K050263

510(k) SUMMARY

mocom
Sistemi innovativi di sterilizzazione

The information required by **21 CFR § 807.92** is listed below.

Submitter: M.O.COM. s.r.l.
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20090 Buccinasco (MI) - Italy

NOV 2 1 2006

Contact Person: Daniele Tosi
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Date of Submission: 2005, February 1st

Device Name:
Proprietary: MILLENNIUM series (B, B+, B^2, Bμ)
Common: Steam Sterilizer (or Autoclave)
Classification: 880.6880 FLE: Sterilizer, Steam

Devices to which the Millennium series claims equivalence:
W&H Lisa (510(k) number K022816)
Midmark M9 UltraClave (510(k) number K023348)

Device Description

MILLENNIUM series are sophisticated equipments but of very friendly use, adaptable to the different demands thanks to the wide possibilities of configuration and choice of the cycles.

The equipments are able to treat in fast way every type of load through various patented systems and hi-tech solutions.

MILLENNIUM series sterilizers are equipped with a 5.5, 17 or 21 litres sterilization chamber and are characterized by an advanced fractionated vacuum system for the complete air removal also from hollow and porous materials as well as by an effective final vacuum drying phase able to eliminate any trace of condensation from the load.

An exclusive steam generation system, combined with the advanced control system, guarantees an high process speed and high stability of the thermodynamic parameters during the whole sterilization process and consequently full safety and perfect result.

The equipment offers sterilization programmes optimized for an effective, fast sterilization of different tools and materials used in medical environment, particularly the dental one.

The sterilization program of a MILLENNIUM series sterilizer can properly be described by a sequence of phases, each with a well defined activity.

Considering a standard program (i.e. program at 273 °F – 4' for porous load), after arranged the material in the chamber, closed the door, selected the program, started the cycle by the START key (with activation of the door locking device), the following sequence will run:

1. Pre-heating of the steam generator and sterilization chamber;
2. Chamber air removal and steam penetration inside the load through a series of vacuum stages and pressure phases;
3. Pressure rise-up, with consequent steam temperature increasing up to the preset sterilization conditions (for the example, **273 °F**);
4. Stabilization of the pressure and temperature conditions inside the sterilization chamber;
5. Run of the sterilization process for the preset time (for the example, **4 minutes**);
6. Chamber pressure decreasing through steam discharge;
7. Vacuum drying phase;
8. Venting phase through sterile air;
9. Chamber pressure leveling up to atmospheric value.

As reached this last phase the door locking mechanism will be released and the door can be opened to recovery the load from the sterilization chamber paying attention to use proper precautions.

Intended Use

The device is intended to be used in medical and dental practices, hospitals, clinics, nursing homes, laboratories and other facilities to sterilize re-usable surgical instruments (including dental hand-pieces) and medical materials, heat and moisture resistant and compatible with steam sterilization process.

NOTE: make reference to the Table of the Available Programs on the following pages for detailed information on each model.

Table of the Available Programs (Millennium B)

