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Test method for the microbial barrier properties of packaging for medical devices; RIVM-method

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PREFACE

The authors wish to thank:
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ABSTRACT

One of the most important qualities of packaging for medical devices is the ability to keep the contents sterile. The quality of the packaging is determined by the quality of the material and the quality of the seals. The former is usually tested with test methods using micro-organisms.
In hospitals many packages are formed by wrapping instrument trays in sheet material. The seals are formed by folding the sheet material several times. There is however no standard test method available to test the quality of these kind of seals. The same problem occurs with container packaging system. The filters or valves can be tested with a microbial challenge, but not the complete unit.

In 1990 the RIVM developed a physical test method. In contrast to existing testmethods, which only test the barrier properties of a sample of the material, the RIVM method is capable of testing all aspects of a pack which influence the barrier properties of the pack after the pack is formed, sealed and sterilized.
The initial method was not very accurate and had a poor reproducibility. The method has now been modified.
This study shows that the modified RIVM method is both accurate and reproducible.

SAMENVATTING

Een van de belangrijkste kwaliteiten van verpakkingen voor medische hulpmiddelen is de mogelijkheid tot het bewaren van de steriliteit van de inhoud. De kwaliteit van de verpakking wordt bepaald door de kwaliteit van de materialen en de naden. De eerste wordt vaak bepaald door middel van testmethoden waarin micro-organismen worden gebruikt.
In ziekenhuizen worden veel verpakkingen gemaakt door instrumentennetten te verpakken in vellen materiaal. De naden worden gesloten door de vellen een aantal malen in elkaar te vouwen. Er bestaat echter geen standaard testmethode om de kwaliteit van dit soort naden te testen. Het zelfde probleem treed op bij containers. De filters of kleppen kunnen wel getest worden met een micro-biologische methode, echter niet de gehele container.

In 1990 is door het RIVM een fysische testmethode ontwikkeld. In tegenstelling tot de bestaande testmethoden, waarin slechts een monster van het materiaal wordt getest, is de RIVM methode in staat om alle aspecten te bepalen die de kwaliteit van een verpakking bepalen. Dit nadat de verpakking is gemaakt, gesloten en gesteriliseerd.
De oorspronkelijke methode bleek echternochnauwkeurig, noch reproduceerbaar te zijn. De methode is nu aangepast.
Dit onderzoek toont aan dat de gewijzigde RIVM methode zowel nauwkeurig als reproduceerbaar is.

1. INTRODUCTION

One of the most important purposes of the packaging of a medical device is to prevent the ingress of micro-organisms to the medical device in order to maintain the sterility of the medical device. A number of parameters determine the effectivity of the packaging as a microbial barrier. Apart from the material itself the seals are an important factor whether they are formed by thermal fusion, adhesive fusion or folding of layers. The micro biological barrier properties of packaging for medical devices are in general tested by complicated testing methods on a piece of the packaging material. The available testing methods are either physical (determination of the porosity of a sample of the wrapping material) or microbiological (determination of the bacterial spore retention of a sample of the wrapping material). The major disadvantage of these methods is that they are not general applicable because only the barrier properties of a sample of the wrapping material is tested. At this moment there is no test method available to test barrier properties of permeable seals e.g. seals formed by folding layers of sheet material.
The existing test methods for sheet materials do not take into consideration the possible influences of the forming of the pack and sterilisation on the quality of the material.
According to the draft european norm (EN 868) all the parameters must be tested separately. However the only testmethods which are available at this moment are for the determination of the microbial properties of sheet material.
In opinion of the RIVM the testing of the packaging concept is best done by testing the complete pack after it is formed, sealed and sterilized. Since test methods for seals formed by folded sheet material are not available, the only way to test the barrier properties of a packaging is by use of a final pack test. The result of this test gives the sum of the barrier properties of the material and the seals after forming and sterilization and therefore a value for the quality of the design of the total pack.
The first configuration and results of the final pack test method is described in RIVM-report 919000 001, June 1990. As a result of the comments made by CEN TC102 wg4 the test method was altered and research was done by Wagner RIVM and LNE (RIVM report 319011007). The "new approach" proved to give some advantages but in general showed to give the same problems as the original test method. The need for a special test chamber and dust challenge made the performance of the test even harder. Therefore it was decided by the RIVM to improve the original test method on all points it was commented upon, especially the reproducibility.

1.1. Principle of the test method.

In air micro-organisms may occur in the form of free units or be borne on dust particles or in aerosols. Since under proper storage and transport conditions sterilized materials will not be challenged with droplets the packaging of the medical device shall form a microbial barrier shall prevent the penetration of dry particles.
The ability of the pack to prevent the penetration of particles depends on a number of factors:

a. Quality of the packaging material and/or filters
b. Quality of the seals and/or closures
c. The airflow through the permeable parts of the pack.
d. The number of particles challenging the pack

Factor a. is mostly determined by the specifications of the material used. However the material specification may be altered during the process of forming and sealing of the pack. The material may be stretched resulting in a larger pore size or be damaged during handling.
Factor b. is dependent on both the design of the seal and/or closure as well as on the forming of the seal and/or closing of the system. In many applications sheet material is folded to form a seal (the main packaging method in hospitals) thus the wrapping method may be of great influence.
Factor c. depends on the pressure difference which might occur during the shelf life of the pack (from the unloading of the sterilizer to the moment of use) and of the area of the permeable parts. In case of a small permeable area on relative large pack one may find large airflows. The largest pressure difference and therefore airflow through the permeable parts occurs immediately after sterilization when the pack is unloaded from the sterilizer and the pack is allowed to cool down. The airflow can be determined by measuring the temperature drop per time and calculating the volume contraction of air inside. In theory the maximum airflow will be very large for a very small time. In order to obtain a realistic value the temperature drop over the first minute is used.
Factor d. is only dependent on the challenge during the cooldown period and the shelflife. During the test the natural challenge in the laboratory is used.

The principle of the test method is uncomplicated. The packaging shall prevent the penetration of particles when the surrounding air is entering the pack. If the air that enters the pack is passed through a particle counter, the count should, in case of a ideal packaging concept, go down to zero. In practice none of the available packaging concepts is an absolute particle barrier. A fraction of the particle challenge passes through the barrier. If the challenge is known the filtering effectivity of the pack can be calculated and expressed as a numeric value. The sample volume of the particle counter is adapted to create an airflow as calculated from the temperature drop.
For the test procedure it is not relevant whether the air is sampled from a container, a sheet-wrapped wiremesh tray, a paper bag or pouch wrapped tray. The test method can be used for all air permeable final packs.

1.2. Comments.

After publication of the report the work of the RIVM was evaluated by CEN TC102 wg4 (packaging materials) and a number of comments were given. A summary of the major comments is given below. The authors of the report also recognized a number of points which needed to be addressed in order to improve the reproducibility of the test method. Based on the comments proposals for modifications in the test method were made. Evaluation of the proposed modifications are given in clause 3.
The modifications that led indeed to improvement of the test method are processed in the final test protocol (annex 7).
In the text below the comments on the initial setup are marked with a "-", the solution to the problem is marked with a "+".

1.2.1. Hardware:

The test results were found to depend on:

- The material of the tubes used for sampling the air.
- The length of the tubes.
- The crookedness (curvature) of the tubes.

+ The material, the length and the configuration of the tubes standardized in the test. Figure 2.1. shows the configuration of the tubing. Tube A is PVC transparent, length 50 cm. Tube B is polyethylene, diameter 6 mm, length 40 cm. All other tubes carry only particle free air. Specifications are therefore not critical.

1.2.2. The counters:

- It was found to be necessary to have both counters sampling the same amount of contaminated air, because the method to sample 100% contaminated air with the outside measuring counter and only 10% mixed with 90% clean air with the inside measuring counter and then "correct" the values manual by multiplying the value of the inner counter by 10 (to obtain comparable figures relating to the same sampled volume again) was found to produce non repeatable results, especially with low contamination levels.
- Concerning the exactness of the measurement: the used counters comply to the US Federal Standard 209 C. Appendix B of this Standard "Operation of optical particle counters" refers to calibration, system Limitations, inter instrument correlations and the allowed tare: a tare of 10% is allowed for the result when a calibrated counter measures a certain, known contamination.
  This means that two counters measuring one and the same air quality may show the result ±10% of the real value.

+ The problems can be solved by:
  a. Determining the "no-material effectivity" of the system. This is the effectivity of the total system, including tubing and the difference in particle counter calibration.
  b. Repeat the measurement on the test-object with switched counters. (The counter used for the measurement of outside contamination in the first setup is used for the measurement of the particles from the pack and vice versa.)
  The effectivity values found in both counter configurations will be different. The average value is considered to be the correct effectivity value.

+ The difference in calibration between the two counters exists and cannot be solved by re-calibration of the counters. It is not possible to calibrate both counters to exact the same value. With both counters having a inaccuracy of 10% the result of the measurement leads to a fault of 2% on a calculated effectivity of 90%. The fault gets smaller when the effectivity of the barrier becomes larger.

1.2.3. Reproducibility:

- It was found that a contamination peak outside needs typically 20-30 minutes until it was fully registered inside (depending on the material). This means that the calculation of the effectivity is based on wrong figures, as the high outside count is compared to a still low inside count or, later, when the outside count went down again, it is compared to a still high inside count. Therefore the effectivity diagrams are unsteady (annex 2). For the above reason, a statistical/mathematical interpretation of the results is not possible: it must be judged on a subjective basis, so that it is definitely necessary to define the criterias for interpretation of the figures (as otherwise no reproducible results will be found).

- In some cases, the judgement of the effectivity was hard to do, as the effectivity showed a breakdown to rise during the test period (annex 1).
+ The data from the particle counters is no longer processed into a graph which is indeed hard to interpret. Instead the data from each measurement are calculated to the filter effectivity value of the pack. A normal test period gives hundred values for the effectivity which is calculated in each case from measurements taken during ten minutes. The hundred effectivity values are averaged and the standard deviation is calculated. Strong fluctuations in the outside count lead to a high standard deviation value. The result can be smoothed by elimination of count values that deviate from the average value by more than 3-sigma.
  To lose the influence of the delayed penetration into the pack the average effectivity can be also calculated from the total number of counted particles inside and outside of the pack, during the 100x10 minutes test period. In theory the average value and the value based on total count may not differ from each other.

- As a general requirement it is desirable to create and maintain a high level of contamination without rapid changes over several hours, otherwise the results may not be judged correctly.
+ The room in which the tests are performed at RIVM is connected to the central air conditioning unit. As long as there is no activity in the lab the fluctuation in the amount of particles is small. Measurements are performed during nighttime (no activity) as well as during day time (varying activity).

