



Health  
Canada

Santé  
Canada

Health Protection  
Branch

Direction générale de la  
protection de la santé

Medical Devices Bureau  
Statistics Canada Main Bldg.  
Room 1605, Tunney's Pasture  
Address Locator 0301H1  
Ottawa, Ontario K1A 0L2  
Tel: (613) 954-9398  
Fax: (613) 941-4726

Mr. Chris Schmelzle  
Manager of Inside Operations  
Nutech Energy Systems Inc.  
511 McCormick Blvd.  
London, Ontario  
N5W 4C3

February 19, 1997

Our Reference: 111488

Dear Mr. Schmelzle,

This acknowledges receipt of your material dated May 13, 1996, for the following product(s):

<u>Product(s)</u>	<u>Device I.D. #(s)</u>
• Lifebreath T.F.P. Air Cleaner (Model #TFP)	175978

The information has been added to our file and the Device Identification Number(s) assigned to the associated product(s) should be quoted in future correspondence with the Bureau.

This will confirm that the notification information submitted satisfies the requirements pursuant to Part II Section 24 of the Regulations. It is pointed out that this acknowledgement does not constitute or imply approval of the product(s) notified. Also please note that all Medical Devices are subject to Sections 3 to 5 as well as Parts I, III, and IV of the Regulations.

Please note that we consider the manufacturer to be the company name and address that appears on the labelling material.

Please find enclosed a copy of *Medical Devices Electronic Bulletin Board Service* newsletter, which explains how you can make use of this convenient service.

If we can be of any help, please let us know.

Yours truly,

Linda Gardiner  
Notification and Tracking Section

LG/kb

PCOMMONNOTIFLETTERS\FEB97\111488.1

Canada

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0059.  
Expiration Date: February 28, 1999.

DEVICE LISTING

Complete and Return to:

Food and Drug Administration  
Center for Devices and Radiological Health  
Information Processing and Office Automation Branch (HFZ-308)  
2098 Gaither Road  
Rockville, MD 20850

**NOTE:** This form is authorized by Section 510 of the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.

1. DOCUMENT NUMBER  <b>A 978732</b>	2. REASON FOR SUBMISSION  <input checked="" type="checkbox"/> New Listing <input type="checkbox"/> Update to Device Already Listed <input type="checkbox"/> Delete Listing	3. REPORT DATE	4. OWNER / OPERATOR ID NUMBER  <b>9032884</b>
		MO. DAY YR.	

5. OWNER / OPERATOR NAME  
**NUTECH ENERGY SYSTEMS INC.**

6. ADDRESS (Check ☐ if same as submitted on FDA Form 2891)

a. NUMBER and STREET **511 McCormick Blvd.**

b. CITY, STATE, ZIP CODE **London, Ontario. N5W 4C8**

c. FOREIGN COUNTRY **CANADA**

7. CLASSIFICATION NAME  
**CLASS 1 GENERAL CONTROLS**

8. CLASSIFICATION NUMBER  
**FKF**

9. PROPRIETARY NAME (Brand Name)  
**LIFEBREATH T.P.P. AIR CLEANER**

10. COMMON OR USUAL NAME  
**TFP**

11. FOR U.S. DESIGNATED AGENTS OF FOREIGN ESTABLISHMENTS

a. NAME

b. REGISTRATION NUMBER

12. ESTABLISHMENT NAME AND ADDRESS  
(Identification of Sites Where Listed Device is Produced)

REGISTRATION NO.	(Name, Street Number, City, State or Country, ZIP or Postal Code)	ESTABLISHMENT TYPE				
A		M	R	S	T	X
		X				
B						
C						
D						

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Director, Reports Clearance Office  
Paperwork Reduction Project (0910-0059)  
Hubert H. Humphrey Building, Room 531-H  
200 Independence Avenue, S.W.  
Washington, DC 20201

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Please DO NOT RETURN this form to this address.