PROGRAM DESCRIPTION	Temperature (°C)	Pressure (bar relative)	Holding time (min)	Pre-vacuum [1] (F= fract.; S= single)	Standard drying [2] (L= long; S= short)	Total cycle time [3] (approx.)	Average H2O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	TYPE OF LOAD	MAX TOTAL MASS (kg)	MAX MASS PER TRAY (kg)	MAX MASS PER ARTICLE (kg)
134°C POROUS	134	2.10	4	F	L	41'	525	0.8	Unpackaged porous material	**1.00**	0.30	0.30
									Porous material in single package	**0.75**	0.25	0.25
									Porous material in double package	**0.60**	0.20	0.20
									Solid material / handpieces in single package	**3.00**	1.00	0.25
									Solid material / handpieces in double package	**1.50**	0.50	0.25
121°C POROUS	121	1.10	20	F	L	56'	550	0.8	Unpackaged porous material	**1.00**	0.30	0.30
									Porous material in single package	**0.75**	0.25	0.25
									Porous material in double package	**0.60**	0.20	0.20
									Solid material / handpieces in single package	**3.00**	1.00	0.25
									Solid material / handpieces in double package	**1.50**	0.50	0.25
134°C HOLLOW	134	2.10	4	F	S	31'	525	0.7	Unpackaged handpieces	**6.00**	1.20	0.50
121°C HOLLOW	121	1.10	20	F	S	45'	550	0.7	Unpackaged handpieces	**6.00**	1.20	0.50
134°C WRAPPED	134	2.10	4	S	L	34'	300	0.6	Solid material in single package	**3.00**	1.00	0.25
121°C WRAPPED	121	1.10	20	S	L	48'	325	0.6	Solid material in single package	**3.00**	1.00	0.25
134°C SOLID	134	2.10	4	S	S	26'	300	0.5	Unpackaged solid material	**6.00**	1.20	0.50
121°C SOLID	121	1.10	20	S	S	40'	325	0.5	Unpackaged solid material	**6.00**	1.20	0.50
134°C EMERGENCY	134	2.10	3	S	S	16'	300	0.45	Unpackaged solid material	**0.50**	0.50	0.50
134°C or 121°C CUSTOM [4]	134 or 121	2.10 or 1.10	> 4 or > 20	F/S	L/S	56' (max)	550 (max)	0.9 (max)	Unpackaged solid material	**6.00 (max)**	1.20 (max)	0.50 (max)
BOWIE & DICK TEST	273	2.10	3,5	F	S	22'	-	-	Test pack only *(without any other load)*	-	-	-
VACUUM TEST	-	-0.80	-	-	-	22'	-	-	Empty chamber	-	-	-

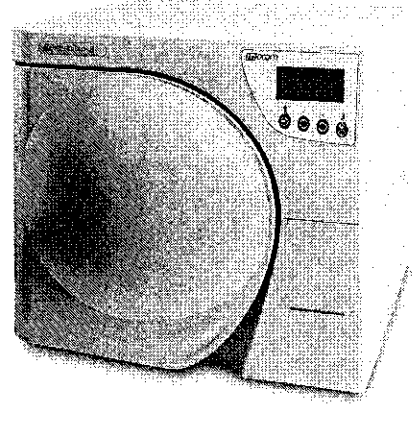


Table of the Available Programs (Millennium B+)

PROGRAM DESCRIPTION	Temperature (°C)	Pressure ($bar_{relative}$)	Holding time (min)	Pre-vacuum [1] (F= fract.; S= single)	Standard drying [2] (L= long; S= short)	Total cycle time [3] (approx.)	Average H_2O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	TYPE OF LOAD	MAX TOTAL MASS (kg)	MAX MASS PER TRAY (kg)	MAX MASS PER ARTICLE (kg)
134°C POROUS	134	2.10	4	F	L	33'	525	0.8	Unpackaged porous material	**1.00**	0.30	0.30
									Porous material in single package	**0.75**	0.25	0.25
									Porous material in double package	**0.60**	0.20	0.20
									Solid material / handpieces in single package	**3.00**	1.00	0.25
									Solid material / handpieces in double package	**1.50**	0.50	0.25
121°C POROUS	121	1.10	20	F	L	48'	550	0.8	Unpackaged porous material	**1.00**	0.30	0.30
									Porous material in single package	**0.75**	0.25	0.25
									Porous material in double package	**0.60**	0.20	0.20
									Solid material / handpieces in single package	**3.00**	1.00	0.25
									Solid material / handpieces in double package	**1.50**	0.50	0.25
134°C HOLLOW	134	2.10	4	F	S	25'	525	0.7	Unpackaged handpieces	**6.00**	1.20	0.50
121°C HOLLOW	121	1.10	20	F	S	39'	550	0.7	Unpackaged handpieces	**6.00**	1.20	0.50
134°C WRAPPED	134	2.10	4	S	L	25'	300	0.6	Solid material in single package	**3.00**	1.00	0.25
121°C WRAPPED	121	1.10	20	S	L	39'	325	0.6	Solid material in single package	**3.00**	1.00	0.25
134°C SOLID	134	2.10	4	S	S	18'	300	0.5	Unpackaged solid material	**6.00**	1.20	0.50
121°C SOLID	121	1.10	20	S	S	32'	325	0.5	Unpackaged solid material	**6.00**	1.20	0.50
134°C EMERGENCY	134	2.10	3	S	S	12'	300	0.45	Unpackaged solid material	**0.50**	0.50	0.50
134°C or 121°C CUSTOM [4]	134 or 121	2.10 or 1.10	> 4 or > 20	F/S	L/S	48' (max)	550 (max)	0.9 (max)	Unpackaged solid material	**6.00 (max)**	1.20 (max)	0.50 (max)
BOWIE & DICK TEST	273	2.10	3,5	F	S	20'	-	-	Test pack only *(without any other load)*	-	-	-
VACUUM TEST	-	-0.80	-	-	-	18'	-	-	Empty chamber	-	-	-

