Emission Measurements after Sterilization with ETOX®*

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For cold sterilization with microbicidal gas mixtures, ethylene oxide is applied in gas concentrations of 1,250 - 1,500 g/m³. It is easy to see why especially large-scale plants were interested to learn how much gas is emitted after sterilization and in which radius and for how long MEC (maximum emission concentration) values are exceeded.

The aim of the following tests was to determine the ethylene oxide concentrations directly at the emission opening during evacuation of the sterilization chamber under different conditions. The concentration of ethylene oxide was determined according to the heat-tone principle. The detection limit of ethylene oxide was determined at less than 5 g/m³. In order to first gain a survey of the effect of the abovementioned factors on the emission of ethylene oxide, different ethylene oxide concentrations were dosed into empty chambers and subsequently pumped out immediately.
Graphs 1 and 2 demonstrate how much only the air speed influences the concentration of ethylene oxide next to the rain cap. In both cases, we used a gas concentration of 1,500 g/m³. In graph 1, the air speed was only 0.25 m/sec so that we could measure considerably higher ethylene oxide concentrations at the beginning of the readings as compared to the air speed of 1.4 m/sec. in graph 2. The air speed also affects the length of ethylene oxide emission: At a low air speed (graph 1) ethylene oxide was emitted during a maximum of 6.5 minutes of chamber aeration; at higher air speed, ethylene oxide could already be no longer determined after 3.5 minutes (graph 2).