13. SIGNATURE *Chris Schmelle*

14. TYPED OR PRINTED NAME **CHRIS SCHMELLE**



# AIR FILTER TESTING LABORATORIES, INC.

4632 Old LaGrange Road • Crestwood, Kentucky 40014

Phone (502) 222-5720 • Fax (502) 222-5720

## ASHRAE STANDARD 52.1-1992 STATICALLY TESTED DEVICES

### DEVICE TESTED

REPORT NO.

10449

TEST NO.

1

SHEET NO.

1

Test Requested By NUTECH ENERGY SYSTEMS, INC.  
Manufacturer NUTECH ENERGY SYSTEMS, INC.  
Test Sample Procurement FURNISHED BY MANUFACTURER  
Product Name LIFE BREATH TFP AIR CLEANER 2000  
Model No. LIFE BREATH TFP AIR CLEANER 2000  
Dimensions 21.00 IN. H X 35.00 IN. W X 10.00 IN. D (NOMINAL)  
Product Description

### TEST RESULTS - see attached performance curves

Test Airflow Rate	115	ft <sup>3</sup> /min (cfm)
Initial Resistance	N/A	in. w.g.
Final Resistance	N/A	in. w.g.
Initial Atmospheric Dust Spot Efficiency	84.0	%
Average Atmospheric Dust Spot Efficiency	72	%
Average ASHRAE w/o Carbon Dust Weight Arrestance	97	%
ASHRAE w/o Carbon Dust Holding Capacity	49	g

Test Section Duct Size	N/A	in
Test Dust	ASHRAE W/O CARBON	
Test Dust Feed Rate	2.0	g/1000 ft <sup>3</sup>

### PHYSICAL DESCRIPTION

Face Dimension (Nom. Height)	21.00	in. H
Face Dimension (Nom. Width)	35.00	in. W
Depth Dimension (Nom. Depth)	10.00	in. D
Type Of Media	COLUMBUS INDUSTRIES "MAGNET"	
Type And Amount Of Dust Adhesive	NONE	

NOTE: SELF CONTAINED AIR CLEANER

DATE

01-23-1998

TEST SUPERVISOR

J.P.S.

ENGINEERING

APPROVAL

*David J. Murphy Jr.*





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## ASHRAE STANDARD 52.1-1992 - PERFORMANCE CURVES STATICALLY TESTED DEVICES

### PERFORMANCE CURVES

REPORT NO.

10449

TEST NO.

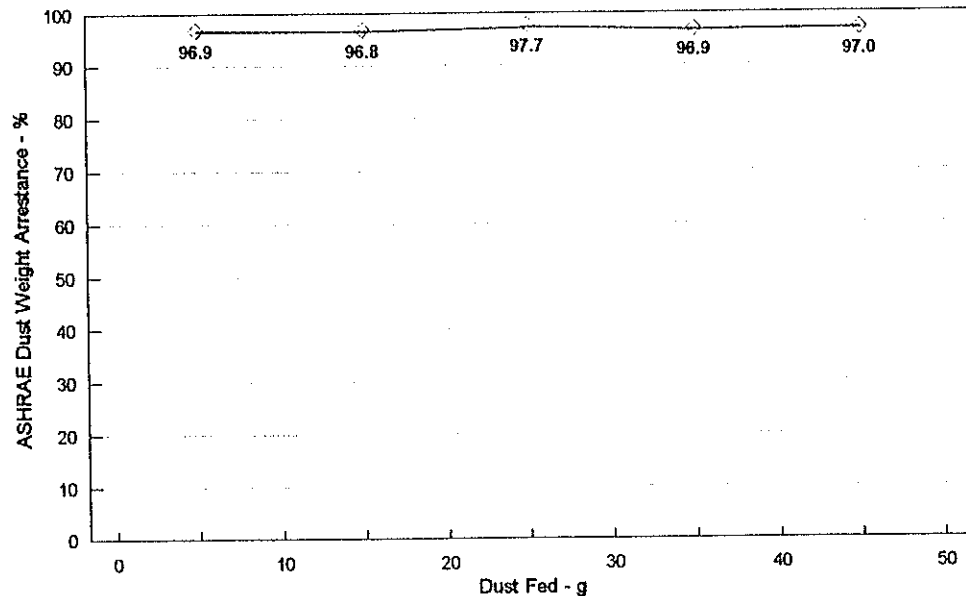
1

SHEET NO.

