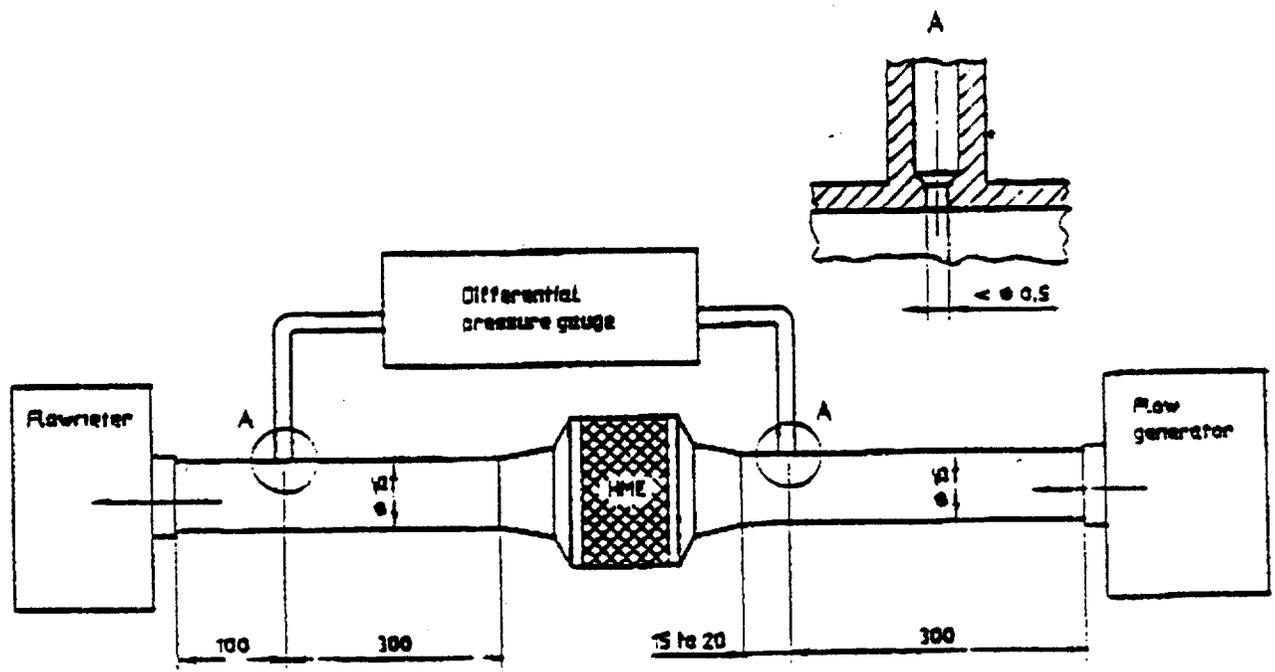


Figure 2 — Pressure drop measuring set-up

6.3.2.11 Reconnect the HME and operate the test apparatus up to the recommended maximum time of use for the HME and record the temperatures at points E and F continuously.

6.3.2.12 Disconnect the HME and weigh the patient model

6.3.2.13 Repeat the procedures given in 6.3.2.1 to 6.3.2.11 but with the patient model connected directly to the ventilator (i.e. without the HME).

6.3.2.14 Repeat the procedures given in 6.3.2.1 to 6.3.2.13 for all conditions given in table 2 which are within the operating range as specified by the manufacturer.

6.4 Calculations

Calculate the HME moisture output, F_M , using the following formula:

$$F_M = 1 - \left[\frac{(m_1 - m_2)}{(m_2 - m_3)} \cdot V_2 / V_1 \right] \times 37.6$$

where

m_1 is the initial mass of the patient model, in grams or milligrams, before testing with the HME;

m_2 is the final mass of the patient model, in grams or milligrams, after testing with the HME;

m_3 is the initial mass of the patient model, in grams or milligrams, before testing without the HME;

m_1 is the final mass of the patient model, in grams or milligrams, after testing without the HME;

V_1 is the total volume of test gas, in litres, transported from the patient model when testing with the HME;

V_2 is the total volume of test gas, in litres, transported from the patient model when testing without the HME

6.5 Measurement of compressible volume

6.5.1 Occlude all orifices of the HME except one and eliminate all leaks. In the case of female conical connectors complying with ISO 5358-1 1987 this shall be by means of the appropriate plug gauge.

6.5.2 Connect the remaining orifice to one arm of a "T" piece and the other arms to a calibrated, gas-tight syringe and a pressure-monitoring device.

The use of an electronic pressure transducer is recommended.

6.5.3 Record the syringe piston position, as a millilitre mark on the barrel (ml), and the pressure reading, p_1 .

6.5.4 Advance the syringe piston sufficiently to increase the pressure reading by 70 hPa (70 cm H_2O) and record the new pressure reading p_2 .