1.2.4. Test duration
- In any case it was necessary to run the test on a pack for several hours. Shorter sampling time led to too much varying results.
+ If the test conditions are controlled to give high contamination levels and with little fluctuation (no activity in the test room) one test session may be performed in two hours. When using four measurements a pack may be evaluated in one working day.

1.2.5. Test conditions:
- As a reduction of the sampling flow was found to produce a higher effectivity on the other hand, the question of a realistic airflow should be discussed, as it is a very important parameter, which certainly shall represent a worst-case situation on the one side but should not be too far away from reality on the other side.
- The tubing with an internal diameter of 6 mm already caused a hindrance for particles in sense of keeping them on surfaces due to too low flow speed and therewith avoid registration by the counter. It is likely that the same effect will also occur in a test pack with 1 sqm inner surface; a number of particles will penetrate inside the pack but will not be registered.
+ The method is only suitable to detect the entrance of air-borne particles into a test pack. Up to a diameter of 1 um particles are considered to be air-borne
+ To prevent the settlement of particles in the tubing when coming from the test object the flow must be as high as possible. On the other hand the flow from the test object must be set to the value that equals the worst case flow, for example when the object is cooling down after sterilisation. This is usually only part of the flow at which the counters are calibrated. The length of tubing in which the

airspeed is low is reduced to a minimum as is shown in figure 2.1. Only in the part that sticks in the test object the speed is relatively low. This part is however only 7 cm long and is not curved. The flow through particle counter 2 (PC2) is set at the value at which the counter is calibrated. The flow from the test object is a fraction of the flow through the particle counter (for example 25%). At the T-junction under the test object HEPA-filtered air (flow = 75% of the flow through the counter) is mixed with the air from the test object to give a flow of 100% to the particle counter. In this manner the flow in the tubing B is maximum and the change for particle to settle reduced to a minimum.

1.2.6. Points that need to be considered as mentioned in the first report.

- The calibration of the airflow through the particle counter. Is it considered to adequate or is extra airflow measurement required?
+ The airflow through the counters and at the mixing point at the test object must be maintained on a constant value throughout the measuring period. In the first test configuration the air from the test object was set with a manual controlled valve. The flow proved to be not constant, it was necessary to re-adjust the flow periodical.
  In the set up as described in this all flows are controlled by electronic mass flow controllers. The flow through the counters is set at the value at which the counters are calibrated.

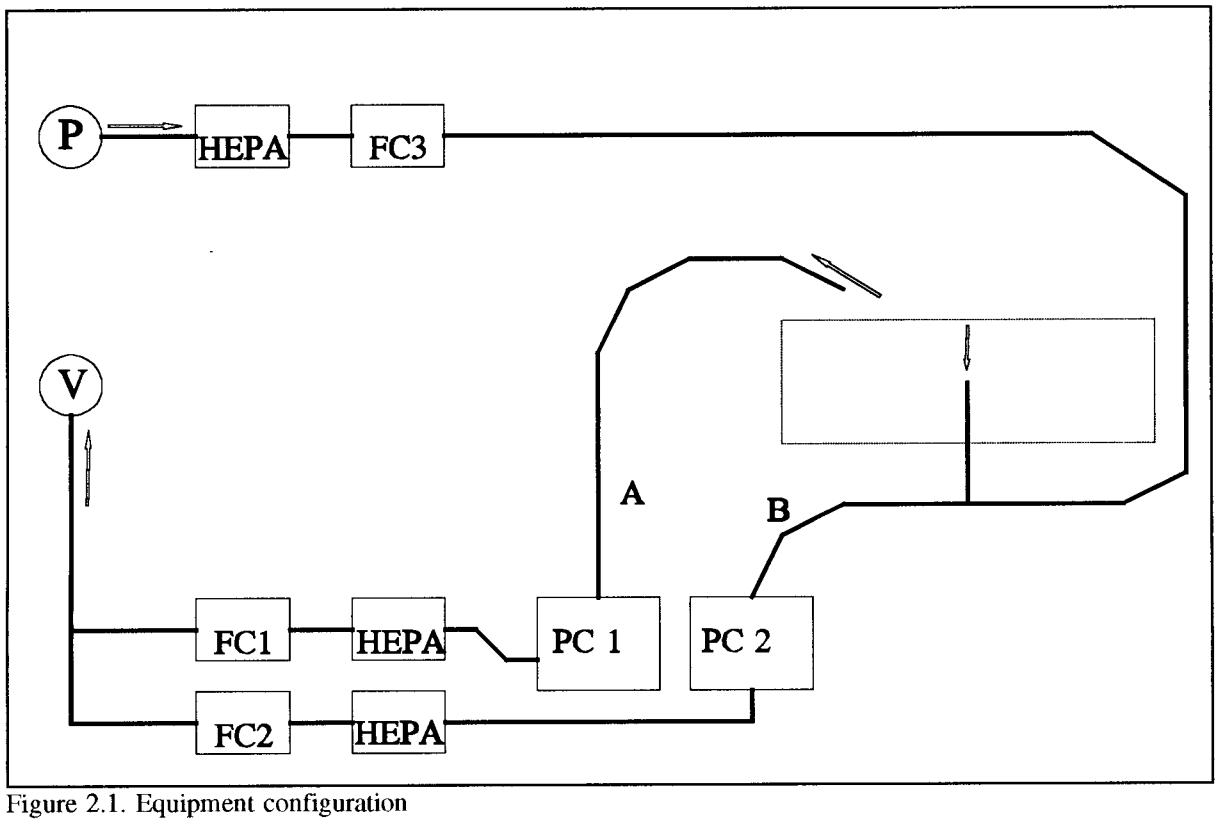


Figure 2.1. Equipment configuration

2. MATERIALS AND METHODS

2.1 Materials.

2.1.1. Two optical particle counters (fig. 2.1.; PC1 and PC2), capable to count particles > 0.5 um. (Met-One 217A)
2.1.2. Three HEPA-filters (fig 2.1.; HEPA). (Pall DFA 3001 V002PV 0.2 um)
2.1.3. Tube A: PVC tubing, transparent, internal diameter 6 mm, length: 50 cm.
Tube B: PE tubing with an internal diameter of 6 mm to connect the counter with the test object.
2.1.4. T-piece to connect the pressure line and counter line to the test object. The T-piece must be fitted with a metal tube, internal diameter 3 mm, of such a length that it fits half the height of the test object (55 mm for the standard test object).
2.1.5. Compressor/reduction valve assembly (fig. 2.1.; P) capable of producing a pressure of 160 kPa at a flow of 3 litres/minute.
2.1.6. Vacuumsystem (fig. 2.1.; V) capable of producing a pressure of 50 kPa at a flow of 6 litres/minute.
2.1.7. Standard test object being an instrument tray 580x245x110mm: volume 0.55 ft^3. When testing real final packs, this standard test object is replaced by the pack to be tested.
2.1.8. Suitable connectors to fit the T-piece on the test object. The T-piece must be inserted into the test object to a depth which equals the geometric centre of the test object.
2.1.9. Three active flow controllers (fig. 2.1.; FC1, FC2 and FC3) with a range from 0 to 3 litres/minute and a accuracy of 1% of the scale range (Brooks 5850E).

2.2. Method 1

2.2.1 Connect the equipment as drawn in figure 2.1.
2.2.2. Determine the "no-material effectivity" of the system. Install the standard test object. The object is not wrapped.
2.2.3. Connect the test object to the T-piece and seal the connection.
2.2.4. Set the flow controllers FC1 and FC2 to the flow at which the particle counter is calibrated. Set FC3 so that the value FC3 - FC2 equals the intended flow from the object (as calculated from the temperature drop direct after sterilization). For the standard test object a flow of 850 ml/min. is used.
2.2.5. Set the vacuum system to a pressure of 50 kPa. Set the compressor or the reduction valve to a pressure of 160 kPa.
2.2.6 Wait a few minutes for the flows to stabilize.
2.2.7 Start the particle counters measuring particles >0.5 um and >1.0 um. The duration per measurement must be 10 minutes.
Note: Try to keep the number of particles in the surrounding air as constant as possible. Preferable the measurements are taken overnight to eliminate strong fluctuations in the particle levels due to activities.
2.2.8 Let the particle counters take measurements until at least 90 measurements are taken.
2.2.9 Make per measurement a correction on the $count_{outside}$ for the difference between

the outside flow and the object flow.
Correction factor = (setpoint FC2 - setpoint FC3)/setpoint FC1.

2.2.10 Calculate per measurement and per particle size the reduction factor. Calculate the average reduction factor from the reduction factor per measurement.
Reduction factor = ($Count_{outside}$ / $Count_{inside}$)

2.2.11 Make correction on the result by deleting the measurements which deviate from the average value with more than ±3sd.

2.2.12 Repeat the measurements at least 4 times. Calculate the average reduction factor. This value is the "no-material reduction factor".

2.2.13 Place the test object in the system.
If the standard test object is to be used wrap it in one layer of the sheet material to be tested. Use the method B as described in DIN 58953 Teil 10. The dimensions of the sheet shall be 90±2 cm x 90±2 cm.
Make sure that all seals are tortuous. If not cover the seal with autoclave tape.

2.2.14 Calculate per measurement and per particle size the reduction factor. Make per measurement a correction on the $count_{outside}$ for the difference between the outside flow and the object flow.
Correction factor = (setpoint FC2 - setpoint FC3)/setpoint FC1.
Calculate the average reduction factor from the reduction factor per measurement. Make correction on the result by deleting the measurements which deviate from the average value with more than ±3sd.
Correct the average reduction factor by dividing it by the "no-material reduction factor". Calculate from this corrected reduction factor the effectivity value of the final pack.
*Effectivity = {1-(1/[Reduction factor/No material reduction factor])}*100%*

2.2.15 Repeat the procedure at least four times. Calculate the average effectivity for the type of final pack.

2.3. Method 2

2.3.1 Connect the equipment as drawn in figure 2.1.

2.3.2. Place the test object in the system.
If the standard test object is to be used wrap it in one layer of the sheet material to be tested. Use the method B as described in DIN 58953 Teil 10. The dimensions of the sheet shall be 90±2 cm x 90±2 cm.
Make sure that all seals are tortuous. If not cover the seal with autoclave tape.

