

Electrostatic Filters & HMEFs

HYGROBAC

HYGROBAC S

HYGROBAC S-A

HYGROBOY

HYGROBABY

BARRIERBABY

BARRIERBAC

BARRIERBAC S

BARRIERBAC S-A



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Healthcare

DAR

The need for heat and moisture

In patients undergoing artificial ventilation, cold and dry respiratory gases remove heat and moisture from the airways, leading to a series of functional and anatomic alterations. In order to minimise the adverse consequences of these alterations during prolonged artificial ventilation, adequate humidification must be provided to intubated patients.

Passive heat and moisture exchangers (HMEs) represent a simple and effective way to replace one of the most important upper airway functions; they retain the heat and moisture of expired air and return it to the inspired gases. As the nasal cavities normally play a very active role in this conditioning, HMEs have also been called "artificial noses".



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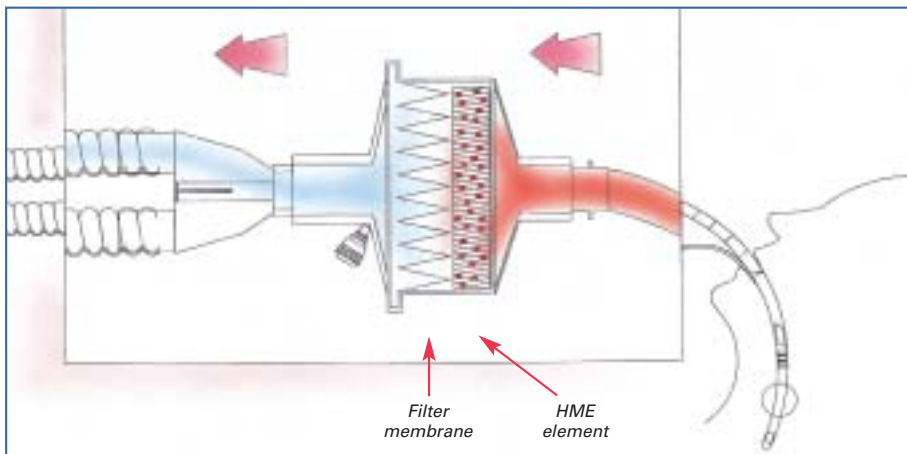
DAR

Humidification and filtration

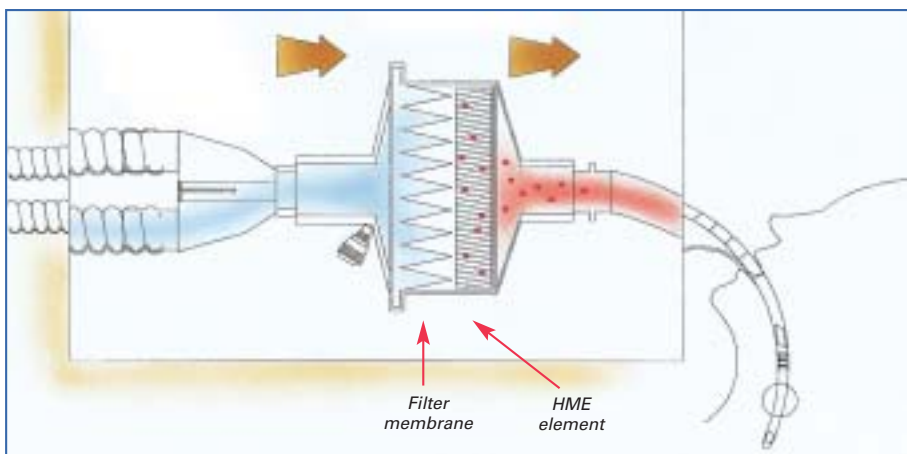
The best way to provide humidity and protect patient, medical staff and equipment from cross contamination risks is to combine an HME element with an efficient bacterial/viral

filter (HMEF). In this way, the gases administered to the patient are not only warmed and humidified, but the patient is also protected against microbial contamination.

The following diagrams illustrate how HMEFs work.



During expiration, the heat and water vapour coming from the patient are retained by the HME element.



During the following inspiration, heat and water are then available to warm and humidify the inspired gases.

DAR HMEFs are equipped with a cellulose humidifying element, specifically processed to maximise its surface area in contact with

the respiratory gases. This gives outstanding results in terms of HME performance.

