

Novaerus  
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***Via email***

**Assessment of Novaerus plasma technology on the basis  
of the Novaerus data and records  
and personal assessment and inspection**

Administration:  
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Datum: 15/07/03

Dear Mr McBrien,

On the basis of our discussions, the personal inspection of your company headquarters in Dublin and the documents given to us, I am reviewing the Novaerus plasma technology with regard to its use in healthcare within central European countries, but particularly in the Federal Republic of Germany.

**1. The Active Principle of Novaerus Plasma Technology**

Plasma sterilisation was introduced in Germany and other European countries as far back as the early 1990s. In order to carry out this procedure, 59% hydrogen peroxide was ionised in a vacuum and could then be used to sterilise thermolabile items.

However, 'cold plasma' generated by plasma coils, for example, also has an antimicrobial effect without a vacuum at normal atmospheric pressure. An extremely short exposure time is required for this. The coils which generate the plasma are made up of two coaxial wire netting coils separated by dielectric glass. Alternating current in the kilovolt range (with a relatively low current flow) ensures an ionisation of the air which passes through the device (intake and output via integrated ventilators). The ionisation takes place on the external coil, which has a higher diameter and a greater mesh width than the internal coil (1).

The ionisation, which is primarily based on electron activity, results in toxic or deactivating radicals which have a different coverage depending on the coil diameter, current strength and air flow, but are unstable in any case. Microorganisms and viruses which come into contact with the radicals during the stable phase are largely deactivated. Similar effects are known from wound care (hydrogen peroxide, activated water but also here the use of plasma) and water hygiene (ozone procedure, anolyte), but the effect here is based almost exclusively on the radicals (O<sub>2</sub>, O<sub>3</sub>, NO, NO<sub>2</sub>, OH) which attack amino acids and fatty acids and the energy used. In addition to this, small amounts of UV light are released at an antimicrobial wavelength of 220–280 nm, triggering damage to the DNA (1).

Additionally, however, due to the low energy level, the Novaerus technology must be implemented in such a way that only few toxic by-products are produced. The disadvantage of the limited range arising from this is compensated for by air being passed close to the coil. The correct term for this procedure can be referred to as 'direct barrier discharge', which means that no ions are able penetrate the interior of rooms equipped with Novaerus technology.

The main effect, however, is based on a breakdown in metabolism due to the damage to the cell membrane in microorganisms and the receptor-binding structures in viruses, for example the envelope in enveloped viruses. Hepatitis B viruses exposed in the serum were also able to be successfully deactivated in this way (2).

The damage to *Escherichia coli* which was exposed to a field of this type was illustrated using an electron microscope and is shown below by way of an example (Fig. 1). The severe damage to the cell wall leads to a breakdown in metabolism, triggering the rapid death of the microorganism affected. Since the damage is caused very rapidly, the short exposure time when passing through the plasma-generating coils is sufficient.

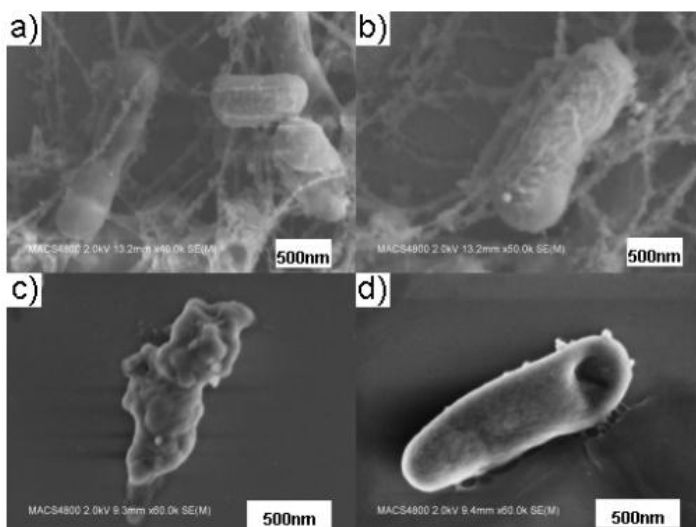


Fig. 1

Untreated (a, b) and treated *Escherichia coli* (source: NASA, 3)

In the literature, there are repeated indications of a very successful reduction of potential pathogens achieved by plasma technology in general. However, due to the various techniques used to manufacture plasma, there are very low levels of comparability.