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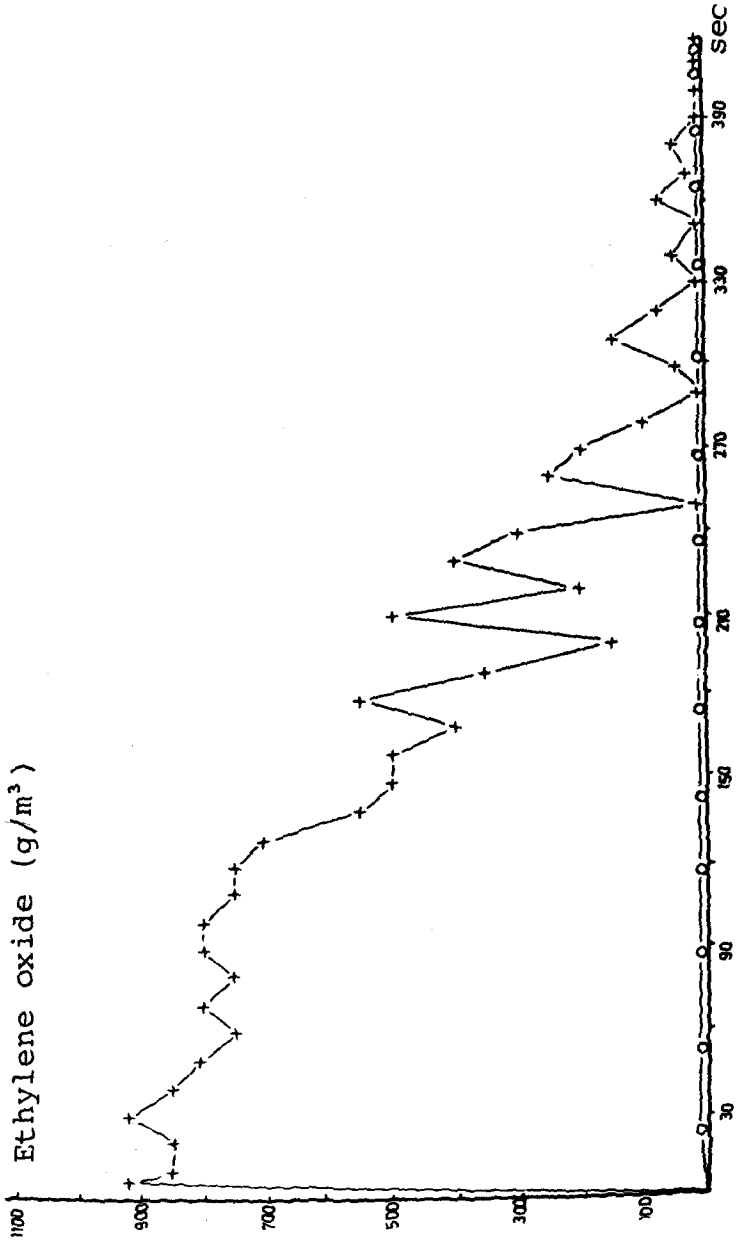
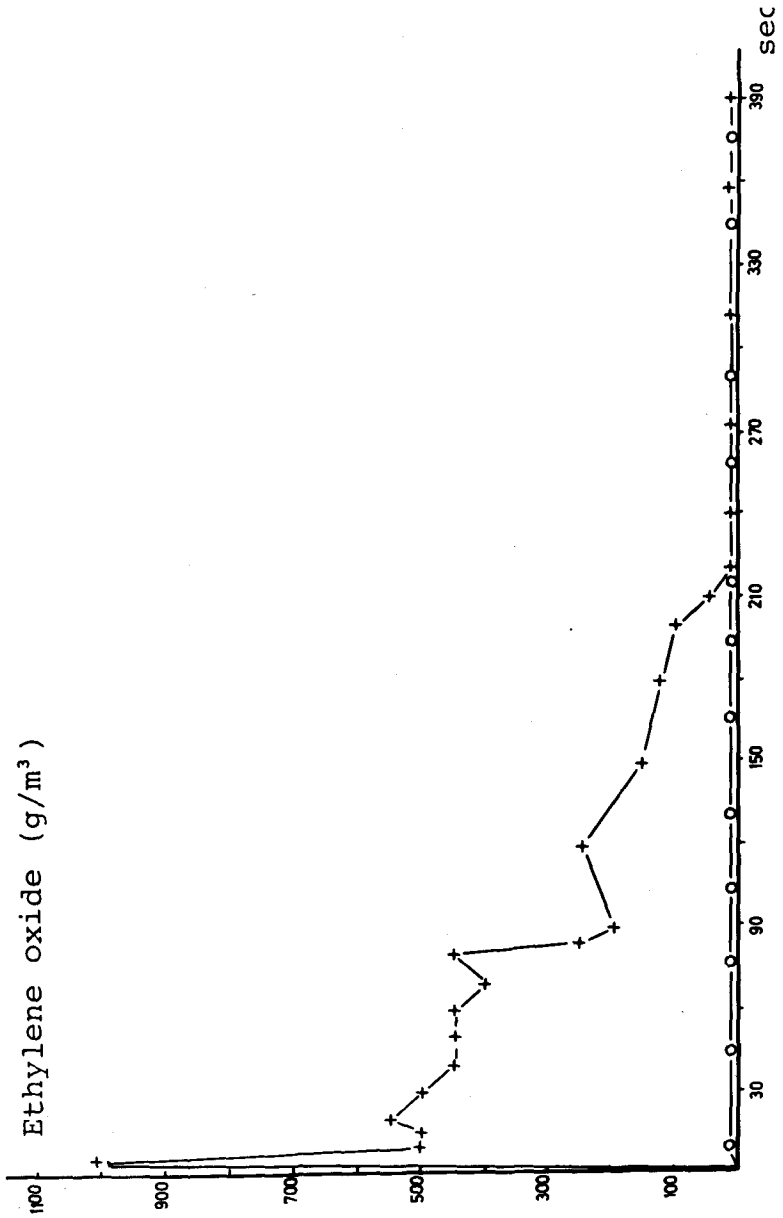
(ETOX = 90 % ethylene oxide
10 % CO_2)

Bulletin of Environmental Contamination & Toxicology,
Vol. 14, No. 4 © 1975 by Springer-Verlag New York Inc.



Graph 1:

Ethylene Oxide emission
Concentration in the chamber: 1.500 g ETOX®/m³
Chamber, 2 m³ capacity, empty
Emission speed v (theoretical) = 15.6 m/sec
Wind velocity: 0.25 m/sec, gusty
Temperature: 24°C (shade, 75.2 °F)
x = emission at the rain hood
o = emission at a distance of 25 cm