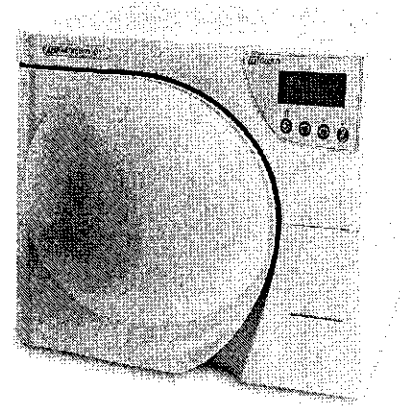


Table of the Available Programs (Millennium B²)

PROGRAM DESCRIPTION	Temperature (°C)	Pressure (bar relative)	Holding time (min)	Pre-vacuum [1] (F= fract.; S= single)	Standard drying [2] (L= long; S= short)	Total cycle time [3] (approx.)	Average H2O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	TYPE OF LOAD	MAX TOTAL MASS (kg)	MAX MASS PER TRAY (kg)	MAX MASS PER ARTICLE (kg)
134°C POROUS	134	2.10	4	F	L	43'	525	0.8	Unpackaged porous material	**1.25**	0.40	0.30
									Porous material in single package	**1.00**	0.30	0.25
									Porous material in double package	**0.75**	0.25	0.20
									Solid material / handpieces in single package	**4.00**	1.25	0.25
									Solid material / handpieces in double package	**2.00**	0.60	0.25
121°C POROUS	121	1.10	20	F	L	58'	550	0.8	Unpackaged porous material	**1.25**	0.40	0.30
									Porous material in single package	**1.00**	0.30	0.25
									Porous material in double package	**0.75**	0.25	0.20
									Solid material / handpieces in single package	**4.00**	1.25	0.25
									Solid material / handpieces in double package	**2.00**	0.60	0.25
134°C HOLLOW	134	2.10	4	F	S	35'	525	0.7	Unpackaged handpieces	**7.50**	1.50	0.50
121°C HOLLOW	121	1.10	20	F	S	50'	550	0.7	Unpackaged handpieces	**7.50**	1.50	0.50
134°C WRAPPED	134	2.10	4	S	L	32'	300	0.6	Solid material in single package	**4.00**	1.25	0.25
121°C WRAPPED	121	1.10	20	S	L	46'	325	0.6	Solid material in single package	**4.00**	1.25	0.25
134°C SOLID	134	2.10	4	S	S	25'	300	0.5	Unpackaged solid material	**7.50**	1.50	0.50
121°C SOLID	121	1.10	20	S	S	39'	325	0.5	Unpackaged solid material	**7.50**	1.50	0.50
134°C EMERGENCY	134	2.10	3	S	S	14'	300	0.45	Unpackaged solid material	**0.50**	0.50	0.50
134°C or 121°C CUSTOM [4] [5]	134 or 121	2.10 or 1.10	> 4 or > 20	F/S	L/S	58' (max)	550 (max)	0.9 (max)	Unpackaged solid material	**7.50 (max)**	1.50 (max)	0.50 (max)
BOWIE & DICK TEST	273	2.10	3,5	F	S	24'	-	-	Test pack only *(without any other load)*	-	-	-
VACUUM TEST	-	-0.80	-	-	-	18'	-	-	Empty chamber	-	-	-