6.5.5 Record the new syringe piston position, " ml ", and the change in volume from that in 6.5.3, y ml.

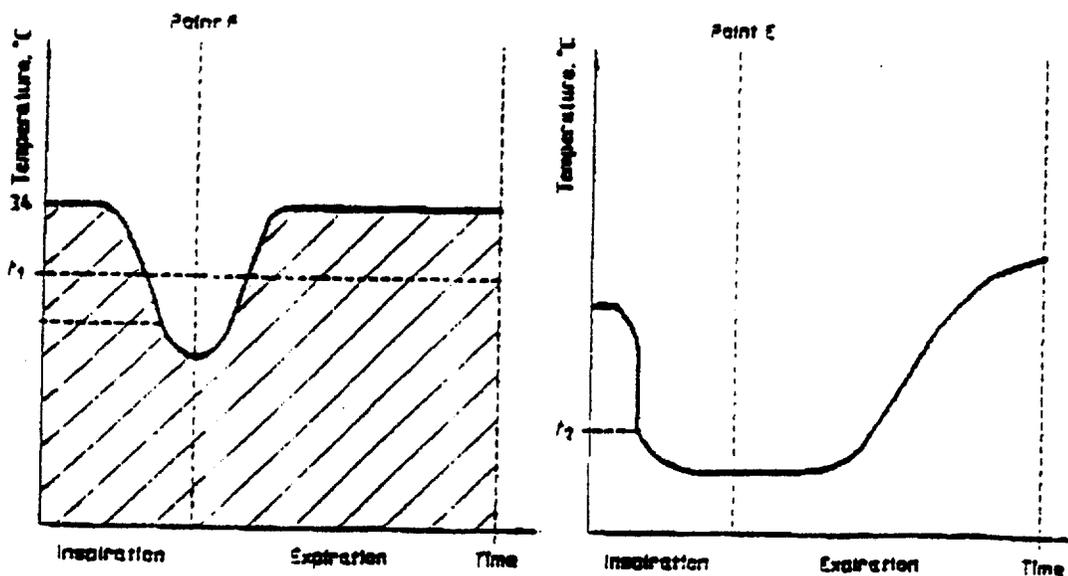


Figure 3 — Temperature variation at points F and E

6.5.6 Remove the HME and insert a suitable plug gauge into the "T" piece and repeat 6.5.3 through 6.5.5. Record the change in volume, x ml.

6.5.7 Calculate the compressible volume, V_c, in millilitres of the device using the following formula:

$$V_c = \frac{p_2(x - v)}{(p_1 - p_2)}$$

6.6 Measurement of gas leakage

6.6.1 Occlude all ports of the HME except one, to which a pressure connection port is attached. Connect this port to a suitable pressure source.

6.6.2 Submerge the HME in a water bath and measure the water depth.

6.6.3 Apply an internal pressure of 30 hPa (30 cm H₂O), compensating for the effect of depth of submersion. Confirm the pressure by a gauge accurate to at least ± 1 % of the reading, and maintain this pressure for a minimum of 5 min

6.6.4 Collect any air leaking from the HME in a suitable calibrated vessel for a period of 5 min. Record the volume of leakage.

6.7 Measurement of pressure drop

6.7.1 Pre-condition the HME in the patient model for 1 h at the conditions appropriate for the intended application of the device as specified in table 2.

6.7.2 Using the apparatus in figure 2, connect the differential pressure gauge across the HME and connect the flowmeter

6.7.3 Determine the pressure drop at the flow appropriate for the intended application of the HME, as specified in table 3, within 5 s of initiating flow through the HME

Table 3 - Flows for measurement of pressure drop

Intended use for	Flow l/min
adult use	90
paediatric use	30
neonatal use	15

6.7.4 Remove the HME and determine the pressure drop at the same flow. Subtract this value from that obtained in 6.7.3. This is the pressure drop attributable to the HME.

6.7.5 Repeat steps 6.6.2 through 6.6.4 after pre-conditioning the HME in the patient model for the recommended maximum time of use at the conditions appropriate for the intended application of the device as specified in table 2.

For recording purposes, the use of an electronic measuring device is recommended.

7 Marking

7.1 Re-usable HMEs shall be marked with at least the following information:

- a) the trade-mark or name of the manufacturer, and the identification mark; for HMEs intended for single use, this marking shall be either on the device or on the package;
- b) direction of orientation towards the patient in the case of orientation-sensitive HMEs;
- c) the letters APG (which is explained in IEC 601-1:1988) if the manufacturer states that the HME is safe for use with flammable anaesthetics.