Data generated from the plasma fields produced using Novaerus technology is therefore examined below. In the present case, the air is to be cleaned by means of a reduction of microorganisms and viruses through circulating air (device takes air in from the room, directs it past the plasma-generating coils and outputs it back into the room).

## 2. Efficacy of Novaerus Technology

### 2.1 In-vitro results

Using an experimental set-up in the laboratory, a reduction factor of 5 (see below) was achieved with the direct blowing in of Methicillin-resistant *Staphylococcus aureus* (MRSA) into a small chamber containing a Novaerus device (4).

In a further experimental structure, various microorganisms were continuously fed into a Novaerus device.

An attempt was then made to grow the microorganisms again. The aim was to determine the number of colony-forming units (CFUs) which had survived the passage through when  $10^5$  CFUs are input. The difference between the microorganisms input and the microorganisms which are able to be regrown is the reduction factor, which is generally expressed in  $\log_{10}$ . A reduction factor of 5 is therefore a reduction from 100,000 CFUs to 1.

The following results were identified:

Microorganism	Input dose (CFUs)	Reduction factor (RF) following passage
Enterobacteria including salmonellas	$2.1-8.2 \times 10^5$	> 5
Waterborne pathogens including pseudomonas	$6.1-8.2 \times 10^5$	> 5
Staphylococci including MRSA	$3.7-3.9 \times 10^5$	> 5
Bacillus group	$2.1-7.9 \times 10^5$	> 5*
Yeast fungi	$4.3-7.2 \times 10^5$	> 5
Mould fungi	$2.9-7.2 \times 10^5$	> 5
Virus deactivation	$10^{12}$	> 10

\*) In another trial (Microsearch, 5) only RF 4 was achieved.

## 2.2 Field studies

The field results are particularly interesting for a procedure to reduce airborne pathogens. In a crossover study carried out by the National Health Service in Great Britain in a 900-bed hospital in London, a 23% lower contamination rate for the floor and a 68% lower contamination of tables (an average of a 49% lower level of contamination compared to periods without the device) was identified when the device was operated in 4-bed and 1-bed rooms compared to the phases when the device was switched off. MRSA on surfaces was even reduced by 97%, and the number of airborne pathogens by 75%.

The number of airborne pathogens was also measured in the Uzsoki Hospital in Budapest, Hungary. The trial, which ran for a period of four weeks, started on 7 October 2014 with a control measurement which took place on the 7th, 14th and 21st day with the devices in constant operation. An 82% reduction in pathogens (21st day vs the control) was determined in the measurement of airborne pathogens. However, this success could not be consistently achieved in other departments and was dependent on the location in which the device was installed and location of the air supply inlets for ventilation (see below).

Similar effects were also achieved in a dialysis unit in Portugal. Here, the trial period was 42 days and the end result was an average reduction in pathogens of 84%. Once again, the result was found to be dependent on other ventilation. In both studies, a significant reduction in odours was described as an additional finding, but this was not quantitatively recorded.