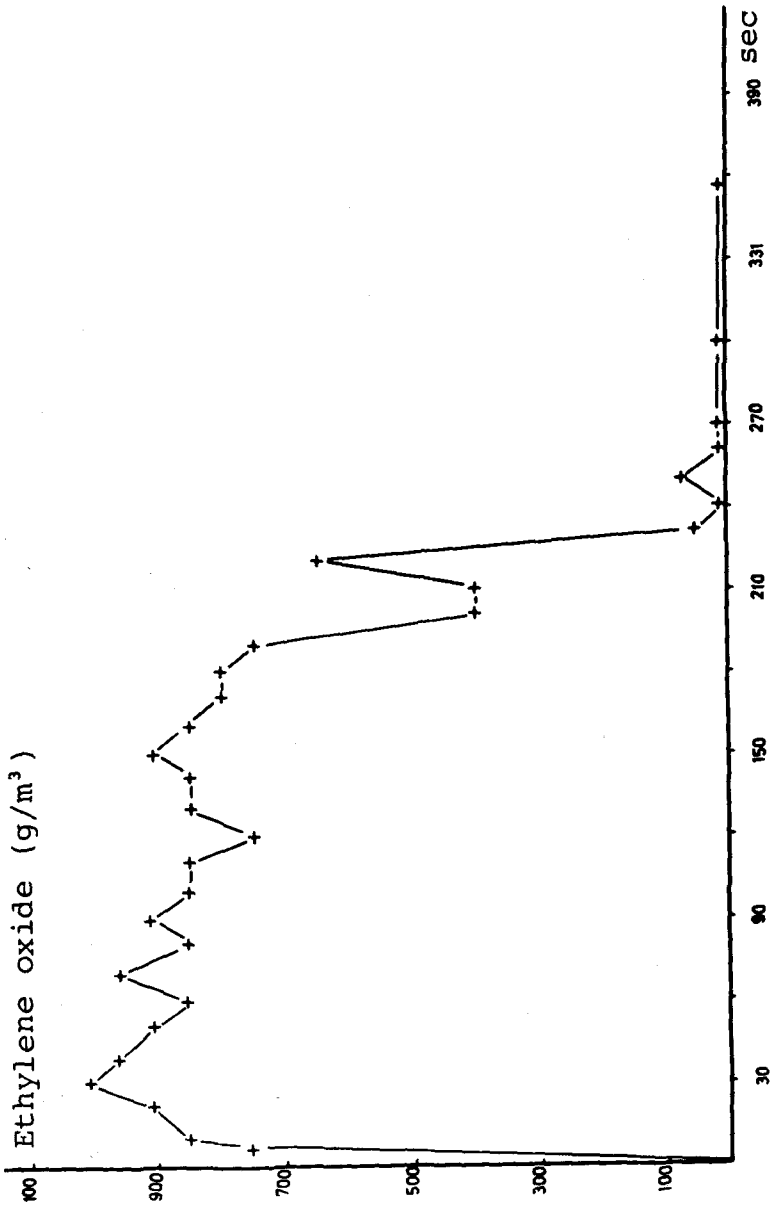


Graph 2:

Ethylene Oxide emission
Concentration in the chamber: 1.500 g ETOX®/m³
Chamber, 2 m³ capacity, empty
Emission speed v (theoretical) = 15.6 m/sec
Wind velocity: 1.4 m/sec, very gusty
Temperature: 24°C (shade, 75.2 °F)
x = emission at the rain hood
o = emission at a distance of 20 cm