7.2 The HME package shall be marked with at least the following information:

- a) an indication of whether or not the HME is intended to be placed in a breathing system;
- b) the word STERILE (or the equivalent), if applicable;
- c) the words SINGLE USE (or the equivalent), if applicable, or symbol 1051 as listed in ISO 7000:1989.
- d) an indication that maintenance of sterility of the contents requires storage under dry, clean and adequately ventilated conditions, if applicable.

8 Information to be provided by manufacturer or supplier

The manufacturer or supplier of the HME shall provide the following information:

- a) the intended use of the HME (for example, in anaesthesia, in respiratory care, at home or in hospital); in particular, whether or not the HME is suitable for use with intubated patients or for inclusion in a ventilator or other positive-pressure breathing systems;
- b) the pressure drop in hPa as a function of flow, at flows of 0.5 l/s, 1.0 l/s and 1.5 l/s when tested in accordance with 6.7;

c) the compressible volume of the HME including its components, when tested in accordance with 8.5:

if applicable, a statement as to the possible hazards of blockage with certain types of inhalants during inhalational therapy;

e) the temperature and moisture output within the operating range of gas flows given in table 2, when tested in accordance with 8.5:

f) instructions for use of the HME;

g) an indication of whether the HME or parts thereof are re-usable. For single-use HMEs, the instructions for use shall contain a statement as to the possible hazards of re-use, for example, the emission of anaesthetic gas from the HME even after discontinuation of anaesthetic gas flow, and that the user should be aware of possible transmission of infection;

h) if the HME or parts thereof are re-usable, instructions for the maintenance and details of cleaning, disinfection and sterilization techniques;

i) if particular agents, such as anaesthetic gases and vapours, degrade the performance of the HME, a statement to that effect;

j) recommended maximum time of use for each unit;

k) recommended shelf-life;

l) a warning of the potential hazards associated with the use of an HME with the active use of a humidifier or nebulizer (if applicable);

m) the specified operating range expressed in tidal volume.

Annex A (informative)

Rationale statement

Remarks made in this annex apply to the relevant clause and subclause of this International Standard. The numbering is, therefore, not consecutive.

[5.2 Gas leakage]

Excessive gas leakage may result in poor device performance, undelivered tidal volume, and pollution by anaesthetic gases and vapours.

[5.3 Pressure drop]

Resistance to flow may increase the work of breathing. It may also interfere with the effectiveness of intermittent mandatory ventilation (IMV) or triggering mechanisms in lung ventilators.

[6.1 Temperature and pressures]

[6.1.1] Extreme temperatures at the machine end will give differences in heat content of the air as it enters the HME and will create non-comparable values of efficiency.

[6.1.2] Too large a variation of temperature would give other heat transfer rates to the HME and the test equipment, and will create non-comparable efficiency values.

[6.1.3] Condensation (especially in the parts between points D and F in figure 1) will produce a transitional rather than a steady state and will also create some added heat and moisture transfer areas which would lead to erroneous performance values.

[6.1.4] The temperature at this point varies with every breath. The temperature curve will resemble figure 3. It is easier to regulate the heating system in the water-bath and to begin with this temperature.

[6.1.5] Too much temperature variation in the inspired air will give erroneous and variable output

data. Measurement of the heat output of an HME is currently beset with serious technical problems. Heat cannot be measured directly. Indirect estimation by temperature is subject to great variability due to a large dependency on the nature and response time of the thermocouple used, complicated by rapid transients produced by the cyclic nature of the respiratory pattern. Inability to measure humidity transients further complicates such determinations. A reasonable measure of heat output by an HME will be obtained by determining the moisture output of the device. Such a correlation derives from the fact that approximately 88 % of the heat output of an HME is the latent heat of vaporization from the very moisture which is recorded as "moisture output". The remainder derives from the heat-sink effect of an HME upon the condensed moisture and warm expired gases. To approach this problem from a physiological perspective, the great majority of the heat conserved in the body by an HME is manifested in the amount of moisture (i.e. moisture output) returned in the inspiratory gases. This moisture spares the lungs from having to vaporize the body's own liquid phase water, with the cost of the equivalent heat of vaporization. Moisture returned, then, is closely related to heat retained. Thus our best approximation of percentage of heat output of an HME will be obtained by referring to the percentage of moisture output (versus input) of an HME.

Too slow a response time for temperature probes at points E and F in figure 1 will give a temperature value closer to the average inspiratory and expiratory temperature; this will not reflect the temperature output of the HME.

[6.3.1.12] It is recognized that the test apparatus itself has a certain heat and moisture exchange capability and because of this it is not possible to calculate the HME efficiency solely from measurement of the mass loss when the HME is connected.