The electrostatic filter membrane



The filter membrane is made of a hydrophobic non-woven polypropylene material, the fibres of which have a permanent bipolar electrical charge induced upon them during manufacture. The mechanism of electrostatic filtration can be likened to magnetism, with opposites attracting each other.

Each fibre (see above) has a bipolar charge positive (+) on one side and negative (-) on the other.

Bacteria and viruses have a superficial electrical charge and these are attracted to oppositely charged sites on the fibres and trapped within the filter membrane.

DAR was the first manufacturer to develop an

efficient HMEF by coupling a high moisture output element with an electrostatic filter membrane.

The name of this device is **Hygrobac**.

From this first and innovative product, DAR has developed a series of products that define the state-of-the-art in the field of heat and moisture exchange technology.

An important aspect of the DAR product line is the diversification of the HME/filter models to suit the end-user requirements.

The DAR range of HMEFs has been tailored to meet the specific needs of both anaesthesia and intensive care.



Quality Assurance and Control

The DAR range of electrostatic filter and HMEFs combines innovation and efficiency with exceptional reliability, the result of excellent design and high standards of quality control.


The DAR Quality System meets all recognised quality assurance standards. The control procedures are perfectly consolidated and the personnel assigned to such procedures have acquired a truly unique experience.

DAR Quality System procedures involve an extensive series of controls in every stage of electrostatic filter production.

Besides the frequent controls made on raw materials, on semi-finished and finished products, each filter undergoes integrity testing at a pressure of 100 cm H₂O in order to detect any leaks or weak points.

The devices, manufactured and packaged in stringently controlled clean rooms, undergo a sterilisation process ensuring extremely high and reliable (SAL, Sterility Assurance Level >10⁶) sterility standards for each production lot.

Finally, further packaging tests ensure these products remain sterile and maintain performance and functionality for the entire period of validity printed on the packaging.

DAR medical devices bear the  Mark according to MDD 93/42/EEC (European Council Directive concerning CE marking of medical devices), which allows their free circulation in the EEC. DAR products are

manufactured and released according to the Company's procedures, under the control of the implemented Quality System.

The MALLINCKRODT DAR Quality System complies with recognised quality management and quality assurance standards: it is certified according to EN ISO 9001 & EN 46001 (Cert. Q1 98 11 22524 011, dtd. 26/11/98), ISO 9001 & ISO 13485 (Cert. Q1 98 11 22524 010, dtd. 26/11/98), Annex II.3 (Cert. G1 98 11 22524 009, dtd. 26/11/98) and Annex V (Cert. G2S 98 11 22524 008, dtd. 26/11/98); furthermore, the manufacturing facilities are regularly inspected by USA/FDA and by EC/TÜV p.s. (acting as MDD Notified Body #0123 and Quality System Certification Body).



Test Centers

The filtration efficiency of DAR Filters and HMEFs has been tested by independent laboratories, in order to prove their efficiency with recognised testing procedures (see references).