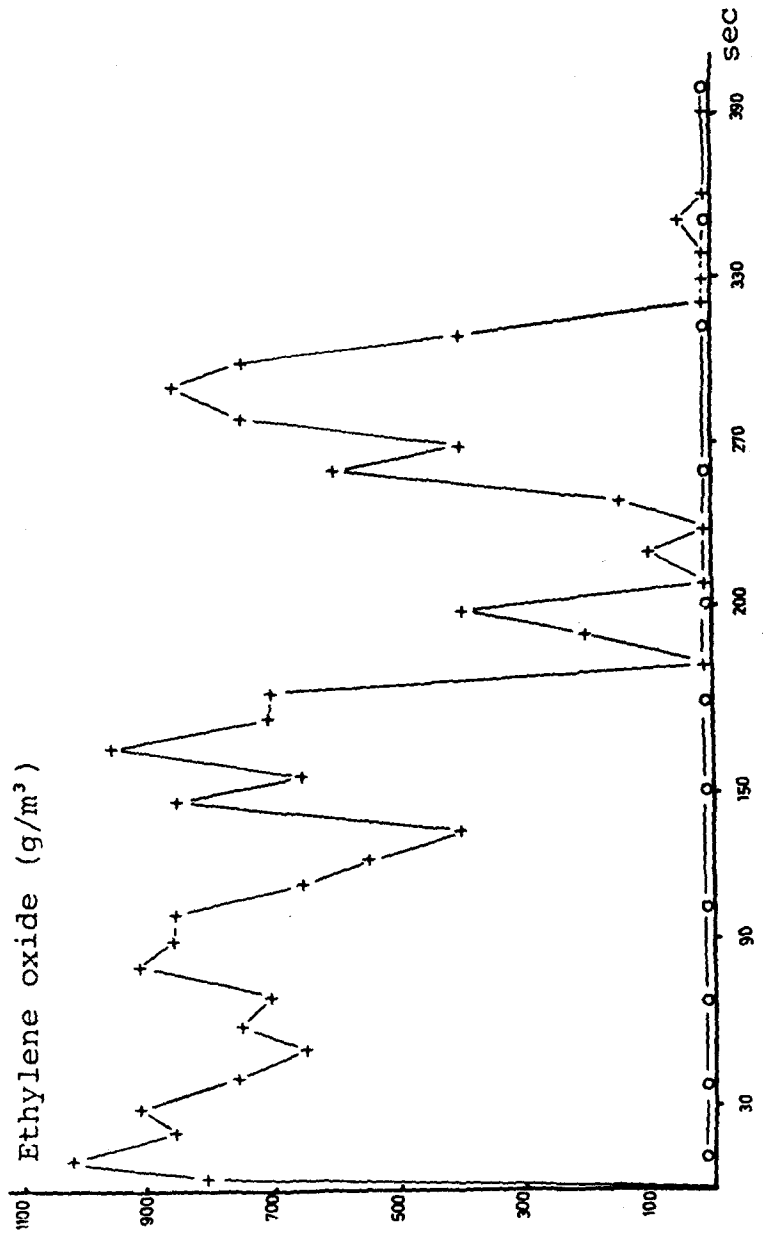
In the following tests we used 1.500 g/m³. In contrast to previous tests, however, we reduced the blow-off speed from previously v (theoretical) 15.6 to 5.9 m/sec.; this was done by widening the exhaust pipe.
When comparing the ethylene oxide concentration curve of graph 3 to that of graph 1 which corresponds approximately, it is astonishing that a reduced blow-off speed results in a definitely higher ethylene oxide concentration next to the rain cap as compared to the higher blow-off speed; the gas concentration level also exists for a longer period of time. Graph 3 shows that this level of approx. 900 g/m³ lasted for almost 3 minutes; only thereafter did the concentration of ethylene oxide decline rapidly. Under these conditions, no more ethylene oxide could be determined directly at the rain cap after 5 minutes. In graph 4 we had reduced the blow-off speed once more to 3.9 m/sec. Readings of the ethylene oxide concentration therefore showed that even after 5 minutes of aeration, we could still determine ethylene oxide in concentrations of 850 g/m³; after another 60 seconds, however, the emission was completed. The total course of curve corresponded to the very gusty wind which registered in high concentration fluctuations.

The tests run so far were only of theoretical interest as the gas was only dosed into empty chambers and was drawn off immediately thereafter. Gas sterilisation under practical conditions is different in that the chambers are filled with more or less adsorbent material. We then tested the effect of sorption during sterilization with ethylene oxide containing gas mixtures on the emission of ethylene oxide during aeration of the chamber. Graph 5 shows gas readings during aeration of a chamber of 2m³ capacity; in this chamber infusion instruments with 1.800 g ethylene oxide/m³ for 24 hours were fumigated. A significant difference between the theoretically possible emission of ethylene oxide according to a gas concentration of 1.500 g/m³ (graph 1) and the emission actually measured in practice (graph 5) became apparent. Whereas graph 1 shows for almost 2 minutes an ethylene oxide concentration of approximately 800 g/m³, graph 5 shows this to be 400 g/m³ for some 60 seconds only. The period of emission was approximately 6 minutes. The previous readings were made using a chamber of 2 m³ capacity, where a maximum of 3.600 g ETOX could be applied. Most industrial sterilization chambers, however, have larger dimensions. For this reason, we made the following readings using a chamber of 15 m³ and sterilizing disposable syringes with 1.330 g/m³ for 6 hours. In this experiment (graph 6) we determined a maximum