Exhibit D

Iso-Gard® HEPA - HME

- Δ HEPA Filtration with HME properties**
- Δ Bacterial and viral filtration efficiency 99.99%**
- Δ Every filter is tested after assembly for filtration efficiency**
- Δ Hydrophobic media**
- Δ Available with gas sampling port**
- Δ For single use**

Iso-Gard® is a registered
Trade Mark.

Specifications

Product No 19302 Iso-Gard® HEPA-HME
19312 Iso-Gard® HEPA-HME with Port

- Δ Dead-space 74 ml
- Δ Weight 45 - 46g
- Δ Connectors 15/22-15 mm, ISO 5356-1, Luer port on P/N 19312.
- Δ Medium: Hydrophobic Micro Glass Paper
- Δ Resistance to flow:
 - at 30 l/min, max 0.5 cm H₂O
 - at 60 l/min, max 1.0 cm H₂O
 - at 90 l/min, max 1.5 cm H₂O
- Δ Moisture output*:
 - 26.6 mg H₂O/1 air at V_T 300 ml
 - 22.2 mg H₂O/1 air at V_T 600 ml
- Δ Packaging:
 - individually packed, 50 units per box.
- Δ Bacterial/viral filtration efficiency **:99.99%
- Δ Instructions for use in individual package.
- Δ Lot number on all packaging.

* Tested in accordance with ISO standard 9360.

** BFE and VFE tests performed by independent laboratory. Records on file.

Caution!

- Replace every 24 hours .
- Replace unit immediately if soiled with secretion or otherwise obstructed.
- Iso-Gard® HEPA is designed for single use only and should not be cleaned and re-used.
- Take total system dead space into consideration if used as an HME.

Contraindications

- If Iso-Gard® HEPA is used as an HME, it should not be used with patients producing fulminating frothy secretions within their airways, or patients with haemoptysis.
- Do not add moisture if used as an HME.

Distributed by:

Manufactured in U.S.A. by Gibeck, Inc.

088

Iso-Gard® HEPA Filter-HME

Product Number 19302

Iso-Gard® HEPA Filter-HME with Port

Product Number 19312

Instructions for use as a bacterial/viral filter

Description:

Iso-Gard® HEPA Filter-HME is a an efficient bacterial /viral filter for use in breathing systems for the protection of the patient and equipment.

For single use only. Maximum use 24 hours.

Do not use if package is broken or product is damaged.

Instructions for use:

Do not remove from package until ready for use.

Firmly connect filter using a twisting motion.

Replace filter every 24 hours or more often if needed.

Pressure alarms should be used at all times.

Caution:

Condensate may accumulate on the patient side of the product. To prevent accumulation of condensate, position filter to allow water to drain away from upstream side of the filter.

Caution:

US Federal law restricts this device to sale by or on the order of a physician.

Warnings:

When used with nebulizers, the filter must be closely monitored and replaced immediately if increased pressure is noted.

Do not soak, rinse, wash or sterilize (gas, steam or cold) this product.

Discard after use.

Replace filter immediately if there is increasing resistance or any suspicion of contamination, occlusion or other indications of malfunction present.

Contraindications:

Make sure if you use drugs with surfactant properties that the hydrophobic pores are not blocked. This can happen if drugs are nebulized in a circuit with a cascade humidifier.

Always consult with your drug manufacturer before nebulization of drugs or solutions for the first time.

Instructions for use as a bacterial/viral filter and heat and moisture exchanger (HME)

Description:

Iso-Gard® HEPA Filter-HME is an efficient bacterial/viral filter. The heat and moisture exchanging properties are limited to V_T 350-600 when used in open breathing systems.

Dead space 74 ml.

For single use only. Maximum use 24 hours.

Do not use if package is broken or product is damaged.

Instructions for use:

Do not remove from package until ready for use.

Firmly connect filter using a twisting motion.

Replace filter every 24 hours or more often if needed.

Pressure alarms should be used at all times.

Take total dead space into consideration before use.

Caution:

Condensate may accumulate on the patient side of the product. To prevent accumulation of condensate, position filter to allow water to drain away from upstream side of the filter.

Caution:

US Federal law restricts this device to sale by or on the order of a physician.

Warnings:

Do not soak, rinse, wash or sterilize (gas, steam or cold) this product.

Discard after use.

Replace filter immediately if there is increasing resistance or any suspicion of contamination, occlusion or other indications of malfunction present.

Contraindications:

Iso-Gard® HEPA Filter-HME should not be used with patients producing fulminating frothy secretions within their airways, or patients with haemoptysis.

Do not use in conjunction with conventional humidifiers and nebulizers.

Lot Number: _____

Gibeck, Inc.