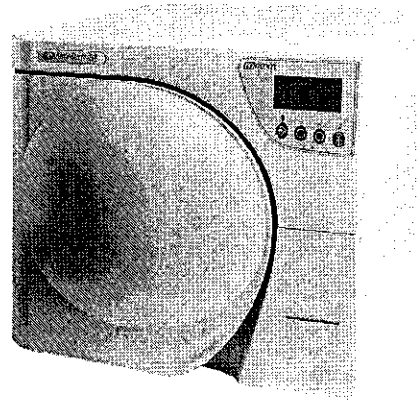
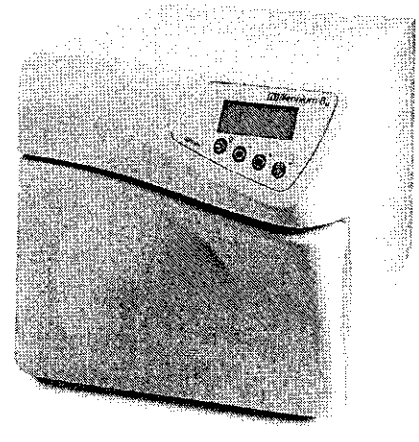


Table of the Available Programs (Millennium Bμ)

PROGRAM DESCRIPTION	Temperature (°C)	Pressure (bar relative)	Holding time (min)	Pre-vacuum [1] (F= fract.; S= single)	Standard drying [2] (L= long; S= short)	Total cycle time [3] (approx.)	Average H2O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	TYPE OF LOAD	MAX TOTAL MASS (kg)	MAX MASS PER TRAY (kg)	MAX MASS PER ARTICLE (kg)
134°C POROUS	134	2.10	4	F	L	19'	200	0.6	Unpackaged porous material	**0.30**	0.30	0.30
									Porous material in single package	**0.30**	0.30	0.25
									Porous material in double package	**0.30**	0.30	0.20
									Solid material / handpieces in single package	**1.00**	0.50	0.25
									Solid material / handpieces in double package	**0.50**	0.25	0.25
121°C POROUS	121	1.10	20	F	L	34'	210	0.6	Unpackaged porous material	**0.30**	0.30	0.30
									Porous material in single package	**0.30**	0.30	0.25
									Porous material in double package	**0.30**	0.30	0.20
									Solid material / handpieces in single package	**1.00**	0.50	0.25
									Solid material / handpieces in double package	**0.50**	0.25	0.25
134°C HOLLOW	134	2.10	4	F	S	17'	200	0.6	Unpackaged handpieces	**1.80**	0.90	0.50
121°C HOLLOW	121	1.10	20	F	S	32'	210	0.6	Unpackaged handpieces	**1.80**	0.90	0.50
134°C WRAPPED	134	2.10	4	S	L	16'	125	0.5	Solid material in single package	**1.00**	0.50	0.25
121°C WRAPPED	121	1.10	20	S	L	31'	130	0.5	Solid material in single package	**1.00**	0.50	0.25
134°C SOLID	134	2.10	4	S	S	13'	125	0.4	Unpackaged solid material	**1.80**	0.90	0.50
121°C SOLID	121	1.10	20	S	S	28'	130	0.4	Unpackaged solid material	**1.80**	0.90	0.50
134°C EMERGENCY	134	2.10	3	S	S	9'	125	0.4	Unpackaged solid material	**0.20**	0.20	0.20
134°C or 121°C CUSTOM [4]	134 or 121	2.10 or 1.10	> 4 or > 20	F/S	L/S	34' (max)	210 (max)	0.7 (max)	Unpackaged solid material	**1.80 (max)**	0.90 (max)	0.25 (max)
BOWIE & DICK TEST	273	2.10	3,5	F	S	16'	-	-	Test pack only *(without any other load)*	-	-	-
VACUUM TEST	-	-0.80	-	-	-	16'	-	-	Empty chamber	-	-	-



GENERAL NOTES (for the Tables of the Available Programs above)

(1) **FRACTIONATED** = Pre-vacuum stage made by a sequence of 3 vacuum pulses + 3 pressure pulses.
"Fractionated vacuum cycles" are dedicated to the sterilization of porous materials or hand-pieces.