	Filtration efficiency (%) Airborne particles (Bacterial = B - Viral = V)	Filtration efficiency (%) Liquid borne particles
Hygrobac	Data from Nelson Lab. >99.99 Staphylococcus aureus (B) ¹ >99.99 Bacteriophage Φx174 (V) ² Data from Institut Fresenius³ >99.999 Pseudomonas aeruginosa (B) >99.99 Staphylococcus aureus (B) Data from Borghi >99.99999 Staphylococcus rosaceus (B) ⁴ >99.999 MS-2 bacteriophage (V) ⁵ 99.99999 HSV (V) ⁶ Data from Hygiene-Institut der Universität Graz⁷ >99.999 Micrococcus luteus (B) Data from Holton/Webb⁸ >99.999 Serratia marcescens (B) >99.99 Bacteriophage MS-2 (V)	Data from CAMR⁹ 100% Hepatitis C Virus Filter prevents transfer of HCV
Hygrobac S Hygrobac S-A	Data from Nelson Lab. >99.99 Staphylococcus aureus (B) ¹⁰ >99.99 Bacteriophage Φx174 (V) ¹¹ Data from Institut Fresenius¹² >99.997 Pseudomonas aeruginosa (B) >99.9 Staphylococcus aureus (B) Data from IKI¹³ 100% Mycobacterium tuberculosis (B)	Data from CAMR 100% Hepatitis C Virus ¹⁴ Filter prevents transfer of HCV 100% HIV-1 ¹⁵ Filter prevents passage of HIV-1
Hygroboy	Data from Institut Fresenius¹⁶ >99.999 Pseudomonas aeruginosa (B) >99.998 Staphylococcus aureus (B) Data from Borghi >99.9997 Staphylococcus rosaceus (B) ⁴ >99.997 Micrococcus luteus (B) ¹⁷ >99.997 MS-2 bacteriophage (V) ¹⁷	
Hygrobaby Barrierbaby	Data from Institut Fresenius¹⁸ >99.996 Pseudomonas aeruginosa (B) >99.995 Staphylococcus aureus (B) Data from Borghi >99.9998 Staphylococcus rosaceus (B) ⁴ >99.999 Micrococcus luteus (B) ¹⁷ >99.994 MS-2 bacteriophage (V) ¹⁷	
Barrierbac	Data from Nelson Lab. >99.99 Staphylococcus aureus (B) ¹⁹ >99.99 Bacteriophage Φx174 (V) ²⁰ Data from Borghi >99.9999 Staphylococcus rosaceus (B) ^{4 5} >99.997 MS-2 bacteriophage (V) ⁵ >99.9999 HSV ⁶	
Barrierbac S Barrierbac S-A	Data from Nelson Lab. >99.99 Staphylococcus aureus (B) ²¹ >99.99 Bacteriophage Φx174 (V) ²²	Data from CAMR²³ 100% Hepatitis C Virus Filter prevents transfer of HCV

Note: For references 1-23 see backpage.

Hygrobac

Hygrobac offers a high level of microbial filtration for patient and staff safety and an exceptional moisture output for effective airway humidification.

The resistance to air flow is low, for safe use in any ventilation technique.

Bacterial Filtration Efficiency (BFE)*	>99.999%
Viral Filtration Efficiency (VFE)**	>99.9999%

Moisture output ***

Tidal Vol.	2 hrs	24 hrs
VT 250 ml	33.9 mg/l	33.0 mg/l
VT 500 ml	33.3 mg/l	32.7 mg/l
VT 1000 ml	32.4 mg/l	31.8 mg/l

Temperature output ***

Tidal Vol.	2 hrs	24 hrs
VT 250 ml	32.0°C	31.9°C
VT 500 ml	32.1°C	31.8°C
VT 1000 ml	32.2°C	31.9°C

Relative Humidity during inspiration phase****

92 - 98% at 32°C

Resistance to flow after 24 hrs use ***

at 30 l/min	0.9 cm H ₂ O
at 60 l/min	2.1 cm H ₂ O
at 90 l/min	3.5 cm H ₂ O

Compressible Volume ***

Weight	50 g
Type of filtration	Electrostatic
Filtration surface	43 cm ²
Connections	22M/15F - 22F/15M ISO Luer-lock capnograph port

Single use

Not to be cleaned, sterilised and/or reused

Sterile

Sterilised by ETO

Max. sterile life

5 years

Recommended use

single-patient only

Recommended cycle

Intensive Care:

up to 24 hrs

Anaesthesia:

single-patient

*Institut Fresenius, Ref. 94TM109210, 12 Dec. 1994.

Borghì V. et al., "Bacterial removal efficiency of Filters-HME for anaesthesia and intensive care in 24-hour tests", Acta Anaesth. Italica, 43, Suppl. 1, 93-97, 1992.

"Comparative evaluation of the bacteria and virus removal efficiency of filters used in anaesthesia and intensive care", Acta Anaesth. Italica, 1990.

**Borghì V. et al., "Efficiency of virus remotion in Barrierbac and Hygrobac filters membrane by Darex", 1988.

***Wilkes T., Technical Evaluation Report No. 930001, University of Wales College of Medicine, Cardiff, 1993.

****Conti G. et al., Acta Anaesth. Italica 1988, 4, 39:417-421.

Hygrobac S Hygrobac S-A

Combining a good filtration efficiency and moisture output with a reduced dead space, Hygrobac S is the filter/HME of choice in most cases. Available in a number of pre-assembled configurations.

It is now also available in an angled version.