2.3.3. Connect the test object to the T-piece and seal the connection.

2.3.4. Set the flow controllers FC1 and FC2 to the flow at which the particle counter is calibrated. Set FC3 so that the value FC3 - FC2 equals the intended flow from the object, as calculated from the temperature drop. For the standard test object a flow of 850 ml/min. is used.

2.3.5. Set the vacuum system to a pressure of 50 kPa. Set the compressor or the reduction valve to a pressure of 160 kPa.

2.3.6 Wait a few minutes for the flows to stabilize.

2.3.7 Start the particle counters measuring particles >0.5 um and >1.0 um. The duration per measurement must be 10 minutes.
Note: Try to keep the number of particles in the surrounding air as constant as

possible. Preferable the measurements are taken overnight to eliminate strong fluctuations in the particle levels due to activities.

2.3.8 Let the particle counters take measurements until at least 90 measurements are taken.

2.3.9 Make per measurement a correction on the $count_{outside}$ for the difference between the outside flow and the object flow.
Correction factor = (setpoint FC2 - setpoint FC3)/setpoint FC1.

2.3.10 Calculate per measurement and per particle size the effectivity value. Calculate the average effectivity and the standard deviation. Calculated the effectivity based on the total number of counted particles.
$Effectivity = ([count_{outside} - count_{inside}]/count_{outside})*100\%$

2.3.11 Make correction on the results by deleting the measurements which deviate from the average value with more than 3 sd.

2.3.12 Repeat the measurements at least 1 time with this counter setup. Switch the counters and repeat the measurements with this setup the same number of times as done with the first setup.
Calculate the average effectivity from all the measurements

3. RESULTS

In this clause the proposed modifications on the final pack test method as developed by the RIVM in 1990 are evaluated.

3.1.; ad. 1.2.5.
Annex 5 and annex 6 show the graphical presentation of a number of testresults. The data in annex 5 is obtained by performing 100 measurements of a 10 minute measuring period. The data presented in annex 6 is obtained with measurement periods of 1 minute.
It is clear that the results obtained with the longer measurement periods are more reliable. Based on the criteria on which it is decided whether a test result is valid, hardly any of the measurements taken in 1 minute measuring periods is valid.
The reliability of the test result is higher when longer measurement periods are used.

3.2.; ad. 1.2.3.
Annex 3 shows an example of a printout of the results from the effectivity calculations.
At the bottom of second page the result is shown in which all data is processed. The third page shows the result from the same calculations but now the effectivity values which deviate from the average value with more than respectively 3sd (3 times standard deviation), 2sd and 1sd are excluded from the calculations.
The effectivity value based on the total of counted particles only deviates little from the average value. This indicates that the fluctuations around the average effectivity value are symmetrical above and below the average value. The standard deviation is also very small. The result of this test period is therefore valid.

Annex 4 shows an example of a test result which is not valid. The print out shows that the concentration of particles outside the test object started to fluctuated at about 6.35 pm (count number 68 and further). As a consequence the standard deviation from the average value is large. Also the difference between the average effectivity value and the value obtained on basis on the total count is too large.
To obtain valid test results it is necessary that the concentration of particles in the environment does not fluctuate drastic in short periods of time. A test result is valid when the standard deviation is not more than 5% of the average effectivity value and the difference between the average effectivity value and the value based on the total count is not more than 2% (relative).

3.3.; ad. 1.2.2.
To determine the suitability of the particle counters used in the research work 18 tests were performed on the standard test object wrapped in a single layer of commonly used packaging material; creped paper.
The tests were performed in two series. The tests performed in series 2 were made over a rather large period of 3 months, 1 month after series 1.

3.3.1. Stability in time.
The objective was to determine whether the test result changes significantly when measurements are performed during a longer period of time.

Tables 3.1.a. and 3.1.b. show the results from the tests. The heading of the columns represent the following:

Nr: Number of measurement

Tot: Effectivity value based on the total count, expressed as percentage.

Eff: Average of the effectivity values per measurement expressed as percentage.

Sd: Standard deviation.

Sd/Eff: The standard deviation expressed as a percentage of the average effectivity value.

Tot-Eff/Eff: The difference between the effectivity value based on the total count and the average effectivity value expressed as the percentage of the average effectivity value.

Creped paper Series 1 (May-June)

Nr	Tot	Eff	Sd	Sd/Eff	Tot-eff/eff
1	90.9	93.8	5.2	5.5	-3.09
2	94.1	94.1	0.9	1.0	0.00
3	94.1	94.0	1.1	1.2	0.11
4	95.7	95.7	1.2	1.3	0.00
5	94.7	94.3	1.1	1.2	0.42
6	92.9	92.8	0.8	0.9	0.11
7	94.4	94.5	0.9	1.0	-0.11
Average:		**94.2**	$sd_{(n-1)}$=0.9		

Table 3.1.a. Creped paper series 1.

Creped paper Series 2 (July-September)

Nr	Tot	Eff	Sd	Sd/Eff	Tot-eff/eff
1	94.5	94.5	0.8	0.9	0.00
2	93.2	93.2	0.8	0.9	0.00
3	93.8	93.9	0.8	0.9	-0.11
4	93.9	94.0	0.7	0.7	-0.11
5	93.8	94.0	0.9	1.0	-0.21
Average:		**93.9**	$sd_{(n-1)}$=0.5		

Table 3.1.b Creped paper series 2.

The average results from the series 1 and series 2 tests do not differ significantly from each other.

The average results from the series 1 and series 2 tests do not differ significantly from each other. Therefore it may be concluded that the stability of the test system is sufficient for the purpose of testing the barrier properties of final packs.

3.3.2. Inter counter reproducibility.
When using perfect particle counters the test result on a final pack should not change when the counters are switched; the counter for the measurement of the outside contamination is connected to the final pack and visa versa. During test series 2 the counters were switched after the first 5 tests. The results from these tests are printed in tables 3.2.a. and 3.2.b.

Creped paper
Series 2 (July-September)
Counter setup 1

Nr	Tot	Eff	Sd	Sd/Eff	Tot-eff/eff
1	94.5	94.5	0.8	0.9	0.00
2	93.2	93.2	0.8	0.9	0.00
3	93.8	93.9	0.8	0.9	-0.11
4	93.9	94.0	0.7	0.7	-0.11
5	93.8	94.0	0.9	1.0	-0.21
Average:		**93.9**	$sd_{(n-1)}$=0.5		

Table 3.2.a. Creped paper, series 2, counter setup 1.

Creped paper
Series 2 (July-September)
Counter setup 2

Nr	Tot	Eff	Sd	Sd/Eff	Tot-eff/eff
6	87.9	87.8	1.4	1.6	0.11
7	89.1	88.9	1.1	1.2	0.22
8	86.8	86.8	1.2	1.4	0.00
9	86.0	86.1	1.5	1.7	-0.12
10	87.6	87.6	1.0	1.1	0.00
11	86.1	86.1	1.7	2.0	0.00
Average:		**87.2**	$sd_{(n-1)}$=1.1		

Table 3.2.b. Creped paper, series 2, counter setup 2.

Tables 3.2.a. and 3.2.b. show that the counter setup has a large influence on the test result. It also indicates that the accuracy of the result gets better (smaller sd-value) when the effectivity value is higher. This seems to be correct when the results from the tests done with creped paper are compared to results obtained from tests performed with the test object wrapped in plain operation textile (Table 3.3.)

Plain operation textile.
Counter setup 1.

Nr	Tot	Eff	Sd	Sd/Eff	Tot-eff/eff
1	72,4	70,6	4,7	6,7	2,55
2	78,4	77,8	3,5	4,5	0,77
3	72,3	72,3	1,6	2,2	0,00
4	71,8	71,0	3,3	4,7	1,13
5	71,6	71,2	4,0	5,6	0,56
6	70,4	70,1	3,9	5,6	0,43
7	67,1	66,2	6,8	10,3	1,36
8	70,6	70,4	3,8	5,4	0,28
9	75,4	71,9	4,5	6,3	4,87
10	74,8	74,8	2,5	3,3	0,00
11	71,3	71,4	4,8	6,7	0,14
12	69,4	71,1	6,2	8,7	2,39
Average:		**71.6**	$sd_{(n-1)}$=2.8		

Table 3.3. Plain operation textile, counter setup 1.

3.3.3. No-material reduction factor.

When the test are performed without any test object in the system the results from the tests should be zero effectivity. This has been investigated for both counter setups. The results are tabled in table 3.4.a. and 3.4.b.

Material: No material. Test set up 1			
Number	Effectivity	$sd_{(n-1)}$	Reduction factor
1	31.7	3.7	1.46
2	37.0	1.6	1.59
3	24.7	3.7	1.33
4	24.9	5.8	1.33
5	29.1	2.5	1.42
Average $sd_{(n-1)}$			**1.42** 0.11

Table 3.4.a No material, test setup 1.

Material: No material. Test set up 2			
Number	Effectivity	$sd_{(n-1)}$	Reduction factor
6	-50.1	5.4	0.67
7	-36.5	11.0	0.73
8	-29.7	10.1	0.77
9	-33.2	4.8	0.75
10	-39.2	7.4	0.72
Average $sd_{(n-1)}$			**0.73** 0.04

Table 3.4.b. No material, test setup 2.

The results from the non-material tests show that the effectivity values obtained from a test object must be corrected for the "no-material" reduction factor.

3.3.4. Corrected results creped paper.

The results from the series 2 tests are corrected for the no material reduction factor. The test object was packed in creped paper.
The results are shown in table 3.5.a. and 3.5.b.

Material: Creped paper. Test set up 1					
Number	Effectivity	$sd_{(n-1)}$	Reduction factor	Reduction factor; corrected	Effectivity; corrected
1	94.5	0.8	18.2	12.7	92.1
2	93.2	0.8	14.7	10.3	90.3
3	93.9	0.8	16.4	11.5	91.3
4	94.0	0.7	16.7	11.7	91.4
5	94.0	0.9	16.7	11.7	91.4
Average	93.9		16.54	11.6	91.3
$sd_{(n-1)}$	0.47		1.25	0.87	0.66
Effectivity (calculated from the corrected reduction factor)				**91.4**±0.7%	

Table 3.5.a. Creped paper. Test setup 1.

Material: Creped paper. Test set up 2					
Number	Effectivity	$sd_{(n-1)}$	Reduction factor	Reduction factor; corrected	Effectivity; corrected
6	87.8	1.4	8.2	11.2	91.1
7	88.9	1.1	9.0	12.3	91.9
8	86.8	1.2	7.6	10.4	90.4
9	86.1	1.5	7.2	9.9	89.9
10	87.6	1.0	8.1	11.1	91.0
11	86.1	1.7	7.2	9.9	89.9
Average	87.2		7.9	10.8	90.7
$sd_{(n-1)}$	1.13		0.7	0.96	0.80
Effectivity (calculated from the corrected reduction factor)				**90.7**±0.8%	

Table 3.5.b. Creped paper. Test setup 2.