SINGLE = Pre-vacuum stage made by 1 vacuum + 1 pressure pulse.
"Single vacuum cycles" are dedicated to the sterilization of solid materials.

(2) **LONG** = Drying stage for porous material and/or hand-pieces and/or solid material in single/double package.
The validated **LONG** drying times (**STANDARD** option) are **16.5 min** for Millennium **B**, **12.5 min** for **B+**, **16.5 min** for **B^2** and **6 min** for **Bμ**.

The **EXTRA** and **INTELLIGENT** options have **not** been validated.

SHORT = Drying stage for unpackaged solid instruments and/or unpackaged hand-pieces.
The validated "**SHORT drying**" times (**STANDARD** option) are **7 min** for Millennium **B**, **6 min** for **B+**, **8 min** for **B^2** and **4 min** for **Bμ**.

The **FAST** option, having drying times of **2.5 min** for Millennium **B** (up to a load of **1.0 kg** max), **2 min** for **B+** (up to a load of **1.0 kg** max), **2.5 min** for **B^2** (up to a load of **1.0 kg** max) and **1.5 min** for **Bμ** (up to a load of **0.4 kg** max) has **not** been validated.

(3) The **Total Cycle Time** is only indicative.
It represents the time required for the completion of the entire program, from the cycle **START** to the cycle **END** and is calculated with a half-load within the chamber.

(4) The **134°C / 121°C CUSTOM** program has holding times of **4** minutes (or greater) and **20** minutes (or greater) respectively at 134°C and 121°C.
Pre-vacuum type and **Drying type** settable according to the indications given in the notes **(1)** and **(2)** above.

The **134°C / 121°C CUSTOM** program has **not** been validated.

Technological Characteristics Comparison

The comparison shows that the new devices (M.O.COM. s.r.l. Millennium series Steam Sterilizers), which are intended to market, and the predicate devices:

1. Have the same intended use, principles of operation and energy sources.
2. Have the same target population (user group).
3. Have the same (or better) technological characteristics, safeguards and performances.

The physical design, control system, materials of construction and method of manufacture differ slightly from the predicate devices.

There are not any new questions about safety and effectiveness and the new device is safe and effective as the predicate devices.

The M.O.COM. s.r.l. Millennium series Steam Sterilizers **are substantially equivalent** to the W&H Lisa Steam Sterilizer and Midmark M9 UltraClave Steam Sterilizer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Daniele Tosi
Technical Manager
M.O.C.O.M S.r.l.
VIA Delle Azalee 1
Buccinasco (MI),
ITALY 20090

NOV 2 1 2006

Re: K050263
Trade/Device Name: MILLENNIUM Series
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: November 6, 2006
Received: November 8, 2006

Dear Mr. Tosi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number: K050263
(if known)

Applicant: M.O.COM. S.r.l.

Device Name: MILLENNIUM series
(including **Millennium B, Millennium B+, Millennium B^2** and **Millennium Bμ**)

Indication For Use:

The device is intended to be used in medical and dental practices, hospitals, clinics, nursing homes, laboratories and other facilities to sterilize re-usable surgical instruments (including dental handpieces) and medical materials, heat and moisture resistant and compatible with steam sterilization process.
Typical users of this system are trained professionals including, but not limited to, dentists, nurses and other specific medical professionals.

NOTE: The device shall not be used for the sterilization of fluids, liquids or pharmaceutical products.
Also see the "**Table of the Available Programs**", one for each model, on the next pages.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

K050263

INDICATION FOR USE

Table of the Available Programs MILLENNIUM B (temperature in °C and pressure in bar)