10640 E. 59th Street

P.O. Box 36430

Indianapolis, IN 46236

Exhibit E



101 24

Food and Drug Administration
8757 George Avenue
Silver Spring MD 20910

Gineck Respiration, Inc.
Attn: Darryl Lustig
165 E. Commerce Drive
Schaumburg, Illinois 60173

Re: K881657
Humid-Vent Filter
Dated: April 12, 1988
Received: April 15, 1988
Regulatory Class: II

Dear Mr. Lustig :

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

George C. Murray, Ph.D.
Director
Division of Anesthesiology, Neurology,
and Radiology Devices
Office of Device Evaluation
Center for Devices and Radiological
Health

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092

Memorandum

June 23, 1988

Date

REVIEWER(S) - NAME(S)

Laura A. Wang

Subject

510(k) NOTIFICATION

K881657

To

THE RECORD

It is my recommendation that the subject 510(k) Notification:

- (A) Is substantially equivalent to marketed devices.
- (B) Requires premarket approval. NOT substantially equivalent to marketed devices.
- (C) Requires more data.
- (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

see review / telephone memos

The submitter requests:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Class Code w/Panel:

73 BYC Class II

868.5375 Infant and Hoistur. Exeter, N.H. (Artificial Nose)

REVIEW:

(BRANCH CHIEF)

[Signature] *6/24/88*

(DATE)

FINAL REVIEW:

(DIVISION DIRECTOR)

[Signature]

6/24

(DATE)

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093

510K REVIEW

K681657

COMPANY NAME: Gibeck Respiration, Inc.
DEVICE NAME: Humid-Vent Filter

- 1. Life-supporting or life-sustaining: No
- 2. Implant (short-term or long-term): No
- 3. Software-driven: No
- 4. Devices to which equivalence is claimed and manufacturer: Gibeck Respiration, Inc.'s Humid-Vent 2 Flex heat and moisture exchangers without filters, Portex artificial noses
- 5. Submission provides comparative specifications: Yes
comparative in vitro data: No
summary of animal testing: No
summary of clinical testing: No
- 6. Description of device and similarities and differences between device and pre-enactment/predicate device(s), including indications for use, new technology and new kinds of safety issues:

This device is a heat and moisture exchanger with a bacterial filter for humidification of the airway during anesthesia and short-term ventilation. It consists of a housing enclosing a microcorrugated hygroscopic filter paper to retain heat and moisture from the exhaled air and release it into the inhaled air and 3M Filtrete to trap bacteria.

The microcorrugated paper is the same as that used in other Gibeck HMEs, so this device has the same heat and moisture retention characteristics as the predicate devices. The 3M Filtrete material is used in the majority of currently marketed bacterial filters, including those by Pall, K&G, and Life Designs. The firm does not claim a Bacterial Filtration Efficiency (BFE) for this device, but the Filtrete material has repeatedly been shown to have a BFE of 99+ percent and to add very little resistance to the breathing circuit.

This device differs from the other Gibeck HMEs in that it incorporates a bacterial filter. HMEs are often used in conjunction with a separate bacteria filter, so this device is simply combining two parts that are commonly used together into a single unit. The dead space, 61 ml, is greater than that of an HME (<30 ml), but is no more than the combined dead spaces of two separate devices. This modification would not be expected to adversely affect the safety or effectiveness of the device.

- 7. RECOMMENDATION:
I believe that this device is equivalent to: 73 BYD
Classification should be based on:
868.5375 Heat and Moisture Exchanger (Artificial Nose)

Laura A. Alonge
Laura A. Alonge 06/22/88
Class:II

000003

MEMORANDUM OF TELEPHONE CONVERSATION

Between: Mr. Darryl Lustig
President
(312) 882-2910

and

Biologist, HPZ-430

Date: June 20, 1988

Subject: K881657 - Humid-Vent Filter

I called Mr. Lustig to obtain additional information pertaining to the above-referenced device. I asked Mr. Lustig if the microcorrugated paper was the same as in his other Humid-Vent devices. He stated that it is and that the heat and moisture retention characteristics are the same. I asked Mr. Lustig to identify the material used for the bacteria filter. Mr. Lustig stated that the material is 3M Filtrete, which is used in most currently marketed bacteria filters. Mr. Lustig said that they chose this material because of its high bacterial filtration efficiency and its low resistance (these characteristics have been repeatedly demonstrated in predicate devices). I asked Mr. Lustig what the dead space of the Humid-Vent Filter would be. He stated that the dead space is 61 ml.

Laura A. Alonge
Laura A. Alonge

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095

Food and Drug Administration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

APRIL 18, 1988

GEBECK RESPIRATION, INC.
ATTN: DARRYL LUSTIG
165 E. COMMERCE DRIVE
SCHAUMBURG, IL 60173

D.C. Number : K881657
Received : 04-15-88
Product : HUMID-VENT FILTER

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the above referenced device has been received and assigned a unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing your device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or at (301) 427-8162.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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000006

097

Gibeck Respiration

Products to help you breathe easier.