4. DISCUSSION.

1. The average effectivity after correction with the reduction factor obtained without any test pack in the system does not differ significantly for both counter setups.
2. When the result from the correction is compared with the result obtained by averaging the non corrected results from counter setup 1 and setup 2 it is shown that all three values do not differ significantly (See table 4.1.).
3. On page 10 of this report the conditions under which a test is valid are stated: A test result is valid when the standard deviation is not more than 5% of the average effectivity value and the difference between the average effectivity value and the value based on the total count is not more than 2% (relative). These values have no scientific background, but the authors experienced that test results meeting these requirements can be obtained without great difficulty.
   When using valid test results, according to the requirements mentioned above, the test method has an accuracy better than 3% for final packs that give a barrier effectivity for 0.5 um particles of at least 90%.

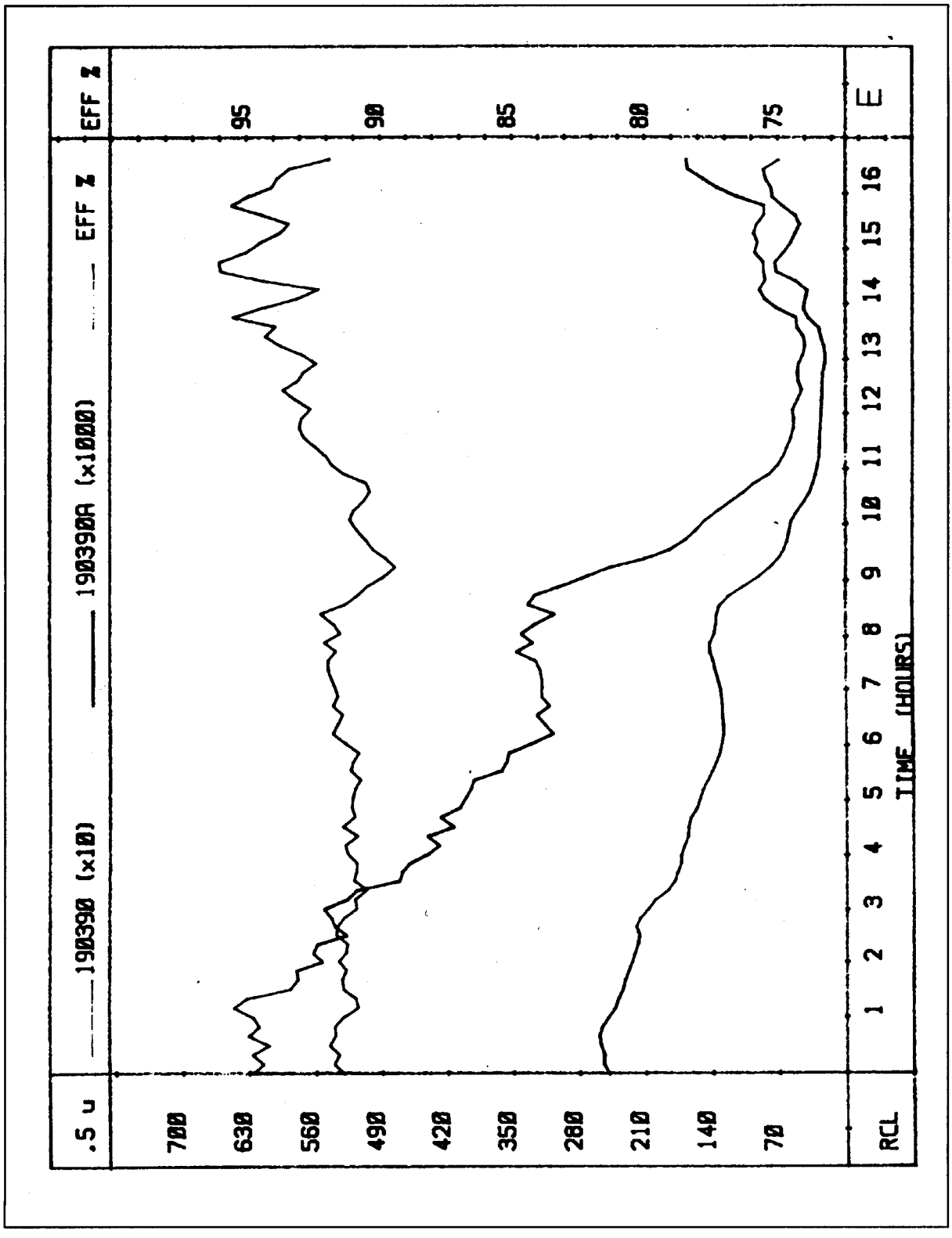
Material: Creped paper. Results matrix	
Effectivity set up 1 (calculated from the corrected reduction factor)	**91.4**±0.7%
Effectivity set up 2 (calculated from the corrected reduction factor)	**90.7**±0.8%
Average of the effectivity values of set up 1 (without correction) and set up 2 (without correction)	**91.8**±0.7%

Table 4.1. Creped paper. Results matrix.

5. CONCLUSIONS

It is demonstrated that the effectivity value found with the counter setup 1 and 2 do actually differ from each other but they may be corrected by measuring the reduction factor without test object and than give the same result.
Taking the average from counter setup 1 and setup 2 gives an average reduction factor which gives the actual effectivity value.
Both calculation techniques give the same result which means that the basic principle is correct and gives reproducible results.
The accuracy of the result is better when the test object is a good barrier.
The accuracy is sufficient to give a go/no go determination of final packs.

Annex 1


.5 u
190390 (x10)
190390A (x1000)
EFF %
EFF %
700
630
560
490
420
350
280
210
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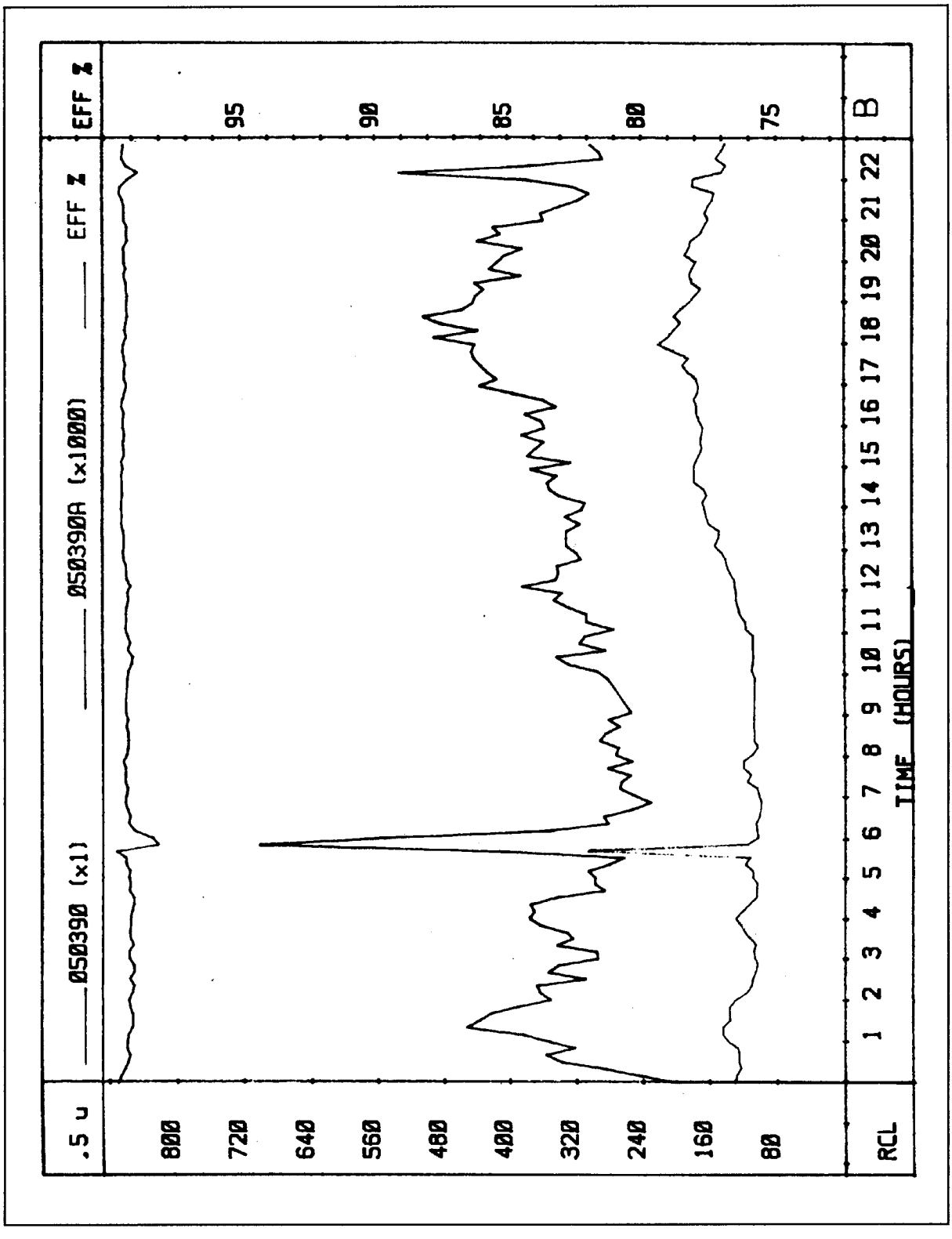
70
95
90
85
80
75
RCL
E
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
TIME (HOURS)

Annex 2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160
80
95
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85
80
75
B
RCL
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22
TIME (HOURS)

Annex 3

EFFICIENTIE EN DOORLAATFACTOR BEREKENING

GEGEVENS PRODUKTMETING: 940607 60794 164025 .5 um 1 um Flow= 850
GEGEVENS OMGEVINGMETING: 940607a 60794 164009 .5 um 1 um Flowa= 2500