Furthermore, you submitted summaries of other studies which could not be completely evaluated on the available data. In the interests of completeness these studies are listed and described below:

No	Location	Institution	Time period	Result
1	Ft. Myers, Florida, USA	Page Rehabilitation and Healthcare (advanced care, dementia)	10/2012–10/2013, control 06/2012–09/2012	The time periods compared were 06–09/2012 (without Novaerus) and 06–09/2013 (with Novaerus) respectively. The number of nosocomial infections fell by approx. 75%, the proportion of those which were respiratory infections fell from 37% to 20%.
2	Boca Raton, Florida, USA	Regent's Park Rehabilitation and long-term care	08, 09, 11, 12/2013, 01, 02/2014	Reduction in nosocomial infections of approx. 52%.
3	Hialeah, Florida, USA	Care home	January–April 2012 (without Novaerus), January–April 2014 (with Novaerus)	Reduction in nosocomial C. difficile infections of 100%, recurrences of approx. 37% (dubious correlation here), decrease in respiratory infections of 33%. Missing data for 2013, missing data on 'best practice' measures in the title
4	Manchester, Connecticut, USA	Care home	06/2013–02/2014 (without) and 06/2014–02/2015 (with)	Reduction in Clostridium difficile of 50%  Respiratory infections of approx. 42%
5	Saint Mark Village Skilled Rehab	Rehabilitation (no further details)	January–July 2014	Comparison with APIC data pool and CDC estimates, missing data on repeatedly mentioned other 'best practice' measures
6	Dublin, Leopardstown	Park Hospital, Geriatrics and care	2009–2012	Presented as graph of staff sick days, three wards (1x control), one ward has significantly fewer, the other does not. Since fall in sick days also for control, probably other measures not documented.

Even if the Novaerus technology at 3 and 5 was apparently only part of a range of measures which were not shown in detail, and this is at least a likelihood at 6, at the very least a contribution to the reduction of nosocomial infections can be presumed. This appears at the very least likely, since the operating principle is sporicidal, bactericidal and virucidal and/or brings with it a significant reduction in the relevant airborne pathogens. The role of the technology in the reduction of Clostridium difficile recurrences requires further evaluation – firstly because, until now, inadequate elimination of, e.g., diverticula has been presumed to be a cause, and secondly exploratory studies point to possible re-infection in the case of cohort isolation.

Furthermore, a study report from Denmark (Rigshospitalet, Copenhagen) dated 23 January 2015 has been submitted. Here, small flashes of light from the device were observed in connection with dust particles; it was, nonetheless underlined that no ions or toxic substances were emitted by the device. On this occasion, the technology was compared in two identical wards, one of which was fitted with the technology. While measuring the overall average levels of airborne microbes revealed no significant effects, the microbial load was demonstrated to be around 50% lower on surfaces with low or no hand-to-skin contact. The infection rates also differed year on year:

Sample types	Dept. 3131 (control)		Dept. 3132 (Novaerus tech.)	
	2013	2014	2013	2014
Sputum	4	8	13	14
Post-operative wounds	2	1	4	2
Other wounds	8	4	13	14
Urine	20	33	49	31
Total	34	46	79	61
Difference	+ 35%		- 23%	

In terms of overall efficacy of the technology it can therefore be stated that a reduction in airborne microbes by approximately a power of ten (50–80%) can be expected under field conditions.

This corresponds to the outcome of ongoing cleaning or disinfection by means of surface cleaning with wipes under field conditions.

On the basis of the in-vitro data, a higher reduction in airborne viruses could be assumed.

### **3. Legal framework for the use of Novaerus plasma technology in healthcare facilities**

#### 3.1 Law on hazardous substances

In accordance with the Ordinance on Hazardous Substances, neither patients in hospitals nor residents in old people's homes nor staff may be put at risk by the use of chemical compounds. Regarding cleaning and disinfection, risk includes the following points:

1. Inhaling potentially toxic substances when handling the concentrates
2. Skin damage caused by contact with potentially toxic/harmful substances
3. Allergenic potential as a result of chemical compounds in cleaning agents and disinfectants.

While points 1 and 2 primarily relate to the staff in the facility, point 3 is also relevant for patients and residents.