K881657

April 12, 1988

Attn: Document Control Clerk
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HF2-401)
8757 Georgia Avenue
Silver Spring, MD 20910

RECEIVED
FDA/CDRH
1988 APR 15 PM 2:57
DOCUMENT CONTROL
CENTER

RE: 510 (K) Pre-Market Notification

Document Control Clerk:

Gibeck Respiration, Inc. is requesting clearance for its product Humid-Vent® Filter. This product is manufactured by Gibeck Respiration AB, in Sweden.

- a. Classification Name: Heat and Moisture Condensor (artificial nose)
Common/Usual Name: Heat and Moisture Exchanger
Proprietary Name: Humid-Vent® Filter
- b. Establishment Registration Number: 1450750
- c. Classification: Class II
- d. Performance Standards: "not applicable", as we are unaware that any have been developed at this time.
- e. Labeling/Promotional Materials: label specimen and draft copies of promotional literature are enclosed.
- f. Substantial equivalent: this product is similar in design, function and material to heat and moisture exchangers marketed by our firm since 1974. In addition, an integral bacterial filter has been added to the heat and moisture exchanger.

000007

Gibeck Respiration, Inc., 165 E. Commerce Drive, Schaumburg, IL 60173 (312) 882-2910, Telex 650-3243794 Fax (312) 882-6316
In Sweden:
Gibeck Respiration AB, Kanalvägen 5, P.O. Box 711, S-19427 Upplands Väsby Sweden. Tel. +46 (0) 760-94165.

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Gibeck Respiration

Products to help you breathe easier.

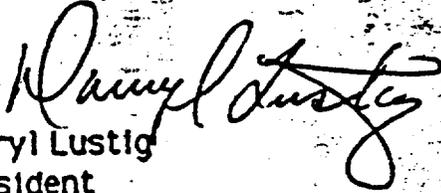
Document Control Clerk

April 12, 1988

Page Two

We would appreciate our earliest attention to this 510 (K) submission.
The "Humid-Vent" filter will not be available for sale until we first
receive FDA clearance of our 510 (K) submission.

Yours truly,



Darryl Lustig
President

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099

Gibeck Respiration

Products to help you breathe easier.

DRAFT TEXT:

Label on the product:

Humid-Vent® Two Filter
Humidity the Human Way
Gibeck Respiration

Label on the single product package:

Humid-Vent® Filter
Heat and moisture exchanger with bacterial filter for humidification
during anaesthesia and short term ventilation. Sterile and for single use.

(the same in German, French, Spanish and Swedish.)

Reference No. 1881

Lot No. XXXXXX

Gibeck Respiration AB, Box 711, S-19427, Upplands Vasby, Sweden.

Printed information on the multiple product package: Humid-Vent® Filter.

Humid-Vent Filter is a single use HME (heat and moisture exchanger) and bacterial filter for humidification during anaesthesia. Replace when needed. Store in dark, dry, temperate conditions.

Important

1. Do not use if package seal is broken or product is damaged.
2. Replace unit if soiled with secretions or otherwise obstructed.
3. Do not use with explosive anaesthetic gases.
4. Do not use together with other active humidification systems, such as electrically heated humidifiers or nebulizers.
5. Take total dead space into consideration before use.

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Gibeck Respiration, Inc., 165 E. Commerce Drive, Schaumburg, IL 60173 (312) 882-2910, Telex 650-3243794 Fax (312) 882-6316
In Sweden:
Gibeck Respiration AB, Kanalvägen 5, P.O. Box 711, S-19427 Upplands Vasby Sweden. Tel. +46 (0) 760-94165.

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Gibeck Respiration

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April 12, 1988
Page Two

Caution: US Federal law restricts this device sold by or on the order of a physician.

Made by: Gibeck Respiration, AB, Box 711, S-19427., Upplands Vasby, Sweden.

(the same information in German, French, Spanish and Swedish.)

Each package of 20 units is also labeled with an adhesive label with the following information:

Humid-Vent 2^o Filter
Reference No. 1881
Lot No. XXXXXX
Contents: 20 units
Sterile for single use.