NUMMER	TIME	A.5	.5	AEFF	ADLF	A1	1	BEFF	BDLF	RH	TEMP
1	164025	5803	284	95.106	4.894	338	5	98.519	1.481	44.2	24.0
2	165030	5948	254	95.730	4.270	341	8	97.652	2@348	44.5	24.0
3	170035	6193	282	95.446	4.554	238	2	99.158	0.842	48.0	23.9
4	171040	5982	282	95.286	4.714	170	0	100.000	0.000	48.5	23.9
5	172045	5804	283	95.124	4.876	137	1	99.270	0.730	45.0	24.0
6	173050	5575	291	94.780	5.220	96	2	97.914	2.086	47.9	23.9
7	174055	5713	282	95.064	4.936	84	2	97.618	2.382	45.5	24.0
8	175100	6295	274	95.648	4.352	78	0	100.000	0.000	45.5	24.0
9	180105	6756	283	95.811	4.189	63	1	98.419	1.581	48.8	23.9
10	181110	7004	287	95.902	4.098	125	0	100.000	0.000	47.4	24.0
11	182115	13665	442	96.765	3.235	435	2	99.540	0.460	44.3	24.6
12	183120	18154	702	96.133	3.867	660	9	98.636	1.364	44.3	24.6
13	184125	20001	912	95.440	4.560	811	16	98.027	1.973	43.1	24.4
14	185130	20479	1074	94.756	5.244	892	10	98.879	1.121	43.1	24.7
15	190135	20614	1341	93.495	6.505	912	24	97.368	2.632	43.0	24.8
16	191140	20111	1335	93.362	6.638	922	22	97.614	2.386	43.0	24.9
17	192145	20234	1363	93.264	6.736	1109	18	98.377	1.623	42.9	25.1
18	193150	21276	1236	94.191	5.809	1305	23	98.237	1.763	44.8	25.3
19	194155	21788	1168	94.639	5.361	1350	31	97.705	2.295	47.1	25.2
20	195200	21798	1103	94.940	5.060	1327	23	98.267	1.733	46.4	25.1
21	200205	21880	1170	94.653	5.347	1243	28	97.747	2.253	42.7	25.3
22	201210	21607	1195	94.469	5.531	1144	29	97.465	2.535	44.8	24.9
23	202215	21481	1161	94.595	5.405	1025	27	97.366	2.634	42.1	25.1
24	203220	21062	1163	94.478	5.522	912	32	96.491	3.509	46.4	25.1
25	204225	20588	1188	94.230	5.770	826	19	97.698	2.302	44.8	24.9
26	205230	20556	1132	94.493	5.507	748	19	97.459	2.541	43.2	24.9
27	210235	20104	1119	94.434	5.566	716	17	97.527	2.373	41.4	25.1
28	211240	19793	1171	94.084	5.916	647	13	97.990	2.010	45.2	25.3
29	212245	19337	1159	94.006	5.994	604	13	97.847	2.153	41.3	25.1
30	213250	18522	1129	93.904	6.096	513	15	97.074	2.926	44.8	25.1
31	214255	18163	1073	94.092	5.908	542	11	97.969	2.031	45.0	25.1
32	215300	17581	1058	93.982	6.018	527	6	98.861	1.139	40.7	25.0
33	220305	17001	1092	93.577	6.423	470	4	99.148	0.852	41.1	25.3
34	221310	16770	1046	93.763	6.237	466	8	98.284	1.716	40.6	24.9
35	222315	16058	967	93.978	6.022	446	12	97.310	2.690	40.3	25.3
36	223320	15628	911	94.171	5.829	453	1	99.779	0.221	39.9	25.0
37	224325	15105	912	93.962	6.038	405	7	98.273	1.727	43.9	25.3
38	225330	14373	902	93.724	6.276	372	10	97.314	2.686	39.6	25.3
39	230335	14137	878	93.789	6.211	403	4	99.007	0.993	41.6	24.9
40	231340	13742	904	93.422	6.578	387	9	97.674	2.326	39.5	25.2
41	232345	13576	816	93.989	6.011	368	5	98.640	1.360	39.3	24.9
42	233350	13369	821	93.859	6.141	374	9	97.591	2.409	39.2	25.3
43	234355	13204	734	94.441	5.559	397	7	98.236	1.764	39.3	24.8
44	235400	13311	799	93.997	6.003	368	6	98.368	1.632	39.4	25.2
45	405	13198	765	94.204	5.796	358	8	97.765	2.235	43.2	25.2
46	1410	13449	745	94@461	5.539	395	6	98.483	1.517	39.1	25.3
47	2415	13315	741	94.435	5.565	372	4	98.924	1.076	39.5	24.9
48	3420	13584	744	94.523	5.477	379	3	99.208	0.792	43.2	25.1
49	4425	13362	718	94.627	5.373	363	4	98.897	1.103	43.6	25.0
50	5430	13275	789	94.057	5.943	389	15	96.147	3.853	39.6	25.2
51	10435	13036	800	93.863	6.137	385	5	98.701	1.299	39.6	25.1
52	11440	13145	764	94.188	5.812	399	5	98.747	1.253	40.7	25.2
53	12445	12796	738	94.232	5.768	381	5	98.688	1.312	39.6	25.1
54	13450	12982	759	94.154	5.846	368	8	97.827	2.173	39.7	25.1
55	14455	12698	750	94.094	5.906	398	6	98.492	1.508	44.0	25.2
56	15500	12644	773	93.886	6.114	404	6	98.513	1.487	39.7	25.0
57	20505	12345	743	93.982	6.018	395	7	98.228	1.772	39.4	24.9
58	21510	12135	664	94.528	5.472	414	6	98.552	1.448	39.3	24.7
59	22515	11866	790	93.343	6.657	402	8	98.009	1.991	39.7	24,9
60	23520	11522	708	93.855	6.145	416	7	98.318	1.682	39.3	24.8
61	24525	11063	695	93.718	6.282	400	5	98.748	1.252	39.4	25.3
62	25530	10510	623	94.072	5.928	385	6	98.441	1.559	40.7	25.1
63	30535	9984	614	93.850	6.150	352	6	98.297	1.703	42.8	24.9
64	31540	9479	568	94.008	5.992	332	8	97.589	2.411	43.6	25.0
65	32545	9055	563	93.783	6.217	342	4	98.832	1.168	39.3	24.8

66	33550	8819	536	93.922	6.078	352	6	98.295	1.705	39.4	25.0
67	34555	8398	540	93.570	6.430	349	8	97.709	2.291	39.1	24.9
68	35600	7955	433	94.557	5.443	329	3	99.088	0.912	39.4	25.0
69	40605	7625	491	93.561	6.439	303	9	97.026	2.974	39.2	25.3
70	41610	7347	471	93.589	6.411	325	7	97.844	2.156	43.7	25.1
71	42615	7130	466	93.464	6.536	335	3	99.105	0.895	43.8	25.1
72	43620	6942	409	94.108	5.892	360	2	99.445	0.555	41.5	25.2
73	44625	6807	386	94.329	5.671	355	9	97.467	2.533	39.2	24.7
74	45630	6836	374	94.529	5.471	347	8	97.695	2.305	43.1	25.1
75	50635	6750	377	94.415	5.585	397	8	97.987	2.013	40.3	25.1
76	51640	6844	371	94.579	5.421	415	6	98.554	1.446	43.8	25.2
77	52545	6656	388	94.170	5.830	417	5	98.800	1.200	39.4	25.1
78	53650	6648	368	94.465	5.535	420	5	98.808	1.192	39.5	25.2
79	54655	6729	331	95.081	4.919	481	5	98.961	1.039	43.9	25.2
80	55700	6761	356	94.734	5.266	550	10	98.181	1.819	39.3	24,9
81	60705	7001	341	95.129	4.871	615	9	98.537	1.463	41.5	25.1
82	61710	7047	367	94.792	5.208	654	9	98.523	1.377	39.4	24.7
83	62715	7171	349	95.133	4.867	740	9	98.783	1.217	39.5	25.1
84	63720	7312	371	94.926	5.074	781	14	98.207	1.793	39.7	24.8
85	64725	7424	378	94.909	5.091	800	20	97.499	2.501	39.8	25.0
86	65730	7554	369	95.115	4.885	784	17	97.832	2.168	43.2	24.9
87	70735	7598	337	95.565	4.435	789	14	98.227	1.773	44.0	25.0
88	71740	7656	370	95.167	4.833	781	18	97.696	2.304	42.8	25.1
89	72745	6912	342	95.052	4.948	719	14	98.052	1.948	40.6	24.8
90	73750	4913	364	92.591	7.409	350	20	94.283	5.717	41.2	24.4
91	74755	3610	281	92.216	7.784	152	4	97.368	2.632	41.6	24.0
92	75800	3185	178	94.411	5.589	90	3	96.658	3.342	44.7	24.1
93	80805	3084	166	94.618	5.382	57	1	98.249	1.751	46.3	23.9
94	81810	3124	108	96.543	3@457	53	0	100.000	0.000	44.7	23.9
95	82815	3093	118	96.185	3.815	53	1	98.102	1.898	46.5	23.7
96	83820	3101	101	96.743	3.257	47	0	100.000	0.000	42.1	23.8
97	84825	3218	98	96.954	3.046	38	0	100.000	0.000	42.4	23.5
98	85830	3229	101	96.872	3.128	36	0	100.000	0.000	41,7	24.0
99	90835	3277	84	97.436	2.564	44	0	100.000	0.000	41.5	23.6
100	91840	3428	78	97.724	2.276	37	0	100.000	0.000	43.2	23.8

GEMIDDELDE EFFECTIVITEIT VOOR .5 um DEELTJES IS 94.6 MET EEN STAND. DEV. VAN 1.0
OP BASIS VAN TOTAL COUNT OVER 100 METINGEN: 94.4
GEMIDDELDE EFFECTIVITEIT VOOR 1 um DEELTJES IS 98.3 MET EEN STAND. DEV. VAN 0.9
OP BASIS VAN TOTAL COUNT OVER 100 METINGEN: 98.1

EFFICIENTIE EN DOORLAATFACTOR BEREKENING

GEGEVENS PRODUKTMETING:	a:940607	60794	164025	.5 um	1 um	Flow-- 850
GEGEVENS OMGEVINGMETING:	a:940607a	60794	164009	.5 um	1 um	Flowa= 2500

UITBIJTER CORRECTIE

90 BEFF 100 AEFF
HET EINDRESULTAAT NA 3 sd UITBIJTER CORRECTIE:
GEMIDDELDE EFFECTIVITEIT VOOR .5 um DEELTJES IS 94.5 MET EEN STAND. DEV. VAN 0.9
OP BASIS VAN TOTAL COUNT OVER 99 METINGEN: 94.4
GEMIDDELDE EFFECTIVITEIT VOOR 1 um DEELTJES IS 98.3 MET EEN STAND. DEV. VAN 0.8
OP BASIS VAN TOTAL COUNT OVER 99 METINGEN: 98.1