PROGRAM DESCRIPTION	Temperature (°C)	Pressure (bar relative)	Holding time (min)	Pre-vacuum [1] (F= fract.; S= single)	Standard drying [2] (L= long; S= short)	Total cycle time [3] (approx.)	Average H_2O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	TYPE OF LOAD	MAX TOTAL MASS (kg)	MAX MASS PER TRAY (kg)	MAX MASS PER ARTICLE (kg)
134°C POROUS	134	2.10	4	F	L	41'	525	0.8	Unpackaged porous material	**1.00**	0.30	0.30
									Porous material in single package	**0.75**	0.25	0.25
									Porous material in double package	**0.60**	0.20	0.20
									Solid material / handpieces in single package	**3.00**	1.00	0.25
									Solid material / handpieces in double package	**1.50**	0.50	0.25
121°C POROUS	121	1.10	20	F	L	56'	550	0.8	Unpackaged porous material	**1.00**	0.30	0.30
									Porous material in single package	**0.75**	0.25	0.25
									Porous material in double package	**0.60**	0.20	0.20
									Solid material / handpieces in single package	**3.00**	1.00	0.25
									Solid material / handpieces in double package	**1.50**	0.50	0.25
134°C HOLLOW	134	2.10	4	F	S	31'	525	0.7	Unpackaged handpieces	**6.00**	1.20	0.50
121°C HOLLOW	121	1.10	20	F	S	45'	550	0.7	Unpackaged handpieces	**6.00**	1.20	0.50
134°C WRAPPED	134	2.10	4	S	L	34'	300	0.6	Solid material in single package	**3.00**	1.00	0.25
121°C WRAPPED	121	1.10	20	S	L	48'	325	0.6	Solid material in single package	**3.00**	1.00	0.25
134°C SOLID	134	2.10	4	S	S	26'	300	0.5	Unpackaged solid material	**6.00**	1.20	0.50
121°C SOLID	121	1.10	20	S	S	40'	325	0.5	Unpackaged solid material	**6.00**	1.20	0.50
134°C EMERGENCY	134	2.10	3	S	S	16'	300	0.45	Unpackaged solid material	**0.50**	0.50	0.50
134°C or 121°C CUSTOM [4]	134 or 121	2.10 or 1.10	> 4 or > 20	F/S	L/S	56' (max)	550 (max)	0.9 (max)	Unpackaged solid material	**6.00 (max)**	1.20 (max)	0.50 (max)
BOWIE & DICK TEST	273	2.10	3,5	F	S	22'	-	-	Test pack only *(without any other load)*	-	-	-
VACUUM TEST	-	-0.80	-	-	-	22'	-	-	Empty chamber	-	-	-

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

INDICATION FOR USE

Table of the Available Programs MILLENNIUM B+ (temperature in °C and pressure in bar)

PROGRAM DESCRIPTION	Temperature (°C)	Pressure (bar relative)	Holding time (min)	Pre-vacuum [1] (F= fract.; S= single)	Standard drying [2] (L= long; S= short)	Total cycle time [3] (approx.)	Average H_2O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	TYPE OF LOAD	MAX TOTAL MASS (kg)	MAX MASS PER TRAY (kg)	MAX MASS PER ARTICLE (kg)
134°C POROUS	134	2.10	4	F	L	33'	525	0.8	Unpackaged porous material	1.00	0.30	0.30
									Porous material in single package	0.75	0.25	0.25
									Porous material in double package	0.60	0.20	0.20
									Solid material / handpieces in single package	3.00	1.00	0.25
									Solid material / handpieces in double package	1.50	0.50	0.25
121°C POROUS	121	1.10	20	F	L	48'	550	0.8	Unpackaged porous material	1.00	0.30	0.30
									Porous material in single package	0.75	0.25	0.25
									Porous material in double package	0.60	0.20	0.20
									Solid material / handpieces in single package	3.00	1.00	0.25
									Solid material / handpieces in double package	1.50	0.50	0.25
134°C HOLLOW	134	2.10	4	F	S	25'	525	0.7	Unpackaged handpieces	6.00	1.20	0.50
121°C HOLLOW	121	1.10	20	F	S	39'	550	0.7	Unpackaged handpieces	6.00	1.20	0.50
134°C WRAPPED	134	2.10	4	S	L	25'	300	0.6	Solid material in single package	3.00	1.00	0.25
121°C WRAPPED	121	1.10	20	S	L	39'	325	0.6	Solid material in single package	3.00	1.00	0.25
134°C SOLID	134	2.10	4	S	S	18'	300	0.5	Unpackaged solid material	6.00	1.20	0.50
121°C SOLID	121	1.10	20	S	S	32'	325	0.5	Unpackaged solid material	6.00	1.20	0.50
134°C EMERGENCY	134	2.10	3	S	S	12'	300	0.45	Unpackaged solid material	0.50	0.50	0.50
134°C or 121°C CUSTOM [4]	134 or 121	2.10 or 1.10	> 4 or > 20	F/S	L/S	48' (max)	550 (max)	0.9 (max)	Unpackaged solid material	6.00 (max)	1.20 (max)	0.50 (max)
BOWIE & DICK TEST	273	2.10	3,5	F	S	20'	-	-	Test pack only *(without any other load)*	-	-	-
VACUUM TEST	-	-0.80	-	-	-	18'	-	-	Empty chamber	-	-	-