Gibeck Respiration, Inc.
165 E. Commerce Drive
Schaumburg, IL 60173

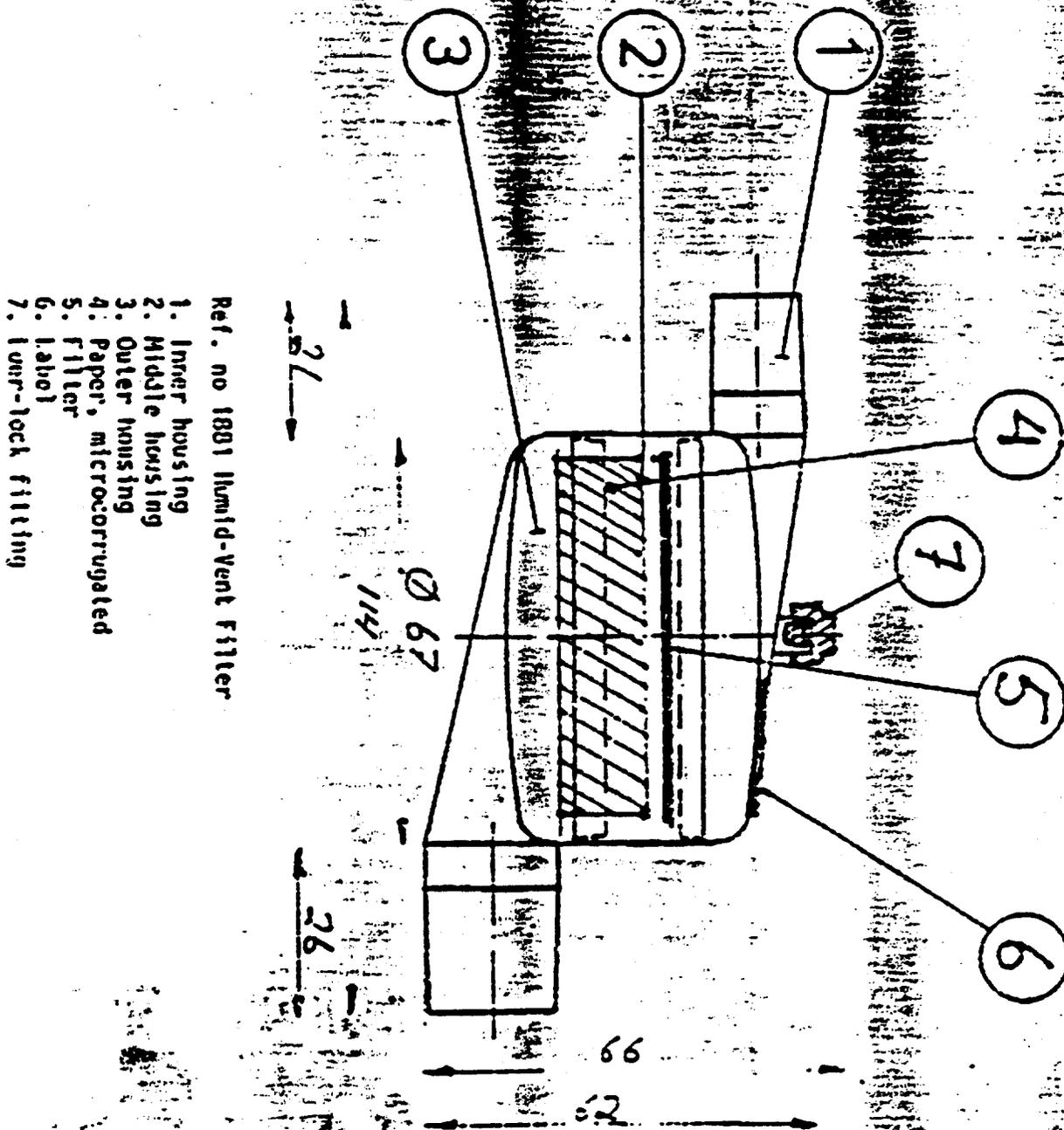
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Gibeck Respiration

Products to help you breathe easier.



- Ref. no 1801 Humid-Vent Filter
1. Inner housing
 2. Middle housing
 3. Outer housing
 4. Paper, microcorrugated
 5. Filter
 6. Label
 7. Turn-lock fitting