11 AEFF 50 BEFF 90 AEFF 90 BEFF 91 AEFF 94 AEFF 96 AEFF 97 AEFF 98 AEFF 99 AEFF 100 AEFF
HET EINDRESULTAAT NA 2 sd UITBIJTER CORRECTIE:
GEMIDDELDE EFFECTIVITEIT VOOR .5 um DEELTJES IS 94.4 MET EEN STAND. DEV. VAN 0.7
OP BASIS VAN TOTAL COUNT OVER 91 METINGEN: 94.3
GEMIDDELDE EFFECTIVITEIT VOOR 1 um DEELTJES IS 98.4 MET EEN STAND. DEV. VAN 0.8
OP BASIS VAN TOTAL COUNT OVER 98 METINGEN: 98.2

2 AEFF 4 BEFF 5 BEFF 8 AEFF 8 BEFF 9 AEFF 10 AEFF 10 BEFF 11 AEFF 11 BEFF 12 AEFF 15 AEFF 15 BEFF 16 AEFF 17 AEFF 23 BEFF 24 BEFF 30 BEFF 33 AEFF 35 BEFF 36 BEFF 38 BEFF 40 AEFF 50 BEFF 59 AEFF 67 AEFF 69 AEFF 69 BEFF 71 AEFF 72 BEFF 87 AEFF 90 AEFF 90 BEFF 91 AEFF 91 BEFF 92 BEFF 94 AEFF 94 BEFF 95 AEFF 96 AEFF 96 BEFF 97 AEFF 97 BEFF 98 AEFF 98 BEFF 99 AEFF 99 BEFF 100 AEFF 100 EEF

HET EINDRESULTAAT NA 1 sd UITBIJTER CORRECTIE:
GEMIDDELDE EFFECTIVITEIT VOOR .5 um DEELTJES IS 94.4 MET EEN STAND. DEV. VAN 0.5
OP BASIS VAN TOTAL COUNT OVER 75 METINGEN: 94.3
GEMIDDELDE EFFECTIVITEIT VOOR 1 um DEELTJES IS 98.3 MET EEN STAND. DEV. VAN 0.5
OP BASIS VAN TOTAL COUNT OVER 76 METINGEN: 98.2

Annex 4

EFFICIENTIE EN DOORLAATFACTOR BEREKENING

GEGEVENS PRODUKTMETING: 940517 51694 191947 .5 um 1 um FLOW= 850

GEGEVENS OMGEVINGMETING: 940517a 51694 191935 .5 um 1 um Flowa= 2500

NUMMER	TIME	A.5	.5	AEFF	ADLF	A1	1	BEFF	BDLF	RH	TEMP
1	191947	3041	197	93.522	6.478	91	2	97.805	2.195	41.0	25.6
2	192952	3226	215	93.335	6.665	109	1	99.081	0.919	41.6	26.0
3	193957	3247	179	94.488	5.512	117	2	98.285	1.715	37.9	25.9
4	195002	3124	190	93.917	6.083	119	2	98.324	1.676	38.0	25.9
5	200007	3122	183	94.138	5.862	139	2	98.558	1.442	40.7	26.2
6	201012	3162	212	93.295	6.705	162	1	99.381	0.619	41.6	26.1
7	202017	3251	202	93.786	6.214	156	2	98.716	1.284	37.7	26.0
8	203022	3241	207	93.613	6.387	175	0	100.000	0.000	37.6	26.0
9	204027	3289	165	94.983	5.017	199	2	98.993	1.007	37.5	26.1
10	205032	3242	198	93.893	6.107	198	2	98.989	1.011	41.6	26.3
11	210037	3260	208	93.620	6.380	199	7	96.487	3.513	41.6	26.3
12	211042	3275	202	93.831	6.169	189	2	98.944	1.056	39.2	26.1
13	212047	3212	204	93.649	6.351	212	5	97.640	2.360	36.9	25.9
14	213052	3207	208	93.514	6.486	209	9	95.703	4.297	37.3	26.1
15	214057	3254	189	94.192	5.808	235	8	96.590	3.410	37.0	25.8
16	215102	3262	186	94.297	5.703	241	3	98.757	1.243	37.2	26.0
17	220107	3333	202	93.939	6.061	229	4	98.252	1.748	37.2	25.8
18	221112	3385	176	94.800	5.200	250	4	98.399	1.601	38.4	25.8
19	222117	3529	164	95.352	4.648	257	5	98.055	1.945	41.8	26.2
20	223122	3510	187	94.673	5.327	263	1	99.620	0.380	41.5	26.2
21	224127	3474	184	94.704	5.296	271	2	99.261	0.739	38.1	25.9
22	225132	3414	184	94.611	5.389	241	2	99.170	0.830	37.3	25.9
23	230137	3425	179	94.773	5.227	265	5	98.112	1.888	37.3	25.9
24	231142	3383	168	95.033	4.967	278	2	99.280	0.720	41.5	26.2
25	232147	3279	152	95.364	4.636	262	0	100.000	0.000	41.3	26.1
26	233152	3339	168	94.968	5.032	267	1	99.625	0.375	36.7	25.8
27	234157	3374	182	94.606	5.394	287	0	100.000	0.000	40.9	26.1
28	235202	3371	175	94.809	5.191	264	4	98.484	1.516	40.6	25.9
29	207	3242	168	94.818	5.182	288	3	98.959	1.041	36.3	25.7
30	1212	3295	160	95.145	4.855	279	1	99.641	0.359	35.8	25.7
31	2217	3347	190	94.324	5.676	271	3	98.892	1.108	36.2	25.8
32	3222	3268	146	95.533	4.467	296	0	100.000	0.000	35.8	25.6
33	4227	3237	186	94.255	5.745	276	1	99.637	0.363	38.3	25.8
34	5232	3251	164	94.955	5.045	300	3	99.001	0.999	40.0	25.8
35	10237	3316	153	95.386	4.614	315	2	99.365	0.635	39.9	25.9
36	11242	3300	185	94.393	5.607	326	2	99.387	0.613	39.6	25.8
37	12247	3130	156	95.015	4.985	293	9	96.926	3.074	36.8	25.6
38	13252	3116	160	94.865	5.135	284	1	99.648	0.352	38.6	25.6
39	14257	3020	146	95.166	4.834	266	3	98.873	1.127	38.8	25.7
40	15302	3041	150	95.067	4.933	274	8	97.084	2.916	34.2	25.6
41	20307	2918	144	95.065	4.935	270	4	98.518	1.482	34.4	25.3
42	21312	2935	157	94.650	5.350	260	3	98.847	1.153	34.2	25.6
43	22317	3017	161	94.663	5.337	276	2	99.276	0.724	36.8	25.3
44	23322	3077	155	94.962	5.038	264	1	99.621	0.379	34.5	25.5
45	24327	3047	144	95.274	4.726	256	3	98.830	1.170	34.5	25.6
46	25332	3121	143	95.417	4.583	272	5	98.159	1.841	34.3	25.3
47	30337	3078	166	94.608	5.392	302	6	98.013	1.987	34.1	25.3
48	31342	3011	159	94.719	5.281	269	2	99.257	0.743	34.2	25.5
49	32347	2904	139	95.213	4.787	263	2	99.240	0.760	33.9	25.3
50	33352	2826	156	94.481	5.519	260	1	99.616	0.384	34.2	25.6
51	34357	2762	133	95.184	4.816	266	3	98.870	1.130	38.4	25.6
52	35402	2674	137	94.877	5.123	236	2	99.152	0.848	35.2	25.6
53	40407	2621	130	95.040	4.960	228	3	98.687	1.313	35.1	25.5
54	41412	2557	104	95.932	4.068	222	3	98.649	1.351	37.9	25.6
55	42417	2459	115	95.324	4.676	184	1	99.455	0.545	37.6	25.6
56	43422	2380	125	94.749	5.251	186	2	98.925	1.075	36.7	25.5
57	44427	2416	117	95.158	4.842	180	3	98.335	1.665	35.2	25.1
58	45432	2331	109	95.323	4.677	184	3	98.369	1.631	34.4	25.3
59	50437	2380	120	94.957	5.043	182	3	98.351	1.649	33.1	25.3
60	51442	2320	105	95.474	4.526	168	1	99.405	0.595	37.8	25.6
61	52447	2232	117	94.759	5.241	170	2	98.826	1.174	36.7	25.4
62	53452	2258	106	95.305	4.695	163	2	98.769	1.231	34.7	25.4
63	54457	2262	92	95.932	4.068	154	1	99.352	0.648	37.2	25.3
64	55502	2309	116	94.975	5.025	152	3	98.026	1.974	33.4	25.2
65	60507	2140	111	94.813	5.187	134	2	98.503	1.497	36.7	25.4
66	61512	2124	120	94.350	5.650	138	4	97.109	2.891	33.3	25.8