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INDICATION FOR USE

Table of the Available Programs MILLENNIUM B^2 (temperature in °C and pressure in bar)

PROGRAM DESCRIPTION	Temperature (°C)	Pressure (bar relative)	Holding time (min)	Pre-vacuum [1] (F= fract.; S= single)	Standard drying [2] (L= long; S= short)	Total cycle time [3] (approx.)	Average H2O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	TYPE OF LOAD	MAX TOTAL MASS (kg)	MAX MASS PER TRAY (kg)	MAX MASS PER ARTICLE (kg)
134°C POROUS	134	2.10	4	F	L	43'	525	0.8	Unpackaged porous material	**1.25**	0.40	0.30
									Porous material in single package	**1.00**	0.30	0.25
									Porous material in double package	**0.75**	0.25	0.20
									Solid material / handpieces in single package	**4.00**	1.25	0.25
									Solid material / handpieces in double package	**2.00**	0.60	0.25
121°C POROUS	121	1.10	20	F	L	58'	550	0.8	Unpackaged porous material	**1.25**	0.40	0.30
									Porous material in single package	**1.00**	0.30	0.25
									Porous material in double package	**0.75**	0.25	0.20
									Solid material / handpieces in single package	**4.00**	1.25	0.25
									Solid material / handpieces in double package	**2.00**	0.60	0.25
134°C HOLLOW	134	2.10	4	F	S	35'	525	0.7	Unpackaged handpieces	**7.50**	1.50	0.50
121°C HOLLOW	121	1.10	20	F	S	50'	550	0.7	Unpackaged handpieces	**7.50**	1.50	0.50
134°C WRAPPED	134	2.10	4	S	L	32'	300	0.6	Solid material in single package	**4.00**	1.25	0.25
121°C WRAPPED	121	1.10	20	S	L	46'	325	0.6	Solid material in single package	**4.00**	1.25	0.25
134°C SOLID	134	2.10	4	S	S	25'	300	0.5	Unpackaged solid material	**7.50**	1.50	0.50
121°C SOLID	121	1.10	20	S	S	39'	325	0.5	Unpackaged solid material	**7.50**	1.50	0.50
134°C EMERGENCY	134	2.10	3	S	S	14'	300	0.45	Unpackaged solid material	**0.50**	0.50	0.50
134°C or 121°C CUSTOM [4] [5]	134 or 121	2.10 or 1.10	> 4 or > 20	F/S	L/S	58' (max)	550 (max)	0.9 (max)	Unpackaged solid material	**7.50 (max)**	1.50 (max)	0.50 (max)
BOWIE & DICK TEST	273	2.10	3,5	F	S	24'	-	-	Test pack only *(without any other load)*	-	-	-
VACUUM TEST	-	-0.80	-	-	-	18'	-	-	Empty chamber	-	-	-

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INDICATION FOR USE

Table of the Available Programs MILLENNIUM Bμ (temperature in °C and pressure in bar)