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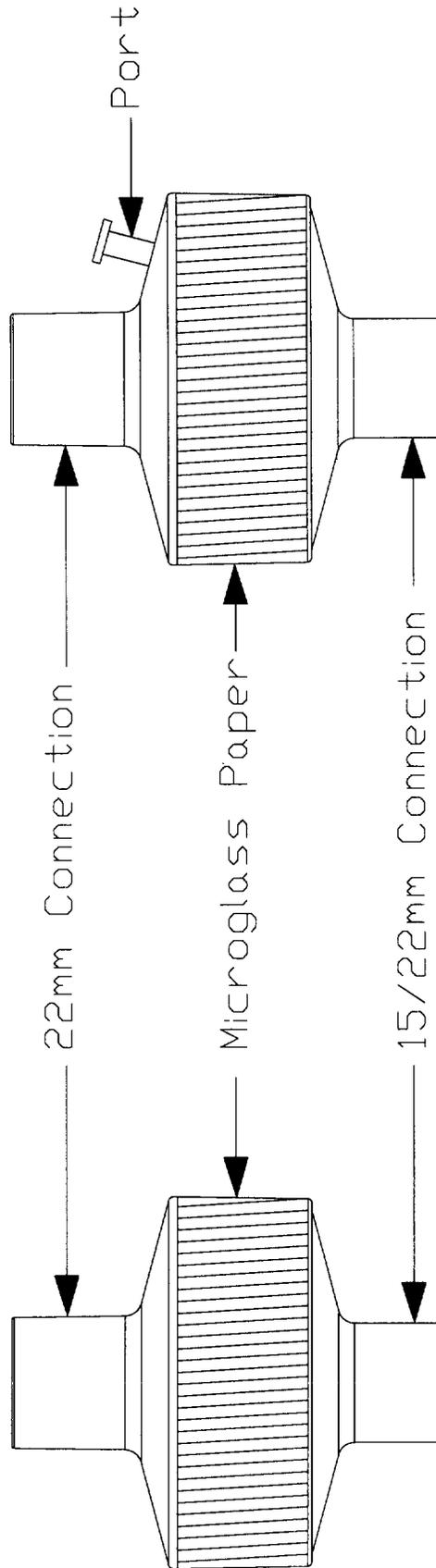
Gibeck Respiration, Inc., 165 E. Commerce Drive, Schaumburg, IL 60173 (312) 882-2910, Telex 650-3243794 Fax (312) 882-6316
In Sweden:
Gibeck Respiration AB, Kanahägen S, P.O. Box 711, S-19427 Upplands Väsby Sweden. Tel. +46 (0) 760-94165.

Exhibit F

Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port/Humid-Vent Filter Comparison Table

<u>Feature</u>	<u>Iso-Gard HEPA Filter-HME, Iso-Gard HEPA Filter-HME with Port</u>	<u>Humid-Vent Filter</u>
Tidal Volume (V_T)	250-1500 ml	350-600 ml
Dead space	63 ml	74 ml
Weight	45-46 g	43-44 g
Connectors	22 mm 15/22 mm	15 mm 15/22 mm
Resistance to flow	0.5 cm H ₂ O at 30 l/min 1.0 cm H ₂ O at 60 l/min 1.5 cm H ₂ O at 90 l/min	0.8 cm H ₂ O at 30 l/min 1.6 cm H ₂ O at 30 l/min 2.9 cm H ₂ O at 30 l/min
Moisture output	26.6 mg H ₂ O/l air, V_T 300 ml 22.2 mg H ₂ O/l air, V_T 600 ml	31.0 mg H ₂ O/l air, V_T 300 ml 30.0 mg H ₂ O/l air, V_T 300 ml
Filtration efficiency	99.99%, minimum	99.90%, minimum
Packaging	Individually packed, 50/box	Individually packed, 20/box
Housing	Styrene-butadiene	Polymethylmethacrylate
Medium (Filtration) (HME)	Microglass fiber paper Microglass fiber paper	Polypropylene fiber Microwell paper

Exhibit G



Iso-Gard HEPA Filter-HME

Iso-Gard HEPA Filter-HME with Port

Exhibit H



Subject: 510(k) Summary of Safety and Effectiveness

Product: Gibeck Iso-Gard® HEPA Filter-HME and
Iso-Gard® HEPA Filter-HME with Port

Summary:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Iso-Gard HEPA Filter-HME and Iso-Gard HEPA Filter-HME with Port are heat and moisture exchangers as described in 21 CFR 868.5375. These products are substantially equivalent to the Humid-Vent Filter heat and moisture exchanger.

The principal differences between the Iso-Gard HEPA Filter-HME, the Iso-Gard HEPA Filter-HME with Port and the Humid-Vent Filter are the design of the housing and the filtration/HME media utilized. These differences are not considered to be critical to the intended therapeutic, diagnostic, prosthetic or surgical use of the device nor should these differences significantly affect the safety or effectiveness of the device when used as labeled.

Submitter/Contact Person

10/12/95

Date

Gibeck, Inc.

10640 East 59th Street • P.O. Box 36430 • Indianapolis, IN 46236

Telephone: (317) 823-6866 • Telefax: (317) 823-1662

A Member of the Gibeck Group

Exhibit I

March 14, 1995

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT *
(As Required By 21 CFR 807.87(j))

I certify that, in my capacity as [The Position Held In Company] of [Company Name], I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.


[Signature]

Brian Grigsby - Director, Quality and Regulatory Affairs
[Typed Name and Title]

Gibeck, Inc.
[Company]

10/19/95
[Date]

[Premarket Notification (510(k)) Number]

* Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter.)