67	62517	1908	94	95.074	4.926	111	0	100.000	0.000	34.3	25.8
68	63522	293	14	95.229	4.771	22	0	100.000	0.000	37.7	25.1
69	64527	3870	115	97.028	2.972	278	4	98.560	1.440	33.4	25.6
70	65532	5089	149	97.072	2.928	355	5	98.591	1.409	33.8	25.6
71	70537	6276	214	96.590	3.410	478	8	98.328	1.672	38.0	25.8
72	71542	7426	318	95.718	4.282	547	11	97.988	2.012	38.3	25.9
73	72547	8489	412	95.147	4.853	602	14	97.676	2.324	34.1	25.7
74	73552	14378	407	97.169	2.831	1679	15	99.107	0.893	34.7	25.6
75	74557	19707	595	96.981	3.019	2397	17	99.291	0.709	37.5	25.7
76	75602	26779	739	97.240	2.760	4528	35	99.227	0.773	39.6	25.8
77	80607	28001	746	97.336	2.664	6544	26	99.603	0.397	36.5	26.2
78	81612	80	4	95.015	4.985	0	0	100.000	0.000	36.6	26.0
79	82617	8540	79	99.075	0.925	2821	3	99.894	0.106	38.3	25.5
80	83622	102493	1125	98.902	1.098	37830	68	99.820	0.180	40.2	25.8
81	84627	122985	2873	97.664	2.336	46996	323	99.313	0.687	35.9	25.7
82	85632	118475	3840	96.759	3.241	44195	535	98.789	1.211	36.5	25.7
83	90637	122509	3863	96.847	3.153	46637	545	98.831	1.169	38.8	25.7
84	91642	132293	4517	96.586	3.414	51600	648	98.744	1.256	39.9	25.9
85	92647	167582	4529	97.297	2.703	63568	714	98.877	1.123	37.4	26.1
86	93652	224953	5898	97.378	2.622	85252	829	99.028	0.972	37.0	25.8
87	94657	96154	6960	92.762	7.238	96154	974	98.987	1.013	41.6	26.3
88	95702	330285	12817	96.119	3.881	330285	1647	99.501	0.499	41.9	26.4
89	100707	116649	21259	81.775	18.225	116649	3103	97.340	2.660	39.5	26.6
90	101712	126128	29813	76.363	23.637	126128	4917	96.102	3.898	39.4	26.6
91	102717	32176	34717	-7.899	107.89	32176	5156	83.975	16.025	39.4	27.1
92	103722	275379	35788	87.004	12.996	132271	4556	96.556	3.444	42.6	27.1
93	104727	209389	31720	84.851	15.149	87978	3881	95.589	4.411	41.0	27.2
94	105732	137646	27227	80.220	19.780	40647	3931	90.329	9.671	46.0	27.9
95	110737	258043	27001	89.536	10.464	131970	4150	96.855	3.145	40.0	27.9
96	111742	131657	32223	75.525	24.475	58479	5250	91.022	8.978	38.5	27.6
97	112747	298898	25219	91.563	8.437	293397	4671	98.408	1.592	40.0	28.0
98	113752	58222	24119	58.574	41.426	16803	3994	76.231	23.769	40.7	28.4
99	114757	321562	24777	92.295	7.705	321562	4134	98.714	1.286	39.5	28.6
100	115802	295525	20470	93.073	6.927	295525	3977	98.654	1.346	36.3	28.9

GEMIDDELDE EFFECTIVITEIT VOOR .5 um DEELTJES IS 92.8 MET EEN STAND. DEV. VAN 11.4
OP BASIS VAN TOTAL COUNT OVER 100 METINGEN: 90.1
GEMIDDELDE EFFECTIVITEIT VOOR 1 um DEELTJES IS 98.2 MET EEN STAND. DEV. VAN 3.0
OP BASIS VAN TOTAL COUNT OVER 100 METINGEN: 97.7

EFFICIENTIE EN DOORLAATFACTOR BEREKENING
GEGEVENS PRODUKTMETING: 940517 51694 191947 .5 um 1 um FLOW= 850
GEGEVENS OMGEVINGMETING: 940517a 51694 191935 .5 um 1 um FLowa= 2500

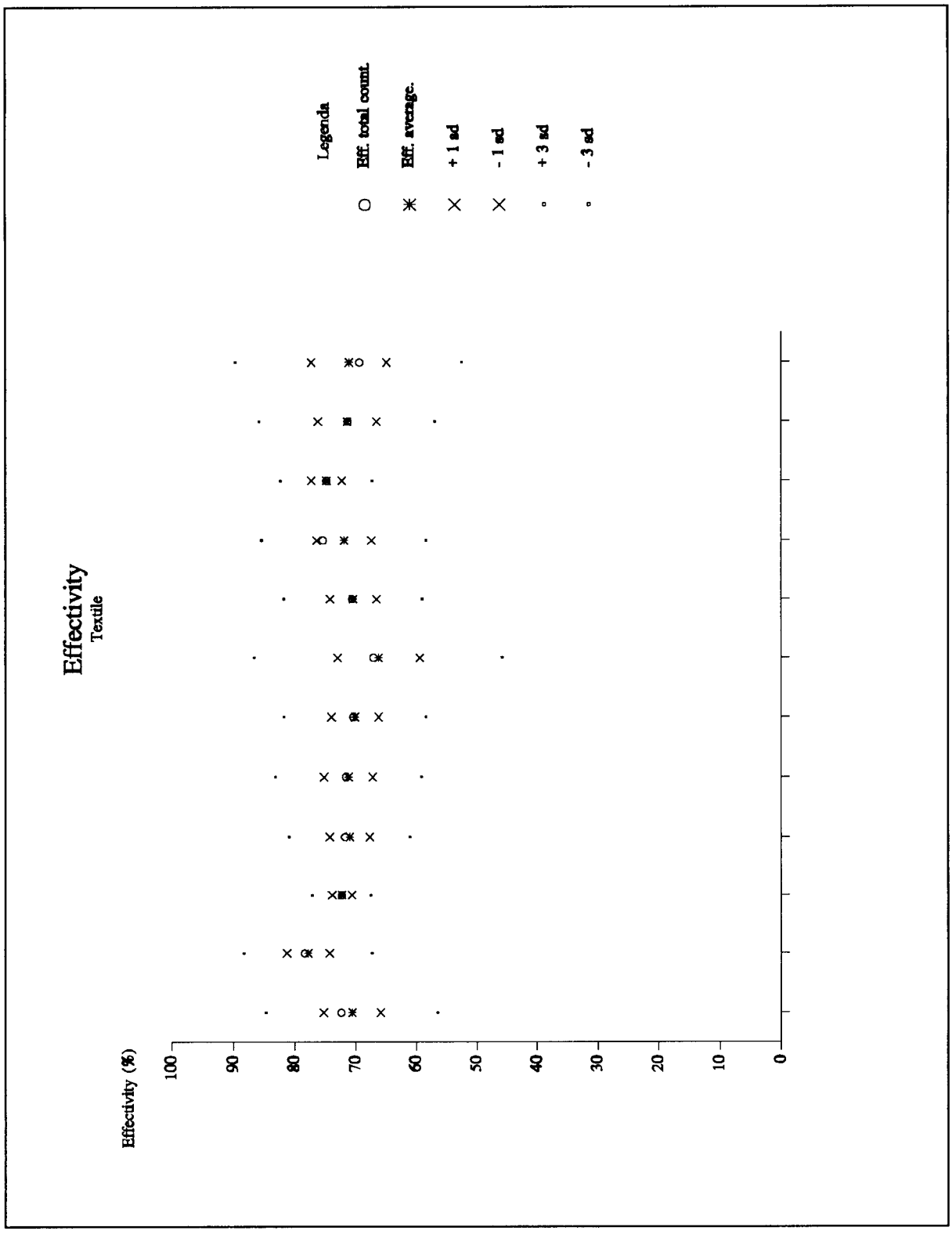
UITBIJTER CORRECTIE

91 AEFF 91 BEFF 98 BEFF
HET EINDRESULTAAT NA 3 sd UITBIJTER CORRECTIE:
GEMIDDELDE EFFECTIVITEIT VOOR .5 um DEELTJES IS 93.8 MET EEN STAND. DEV. VAN 5.2
OP BASIS VAN TOTAL COUNT OVER 99 METINGEN: 90.9
GEMIDDELDE EFFECTIVITEIT VOOR 1 um DEELTJES IS 98.5 MET EEN STAND. DEV. VAN 1.5
OP BASIS VAN TOTAL COUNT OVER 98 METINGEN: 98.0
91 AEFF 91 BEFF 94 BEFF 96 BEFF 98 AEFF 98 BEFF

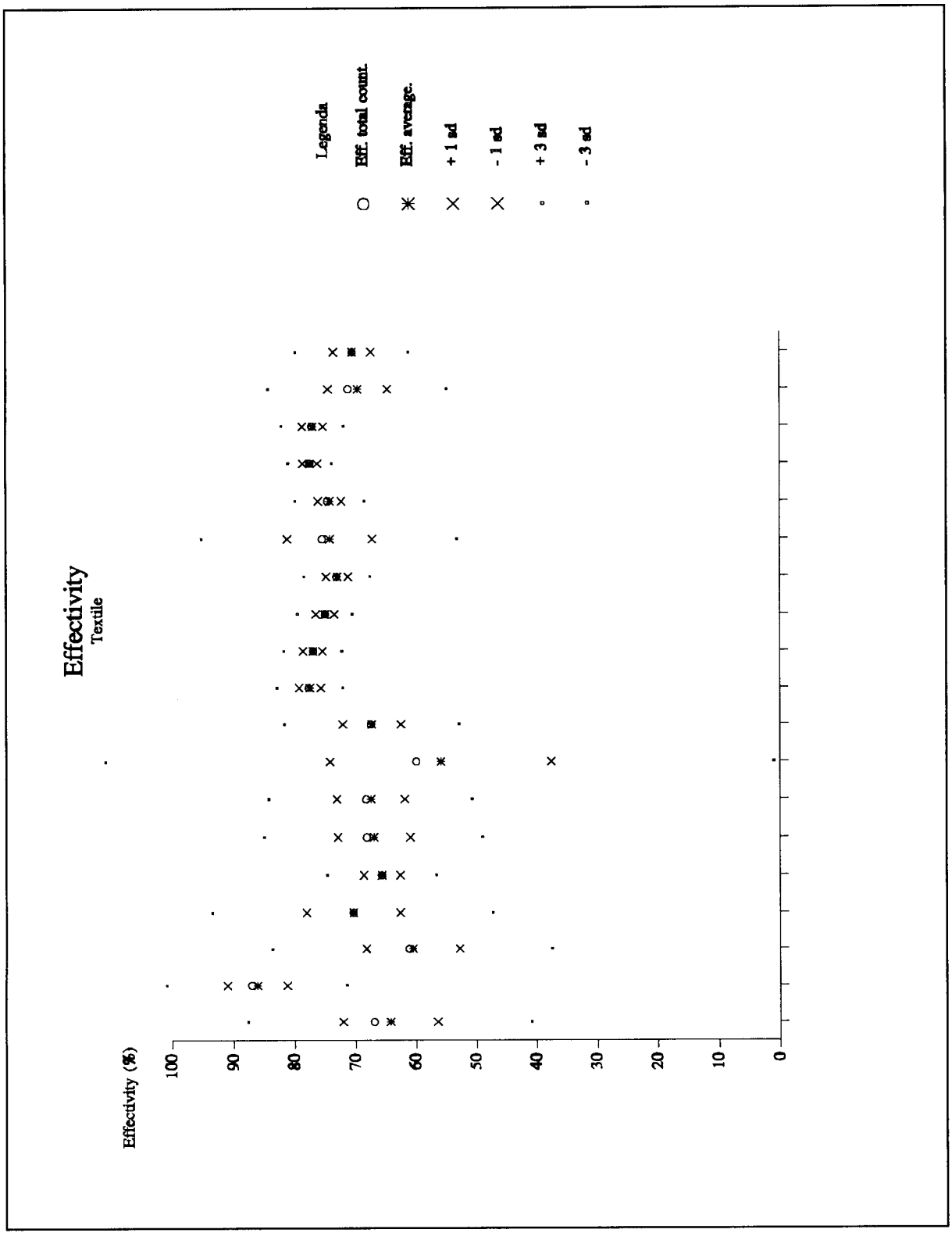
HET EINDRESULTAAT NA 2 sd UITBIJTER CORRECTIE:
GEMIDDELDE EFFECTIVITEIT VOOR .5 u DEELTJES IS 94.2 MET EEN STAND. DEV. VAN 3.8
OP BASIS VAN TOTAL COUNT OVER 98 METINGEN: 91.4
GEMIDDELDE EFFECTIVITEIT VOOR 1 um DEELTJES IS 98.7 MET EEN STAND. DEV. VAN 1.0
OP BASIS VAN TOTAL COUNT OVER 96 METINGEN: 98.3
90 AEFF 91 AEFF 91 BEFF 94 AEFF 94 BEFF 96 AEFF 96 BEFF 98 AEFF 98 BEFF