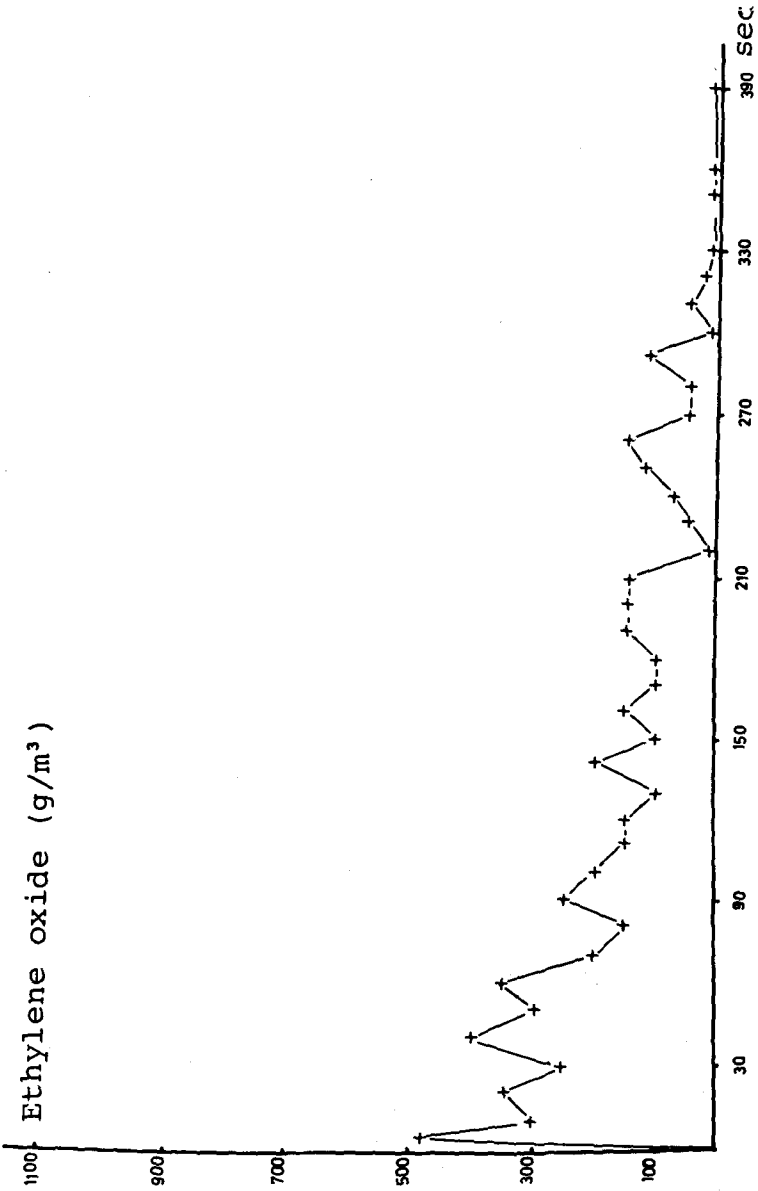
Graph 3:

Ethylene Oxide emission
Concentration in the chamber: 1.500 g ETOX®/m³
Chamber, 2 m³ capacity, empty
Emission speed v (theoretical) = 5.9 m/sec
Wind velocity: 0.15 m/sec
Temperature: 19.5 °C (shade, 67.1 °F)
x = emission at the rain hood