Bacterial Filtration Efficiency (BFE)*	>99.99%
Viral Filtration Efficiency (VFE)*	>99.99%

Moisture output **

Tidal Vol.	2 hrs	24 hrs
VT 250 ml	31.4 mg/l	31.3 mg/l
VT 500 ml	30.6 mg/l	30.7 mg/l
VT 750 ml	30.1 mg/l	30.2 mg/l
VT 1000 ml	29.3 mg/l	29.2 mg/l

Temperature output **

Tidal Vol.	2 hrs	24 hrs
VT 250 ml	31.0°C	31.0°C
VT 500 ml	30.9°C	31.2°C
VT 750 ml	30.6°C	30.4°C
VT 1000 ml	30.2°C	30.1°C

Relative Humidity during inspiration phase

92 - 98% at 31°C

Resistance to flow (ISO 9360)

at 30 l/min	1.0 cm H ₂ O
at 60 l/min	2.5 cm H ₂ O
at 90 l/min	4.7 cm H ₂ O

Compressible Volume (ISO 9360)

45 ml

Weight

30 g

Type of filtration

Electrostatic

Filtration surface

23 cm²

Moisture exchange surface

>1100 cm²

Connections

22M/15F - 22F/15M ISO

Single use

Luer-lock capnograph port
Not to be cleaned, sterilised and/or reused

Sterile

Sterilised by ETO

Max. sterile life

5 years

Recommended use

Single-patient only
(> 20 kg)

Recommended cycle

Intensive Care:

up to 24 hrs

Anaesthesia:

single-patient

*Nelson Laboratories Inc. - Salt Lake City, USA.

**ISO draft 9360 test method.



Hygrobac



Hygrobac S



Hygrobac S-A

Hygroboy



Hygroboy



Hygrobaby / Barrierbaby

Hygroboy is a small volume filter for use on children.

It offers the same advantages of higher volume HMEFs, but the reduced dead space makes it suitable for use on paediatric patients.

Bacterial Filtration Efficiency (BFE)*
>99.99%

Viral Filtration Efficiency (VFE)**
>99.99%

Moisture output
2 hrs
VT 250 ml 32.3 mg/l

Temperature output
2 hrs
VT 250 ml 31.6°C

Relative Humidity during inspiration phase
93 ÷ 97% at 32°C

Resistance to flow
at 10 l/min 0.6 cm H₂O
at 15 l/min 1.0 cm H₂O
at 20 l/min 1.4 cm H₂O

Compressible Volume (ISO 9360) 26 ml
Weight 21 g
Type of filtration Electrostatic
Filtration surface 19 cm²
Connections 22M/15F - 22F/15M ISO Luer-lock capnograph port
Single use Not to be cleaned, sterilised and/or reused
Sterile Sterilised by ETO
Max. sterile life 5 years
Recommended use Single-patient only (VT 75-300 ml)

Recommended cycle
Intensive Care: under clinician's judgement, up to 24 hrs
Anaesthesia: single-patient

*Institut Fresenius, Examination of the breathing system filter Hygroboy concerning the efficiency in bacteria retention, (Report 93/08696-00), 1993.

Borghì V. et al., Bacterial Removal Efficiency of Filters/HME for Anaesthesia and Intensive Care in 24-hour tests, Acta Anaesth. Italica, 43, Suppl. 1, 93-97, 1992.

Borghì V., Report on tests on bacteria and virus retention capacity of the Hygroboy and Hygrobaby filters, 1993.

**Borghì V., Report on tests on bacteria and virus retention capacity of the Hygroboy and Hygrobaby filters, 1993.

Hygrobaby Barrierbaby

Hygrobaby is a simple and effective solution in patients with a tidal volume between 25-100 ml, undergoing short term intubation. It eliminates risks of cross contamination and allows the use of a simple breathing system. Barrierbaby is the electrostatic filter version of Hygrobaby, specifically designed for short anaesthesia treatments.