PROGRAM DESCRIPTION	Temperature (°C)	Pressure ($bar_{relative}$)	Holding time (min)	Pre-vacuum [1] (F= fract.; S= single)	Standard drying [2] (L= long; S= short)	Total cycle time [3] (approx.)	Average H_2O consumption (ml/cycle)	Average energy consumption (kWh/cycle)	TYPE OF LOAD	MAX TOTAL MASS (kg)	MAX MASS PER TRAY (kg)	MAX MASS PER ARTICLE (kg)
134°C POROUS	134	2.10	4	F	L	19'	200	0.6	Unpackaged porous material	0.30	0.30	0.30
									Porous material in single package	0.30	0.30	0.25
									Porous material in double package	0.30	0.30	0.20
									Solid material / handpieces in single package	1.00	0.50	0.25
									Solid material / handpieces in double package	0.50	0.25	0.25
121°C POROUS	121	1.10	20	F	L	34'	210	0.6	Unpackaged porous material	0.30	0.30	0.30
									Porous material in single package	0.30	0.30	0.25
									Porous material in double package	0.30	0.30	0.20
									Solid material / handpieces in single package	1.00	0.50	0.25
									Solid material / handpieces in double package	0.50	0.25	0.25
134°C HOLLOW	134	2.10	4	F	S	17'	200	0.6	Unpackaged handpieces	1.80	0.90	0.50
121°C HOLLOW	121	1.10	20	F	S	32'	210	0.6	Unpackaged handpieces	1.80	0.90	0.50
134°C WRAPPED	134	2.10	4	S	L	16'	125	0.5	Solid material in single package	1.00	0.50	0.25
121°C WRAPPED	121	1.10	20	S	L	31'	130	0.5	Solid material in single package	1.00	0.50	0.25
134°C SOLID	134	2.10	4	S	S	13'	125	0.4	Unpackaged solid material	1.80	0.90	0.50
121°C SOLID	121	1.10	20	S	S	28'	130	0.4	Unpackaged solid material	1.80	0.90	0.50
134°C EMERGENCY	134	2.10	3	S	S	9'	125	0.4	Unpackaged solid material	0.20	0.20	0.20
134°C or 121°C CUSTOM [4]	134 or 121	2.10 or 1.10	> 4 or > 20	F/S	L/S	34' (max)	210 (max)	0.7 (max)	Unpackaged solid material	1.80 (max)	0.90 (max)	0.25 (max)
BOWIE & DICK TEST	273	2.10	3,5	F	S	16'	-	-	Test pack only *(without any other load)*	-	-	-
VACUUM TEST	-	-0.80	-	-	-	16'	-	-	Empty chamber	-	-	-

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GENERAL NOTES

(1) **FRACTIONATED** = Pre-vacuum stage made by a sequence of 3 vacuum pulses + 3 pressure pulses.
"Fractionated vacuum cycles" are dedicated to the sterilization of porous materials or hand-pieces.

SINGLE = Pre-vacuum stage made by 1 vacuum + 1 pressure pulse.
"Single vacuum cycles" are dedicated to the sterilization of solid materials.

(2) **LONG** = Drying stage for porous material and/or hand-pieces and/or solid material in single/double package.
The validated **LONG** drying times (**STANDARD** option) are **16.5 min** for Millennium **B**, **12.5 min** for **B+**, **16.5 min** for **B^2** and **6 min** for **Bμ**.

The **EXTRA** and **INTELLIGENT** options have not been validated.

SHORT = Drying stage for unpackaged solid instruments and/or unpackaged hand-pieces.
The validated "**SHORT drying**" times (**STANDARD** option) are **7 min** for Millennium **B**, **6 min** for **B+**, **8 min** for **B^2** and **4 min** for **Bμ**.

The **FAST** option, having drying times of **2.5 min** for Millennium **B** (up to a load of **1.0 kg** max), **2 min** for **B+** (up to a load of **1.0 kg** max), **2.5 min** for **B^2** (up to a load of **1.0 kg** max) and **1.5 min** for **Bμ** (up to a load of **0.4 kg** max) has not been validated.

(3) The **Total Cycle Time** is only indicative.
It represents the time required for the completion of the entire program, from the cycle **START** to the cycle **END** and is calculated with a half-load within the chamber.

(4) The **134°C / 121°C CUSTOM** program has holding times of **4** minutes (or greater) and **20** minutes (or greater) respectively at 134°C and 121°C.
Pre-vacuum type and **Drying type** settable according to the indications given in the notes **(1)** and **(2)** above.

The **134°C / 121°C CUSTOM** program has not been validated.

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