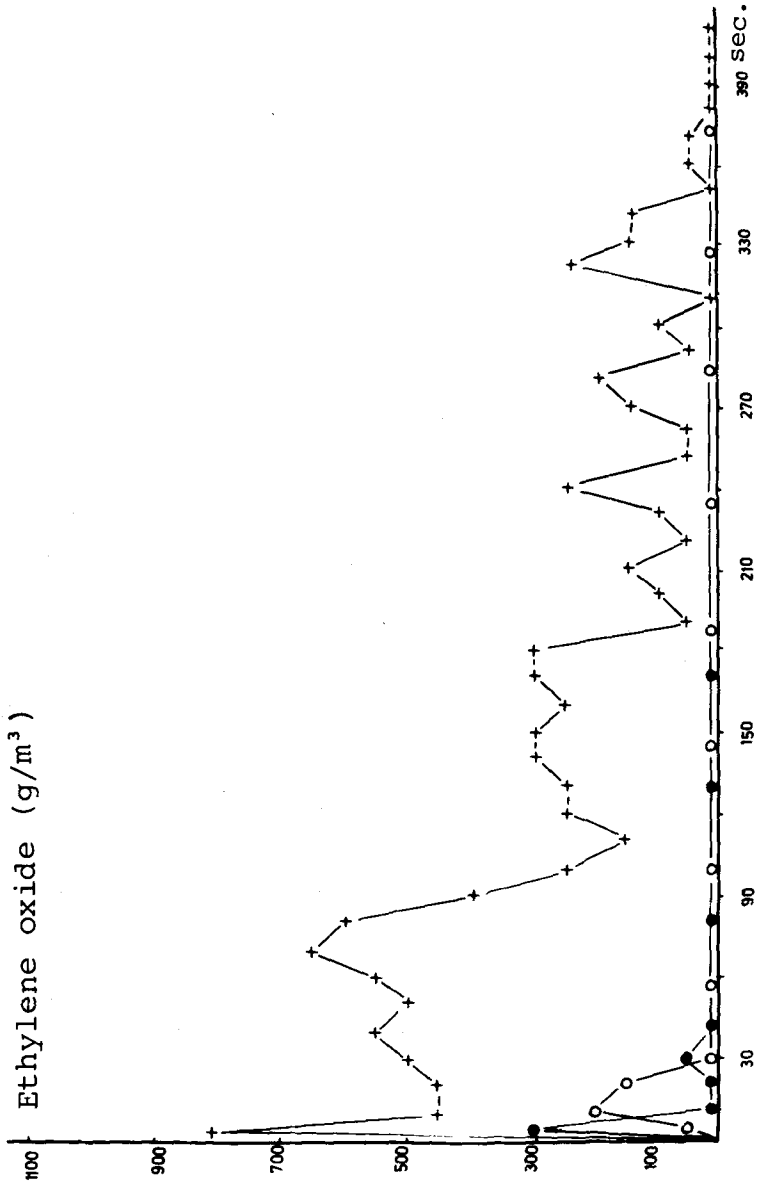
Graph 4:

Ethylene Oxide emission
Concentration in the chamber: 1.500 g ETOX®/m³
Chamber, 2m³ capacity, empty
Emission speed v (theoretical) = 3.9 m/sec.
Wind velocity: 0.3 m/sec, gusty,
Temperature: 24°C (shade, 75.2 °F)
x = emission at the rain hood
o = emission at a distance of 20 cm



Graph 5:

Ethylene Oxide emission
Concentration in the chamber: 1.800 g ETOX®/m³
Chamber, 2 m³ capacity, filled with infusion instrument, Emission speed v (theoretical) = 15.6 m/sec
Wind velocity: 0.1 m/sec
Temperature: 20 °C (shade, 68 °F)
x = emission at the rain hood



Graph 6:

Ethylene Oxide emission
Concentration in the chamber: 1.330 g ETOX®/m³
Chamber 15m³ capacity, filled with disposable syringes
Emission speed v (theoretical) = 29.4 m/sec
Wind velocity: 2.7 m/sec, gusty
Temperature: 26 °C (shade, 78.8°F)
Emission at the rain hood
x = first aeration
o = aeration under vacuum
● = second aeration

ethylene oxide emission of 500-600 g/m³ during the first 2 minutes of aeration. In the four subsequent minutes, emission fell to the detection limit showing significant changes of the concentration. In industrial sterilization, it is often customary to wash the chamber with fresh air for a period of 5 minutes under sustained vacuum, when the first evacuation process has been completed. Graph 6 shows that during this process only immediately after the beginning, approximately 200 g ethylene oxide/m³ could be determined. Following this, the chamber is usually evacuated again, then filled with fresh air, and the second aeration process starts.

In this process, again, we could determine a maximum ethylene oxide concentration of 300 g/m³ only immediately after beginning.

In conclusion, we may summarize as follows:

During the sterilization process with ethylene oxide containing gas mixtures as customary in practice, much lower quantities of ethylene oxide are emitted into the environment as commonly supposed.
By using a high blow-off speed and a considerably long exhaust pipe, the ethylene oxide emitted will very rapidly be reduced to such an extent that even at the beginning of aeration concentrations of more than 5 g/m³ could no longer be detected at a distance of 20 cm from the rain cap.
The emission of ethylene oxide depends very much on the gas concentration per m³ and less so on the total amount of gas used per chamber capacity for sterilization. This is a quite unexpected factor.
The last readings showed a high gas adsorption of medical disposable instruments, this fact making it necessary to sufficiently aerate freshly sterilized material again before use in a room specially provided for this purpose.