2

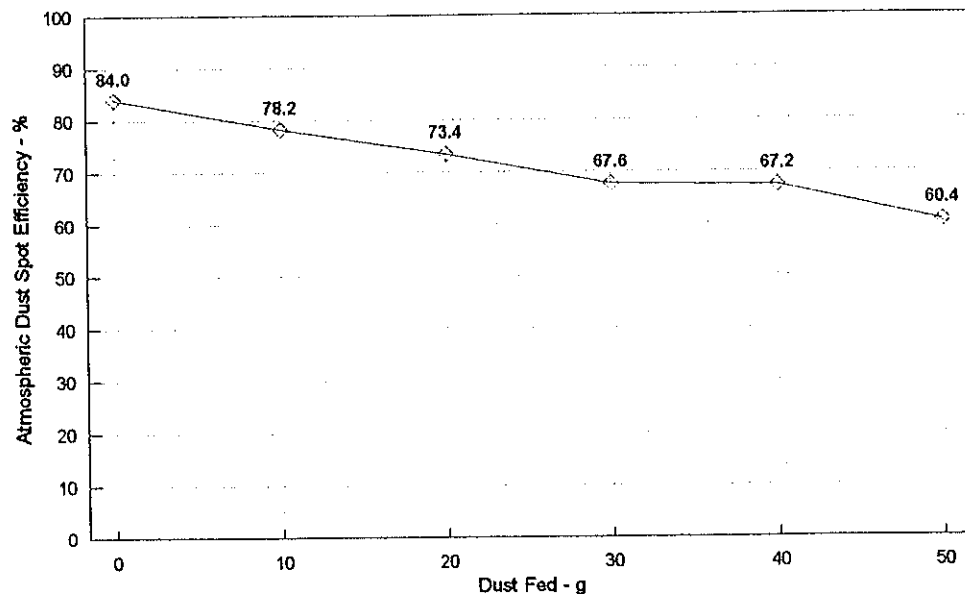
### DUST FED -vs- ARRESTANCE

Dust Increment - 10 g ASHRAE w/o Carbon



### DUST FED -vs- ATMOS. DUST SPOT EFFICIENCY

Dust Increment - 10 g ASHRAE w/o Carbon



DATE

01-23-1998

TEST SUPERVISOR

J.P.S.

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**ASHRAE METHOD 52.1-1992 AIRFLOW -vs- RESISTANCE AND INITIAL PARTICLE SIZE, AMBIENT ATMOSPHERIC DUST -vs- REMOVAL EFFICIENCY; CLEAN DEVICE**

REPORT NO.

10449

TEST NO.

2

SHEET NO.

3

## DEVICE TESTED

Test Requested By	NUTECH ENERGY SYSTEMS, INC.
Manufacturer	NUTECH ENERGY SYSTEMS, INC.
Test Sample Procurement	FURNISHED BY MANUFACTURER
Product Name	LIFEBREATH TFP AIR CLEANER 2000
Model No.	LIFEBREATH TFP AIR CLEANER 2000
Dimensions	21.00 IN. H X 35.00 IN. W X 10.00 IN. D (NOMINAL)
Product Description	MEDIA TYPE - COLUMBUS INDUSTRIES "MAGNET"

## TEST CONDITIONS

Test Airflow Rate	115	ft <sup>3</sup> /min (cfm)
Initial Resistance	N/A	in. w.g.
Air Temperature	23.0	°C
Relative Humidity	50	%
Particle Analyzer	CI-8040 / 226M (white-light)	

## TEST RESULTS - see attached performance curves

Particle Size Ranges (µm)	Init. Removal Efficiency (%)
0.3 - 0.4	73.77
0.4 - 0.5	77.36
0.5 - 0.6	81.03
0.6 - 0.8	83.96
0.8 - 1.0	86.69
1.0 - 1.5	89.60
1.5 - 2.0	93.55
2.0 - 3.0	95.65

DATE

01-23-1998

TEST SUPERVISOR

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ASHRAE METHOD 52.1-1992 AIRFLOW -vs- RESISTANCE AND INITIAL PARTICLE SIZE, AMBIENT ATMOSPHERIC DUST -vs- REMOVAL EFFICIENCY; CLEAN DEVICE

## PERFORMANCE CURVES

REPORT NO.