HET "EINDRESULTAAT NA 1 sd UITBIJTER CORRECTIE:
GEMIDDELDE EFFECTIVITEIT VOOR .5 um DEELTJES IS 94.7 MET EEN STAND. DEV. VAN 2.3
OP BASIS VAN TOTAL COUNT OVER 95 METINGEN: 93.0
GEMIDDELDE EFFECTIVITEIT VOOR 1 um DEELTJES IS 98.7 MET EEN STAND. DEV. VAN 1.0
OP BASIS VAN TOTAL COUNT OVER 96 METINGEN: 98.3

Annex 5


Effectivity
Textile
Effectivity (%)
100
90
80
70
60
50
40
30
20
10
0
Legenda
Eff. total count.
Eff. average.
+ 1 sd
- 1 sd
+ 3 sd
- 3 sd

Annex 6


Effectivity
Textile
Legenda
Eff. total count.
Eff. average.
+ 1 sd
- 1 sd
+ 3 sd
- 3 sd
Effectivity (%)
100
90
80
70
60
50
40
30
20
10
0

Annex 7
Test protocol; final version

MATERIALS AND METHOD

1. Materials.

1.1. Steam sterilizer in conformity with the requirements in EN 285
1.2. Temperature measuring and recording system in conformity with the requirements in EN 285.
1.3. Two optical particle counters (fig. 1; PC1 and PC2), capable to count particles > 0.5um. (Met-One 217A)
1.4. Three HEPA-filters (fig. 1; HEPA). (Pall DFA 3001 V002PV 0.2 um)
1.5. Tube A: PVC tubing, transparent, internal diameter 6 mm, length: 50 cm.
Tube B: PE tubing with an internal diameter of 6 mm to connect the counter with the test object.
1.6. T-piece to connect the pressure line and counter line to the test object. The T-piece must be fitted with a metal tube, internal diameter 3 mm, of such a length that it fits half the height of the test object (55 mm for the standard test object).
1.7. Compressor/reduction valve assembly (fig. 1; P) capable of producing a pressure of 160 kPa at a flow of 3 litres/minute.
1.8. Vacuumsystem (fig. 1; V) capable of producing a pressure of 50 kPa at a flow of 6 litres/minute.
1.9. Standard test object being an instrument tray 580x245x110mm: volume 0.55 ft^3. When testing real final packs, this standard test object is replaced by the pack to be tested.
1.10. Suitable connectors to fit the T-piece on the test object. The T-piece must be inserted into the test object to a depth which equals the geometric centre of the test object.
1.11. Three active flow controllers (fig. 1; FC1, FC2 and FC3) with a range from 0 to 3 litres/minute and a accuracy of 1% of the scale range (Brooks 5850E).

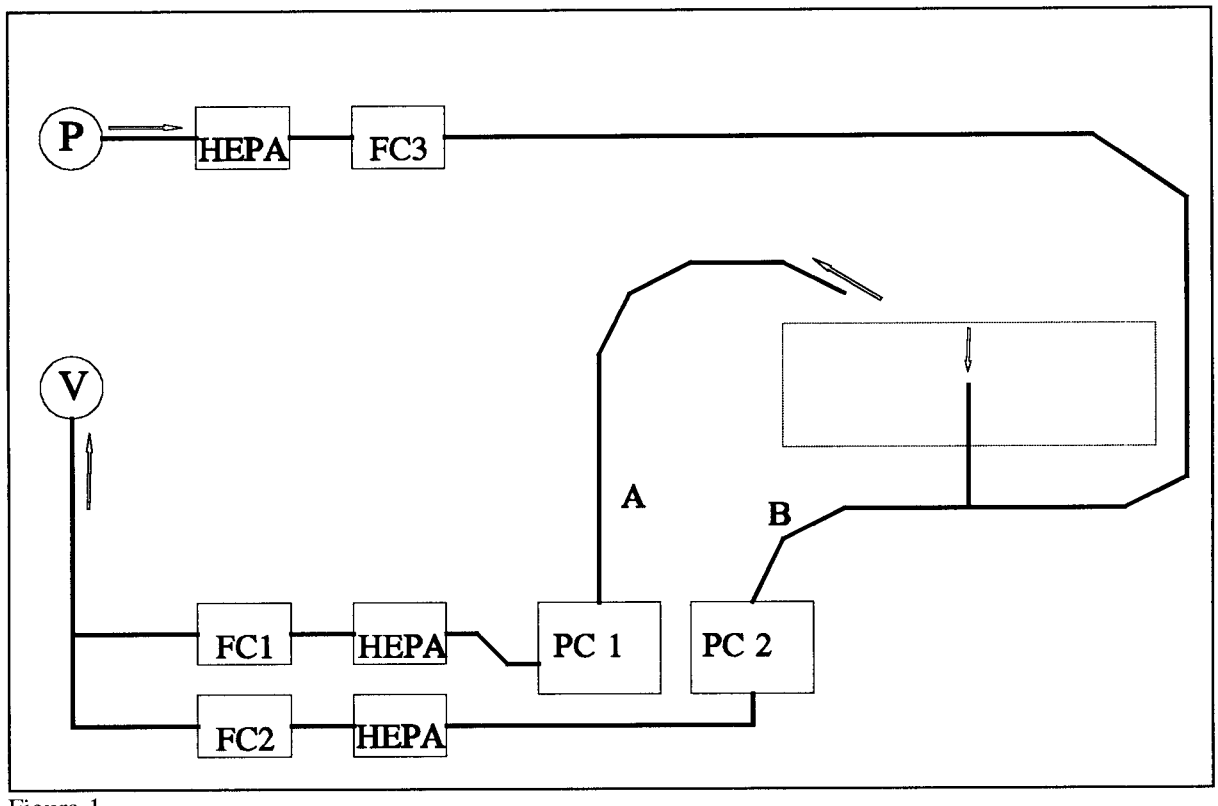


Figure 1.

2. Method

2.1. Connect the temperature measuring and recording system to the sterilizer.
2.2. Pre-heat the sterilizer
2.3. If the final pack must be constructed from sheet material, wrap the instrument tray (1.9), as instructed by the producer of the sheet material. Close and seal the pack as instructed by the producer.
2.4. Put at least three temperature sensors in the final pack to be tested. Position the sensors in locations which are likely to give the largest temperature gradient when cooling. Make sure that the pack is empty except for the temperature sensors and, when necessary, a support to keep the pack in the correct shape. Seal the entrances in a suitable manner.
2.5. Sterilize the pack in a multi vacuum process of 134°C; unless otherwise instructed by the manufacturer of the pack or the producer of the sheet material.
2.6. As soon as the "end of cycle" signal is given, open the sterilizer and remove the pack from the sterilizer chamber.
2.7. Allow the pack to cool to ambient temperature.
2.8. Repeat 2.3. to 2.6 at least 3 times.
2.9. Calculate the largest temperature gradient in a 1 minute time interval.
2.10. Calculate from the temperature gradient the pressure gradient.
2.11. Calculate from the pressure gradient the theoretical volume contraction expressed in ml/min.

2.12. Connect the equipment as drawn in figure 1.
2.13. Determine the "no-material effectivity" of the system.
Install the standard test object. The object is not wrapped.
2.14. Connect the test object to the T-piece and seal the connection.
2.15. Set the flow controllers FC1 and FC2 to the flow at which the particle counter is calibrated. Set FC3 so that the value FC3 - FC2 equals the intended flow from the object (as calculated from the temperature drop direct after sterilization).
2.16. Set the vacuum system to a pressure of 50 kPa. Set the compressor or the reduction valve to a pressure of 160 kPa.
2.17. Wait a few minutes for the flows to stabilize.
2.18. Start the particle counters measuring particles >0.5 um and >1.0 um. The duration per measurement must be 10 minutes.
Note: Try to keep the number of particles in the surrounding air as constant as possible. Preferable the measurements are taken overnight to eliminate strong fluctuations in the particle levels due to activities.
2.19. Let the particle counters take measurements until at least 90 measurements are taken.
2.20. Make per measurement a correction on the $count_{outside}$ for the difference between the outside flow and the object flow.
Correction factor = (setpoint FC2 - setpoint FC3)/setpoint FC1.
2.21. Calculate per measurement and per particle size the reduction factor. Calculate the average reduction factor from the reduction factor per measurement.
Reduction factor = ($Count_{outside}$ / $Count_{inside}$)
2.22. Make correction on the result by deleting the measurements which deviate from the average value with more than ±3sd.
2.23. Repeat the procedure (2.18-2.22) at least 4 times. Calculate the average reduction factor. This value is the "no-material reduction factor".

2.24. If the pack is not already sterilized, sterilize the pack in a multi vacuum process of 134°C; unless otherwise instructed by the manufacturer of the pack or the producer of the sheet material.
2.25. Connect the pack in the test system.
2.26. Calculate per measurement and per particle size the reduction factor. Make per measurement a correction on the $count_{outside}$ for the difference between the outside flow and the object flow.
Correction factor = (setpoint FC2 - setpoint FC3)/setpoint FC1.
Calculate the average reduction factor from the reduction factor per measurement. Make correction on the result by deleting the measurements which deviate from the average value with more than ±3sd.
Correct the average reduction factor by dividing it by the "no-material reduction factor". Calculate from this corrected reduction factor the effectivity value of the final pack.
*Effectivity = {1-(1/[Reduction factor/No material reduction factor])}*100%*
2.27. Repeat the procedure (2.25 to 2.26) at least four times. Calculate the average effectivity for the type of final pack.