Bacterial Filtration Efficiency (BFE)*
>99.99%

Viral Filtration Efficiency (VFE)**
>99.99%

Moisture output
VT 25 ml 27.7 mg/l
VT 50 ml 27.5 mg/l

Temperature output
30.2°C

Resistance to flow (cm H ₂ O)	Hygrobaby (***)	Barrierbaby (****)
at 5 l/min	0.7	0.6
at 7.5 l/min	1.2	0.9
at 10 l/min	1.9	1.3

Compressible Volume (ISO 9360)
10 ml 10 ml

Weight 9 g 8 g

Type of filtration Electrostatic
Filtration surface 10 cm²
Connections 8M/15M-15F ISO Luer-lock capnograph port
Single use Not to be cleaned, sterilised and/or reused
Sterile Sterilised by ETO
Max. sterile life 5 years
Recommended use Single-patient only (VT 25-100 ml)

Recommended cycle
Intensive Care: under clinician's judgement, up to 24 hrs
Anaesthesia: single-patient

Institut Fresenius, Examination of the breathing system filter Hygrobaby concerning the efficiency in bacteria retention, November 12th, 1993.

Borghì V. et al., Bacterial Removal Efficiency of Filters/HME's for Anaesthesia and Intensive Care in 24-hour tests, Acta Anaesth. Italica, 43, Suppl. 1, 93-97, 1992.

**Borghì V., Report on tests on bacteria and virus retention capacity of the Hygroboy and Hygrobaby filters, 1993.

***MDA, Evaluation No 276, Heat and Moisture Exchangers: DAR Hygrobaby, DAR Hygroboy and DAR Hygrobac, April 1996.
****Internal test report (ISO standard).

Barrierbac

Barrierbac S Barrierbac S-A

When a simple and efficient filter is needed, Barrierbac and Barrierbac S are cost effective solutions. They differ only in size and their round shape makes handling easier and minimises the risk of patient harm. They are an excellent choice for short term anaesthesia treatments.

Barrierbac S is now also available in an angled version.

Bacterial Filtration Efficiency (BFE)*	>99.999%
Viral Filtration Efficiency (VFE)**	>99.9999%
Resistance to flow (ISO 9360)	
at 30 l/min	0.65 cm H ₂ O
at 60 l/min	1.55 cm H ₂ O
at 90 l/min	2.80 cm H ₂ O
Compressible Volume (ISO 9360)	99 ml
Weight	35 g
Type of filtration	Electrostatic
Filtration surface	43 cm ²
Connections	22M/15F - 22F/15M ISO
Single use	Not to be cleaned, sterilised and/or reused
Sterile	Sterilised by ETO
Max. sterile life	5 years
Recommended use	At inspiratory and expiratory ports of ventilators. Patient side circuit.
Recommended cycle	
Equipment side:	up to 24 hrs
Anaesthesia:	single-patient

Bacterial Filtration Efficiency (BFE)*	>99.99%
Viral Filtration Efficiency (VFE)*	>99.99%
Resistance to flow (ISO 9360)	
at 30 l/min	0.7 cm H ₂ O
at 60 l/min	1.8 cm H ₂ O
at 90 l/min	3.6 cm H ₂ O
Compressible Volume (ISO 9360)	35 ml
Weight	19 g
Type of filtration	Electrostatic
Filtration surface	23 cm ²
Connections	22M/15F - 22F/15M ISO
Single use	Not to be cleaned, sterilised and/or reused
Sterile	Sterilised by ETO
Max. sterile life	5 years
Recommended use	
straight version	At inspiratory and expiratory ports of ventilators
angled version	Only patient side
Recommended cycle	
Equipment side:	up to 24 hrs
Anaesthesia:	single-patient



Barrierbac



Barrierbac S



Barrierbac S-A

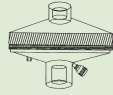
*Borghi V. et al., "Bacterial removal efficiency of Filters-HME for anaesthesia and intensive care in 24-hour tests"; Acta Anaesth. Italica, 43, Suppl. 1, 93-97, 1992.

**Comparative evaluation of the bacteria and virus removal efficiency of filters used in anaesthesia and intensive care"; Acta Anaesth. Italica, 1990.

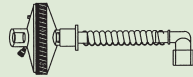
**Borghi V. et al., "Efficiency of virus remotion in Barrierbac and Hygrobac filters membrane by Darex"; 1988.

*Nelson Laboratories Inc. - Salt Lake City, USA.