10449

TEST NO.

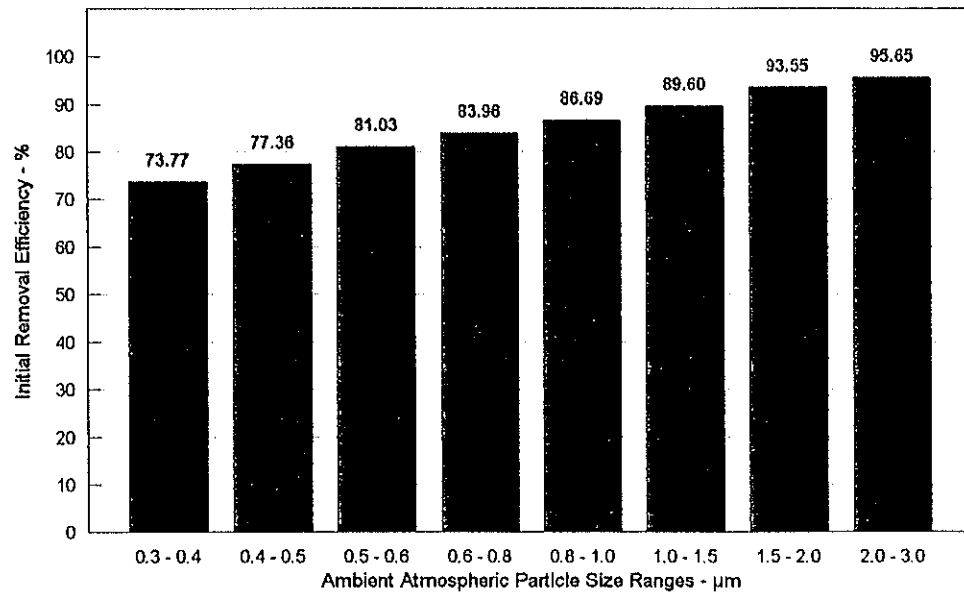
2

SHEET NO.

4

### PARTICLE SIZE -vs- INITIAL REMOVAL EFFICIENCY

Ambient Atmospheric Dust



DATE

01-23-1998

TEST SUPERVISOR

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## ASHRAE STANDARD METHOD 52.1-1992 AIRFLOW -vs- INITIAL RESISTANCE AND INITIAL POLLEN REMOVAL EFFICIENCY; CLEAN DEVICE

### DEVICE TESTED

Test Requested By	NUTECH ENERGY SYSTEMS, INC.
Manufacturer	NUTECH ENERGY SYSTEMS, INC.
Test Sample Procurement	FURNISHED BY MANUFACTURER
Product Name	LIFEBREATH TFP AIR CLEANER 2000
Model No.	LIFEBREATH TFP AIR CLEANER 2000
Dimensions	21.00 IN. H X 35.00 IN. W X 10.00 IN. D (NOMINAL)
Product Description	MEDIA TYPE - COLUMBUS INDUSTRIES "MAGNET"

REPORT NO.  
10449

TEST NO.  
3

SHEET NO.  
5

### TEST CONDITIONS

Test Airflow Rate	115	ft <sup>3</sup> /min (cfm)
Initial Resistance	N/A	in. w.g.
Test Pollen / Size	GIANT RAGWEED / 17 µm	
Test Pollen Increment	10	g

### TEST RESULTS - see attached performance curves

Initial Pollen Removal Efficiency	99.4	%
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DATE  
01-23-1998

TEST SUPERVISOR  
J.P.S.

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