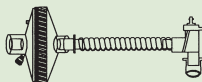
Hygrobac



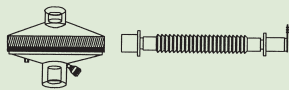
Connections	REF	Pack	Note
22F/15M-22M/15F	352/5411	25	with CO ₂ port
22F/15M-22M/15F	352/5805	25	with CO ₂ port



Connections	REF	Pack	Catheter/Connector	Note
22F/15M-22M/15F	352/5802	25	330/5109	inserted



Connections	REF	Pack	Catheter/Connector	Note
22F/15M-22M/15F	352/5811	25	331/5390	inserted



Connections	REF	Pack	Catheter/Connector	Note
22F/15M-22M/15F	352/5836	25	332/5666	catheter with red cap

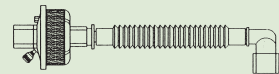
Hygrobac S



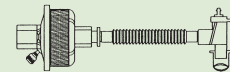
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22F/15M-22M/15F	352/5877	25	with CO ₂ port



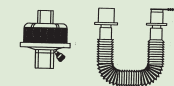
Connections	REF	Pack	Note
22F/15M-22M/15F	352/5996	25	with CO ₂ port



Connections	REF	Pack	Catheter/Connector	Note
22F/15M-22M/15F	352/5978	25	330/5337	inserted



Connections	REF	Pack	Catheter/Connector	Note
22F/15M-22M/15F	352/5893	25	331/5661	inserted

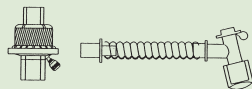


Connections	REF	Pack	Catheter/Connector	Note
22F/15M-22M/15F	352/5855	25	332/5666	catheter with red cap

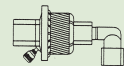
Hygroboy



Connections	REF	Pack	Note
22F/15M-22M/15F	355/5430	25	with CO ₂ port





Connections	REF	Pack	Catheter/Connector	Note
22F/15M-22M/15F	355/5814	25	331/5353	

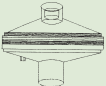
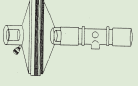


Connections	REF	Pack	Catheter/Connector	Note
22F/15M-22M/15F	355/5884	25	620/5173	inserted




Note: All the above products are supplied sterile.

	Connections	REF	Pack	Note	
	8M/15M-15F	355/5427	25	with CO ₂ port	
	Connections	REF	Pack	Catheter/Connector	Note
	8M/15M-15F	355/5916	50	adapter 22m	inserted reducer

Hygrobaby

	Connections	REF	Pack	Note	
	22F/15M/15F	350/5865	25	without CO ₂ port	
	Connections	REF	Pack	Note	
	22F/15M-22M/15F	350/5422	25	with CO ₂ port	
	Connections	REF	Pack	Catheter/Connector	Note
	22F/15M-22M/15F	350/5924	25	608/5093	inserted

Barrierbac

	Connections	REF	Pack	Note	
	22F/15M/15F	350/5845	25	with CO ₂ port	
	Connections	REF	Pack	Note	
	22F/15M-22M/15F	350S19006	25	with CO ₂ port	
	Connections	REF	Pack	Note	
	22F/15M-22M/15F	350/5879	25	with CO ₂ port	
	Connections	REF	Pack	Catheter/Connector	Note
	22F/15M-22M/15F	350/5882	25	332/5666	catheter with red cap
	Connections	REF	Pack	Catheter/Connector	Note
	22F/15M-22M/15F	350/5420	25	620/5173	inserted

Barrierbac S

	Connections	REF	Pack	Note
	8M/15M-15F	350/19003	25	with CO ₂ port

Barrierbaby

Note: All the above products are supplied sterile.

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- 1) Nelson Laboratories Inc. – Salt Lake City, USA, Rep. No. 52694, 28 July 1993
- 2) Nelson Laboratories Inc. – Salt Lake City, USA, Rep. No. 52695, 26 July 1993
- 3) Institut Fresenius – Chemische und Biologische Laboratorien GmbH – Taunusstein-Neuhof, Germany, Ref. 94TM109210, 12 Dec. 1994
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- 14) CAMR, Centre for Applied Microbiology and Research – Porton Down, UK, Rep. No. 569/99, 16 Aug. 1999
- 15) CAMR, Centre for Applied Microbiology and Research – Porton Down, UK, Rep. No. 608A/99, Re-issued 22 June 2000
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