The law on hazardous substances – Section 7 GefStoffV (Ordinance on Hazardous Substances) – requires the lowest possible level of risk caused by chemical substances with the same effect. In terms of purifying the air of microorganisms and viruses, this would equate to the air being filtered with an F9 filter which is usually installed in air conditioning units

with no or only a marginal germ-reducing effect. If you take the generation of odours as a target criterion, a comparison with standard "air fresheners" such as air sprays would be justified. With Novaerus plasma technology, non-specific toxic radicals are generated; these are, however, unstable and therefore have a low range and remain in the device (1). This means they are not inhaled and have a damage potential equivalent to filtered room air. The described destruction of odour effect, which is probably based on oxidation processes, however, is clearly less harmful than air sprays as these always contain chemicals and scents which can be classed as potentially allergenic.

The radicals produced also include ozone. In order to implement the Ordinance on Hazardous Substances, the coil had to be dimensioned such that the greatest possible deactivation of microorganisms and viruses is achieved inside the device, while ensuring as little ozone as possible escapes. This was also able to be shown (1).

Conclusion: While greater efficiency can be attributed to the reduction of microorganisms and viruses in room air than an F7/F9 standard filter on the basis of the data from Section 2 of this document (as the microorganisms are killed and do not remain in the filter, this also reduces maintenance costs), there is an advantage over chemical air fresheners under the law on hazardous substances as no potential allergens are emitted, and may rather even be reduced by means of oxidation processes.

### 3.2 Occupational safety

Employees in healthcare facilities are exposed to pathogens which are brought into the facility by patients. In the Biological Agents Ordinance and the associated Technical Rules for Biological Working Materials 250 an extensive package of personal protective measures is therefore set out as an implementing provision. In addition to the obligation to wear appropriate protective clothing or personal protective equipment, this also includes the support of the employer to define appropriate procedures for cleaning and disinfection and to describe these in a cleaning and disinfection plan. In accordance with the guidelines of the Commission for Hospital Hygiene and Infection Prevention, mechanical procedures (wipe disinfection) are to be used for cleaning and disinfection, although a nebulisation procedure for hydrogen peroxide was also included on the list in 2013.

The Biological Agents Ordinance and the Technical Rules for Biological Working Materials 250 require the exposure to pathogens to be kept as low as possible for employees and the standard risk should not be exceeded. Novaerus technology can therefore, on the basis of the data listed under Section 2, contribute to preventing illness and infections, particularly those caused by airborne pathogens, without generating risks as described under 3.1, and can therefore be implemented without hesitation. However, in accordance with current legislation, it is not possible to forego disinfection measures or protective clothing where necessary, when operating Novaerus devices.

### 3.3 Protection of patients and residents

People are continuously emitting potential pathogens into the environment. In enclosed rooms these are distributed around the room via the air in thermals, whereby the concentration in the "patient's immediate surroundings", i.e. within a distance of around 1.5 m from the patient, is highest. The microbial load can be reduced by means of a high air exchange rate (dilution effect) or by recirculation devices which filter pathogens out of the air.

Instead of a filter matrix, which over time becomes covered with bacteria and in some cases viruses, Novaerus technology uses plasma-generating coils which, unlike filters, also deactivate potential pathogens too. A lower concentration of pathogens in the air also logically means surfaces with fewer pathogens on them. This decreases the likelihood of transferring pathogens as surfaces with reduced bio-burden mean fewer pathogens are transferred to hands, and therefore that fewer pathogens are transmitted to others or to oneself.

Since only potential pathogens which are in the air flow channelled through the device are captured, in accordance with Section 23 paragraph 3 IfSG (Infectious Diseases Protection Act) in combination with the KRINKO/RKI recommendation "Hygiene Requirements when Cleaning and Disinfecting Surfaces", the Novaerus technology can replace neither cleaning nor disinfection measures, but it can supplement them.

When the room air throughflow rate through the device is at an appropriate level, the effect lasts throughout the day and the speed of recontamination at least of surfaces which are not close to patients is reduced. In the NHS study, an average germ reduction on tables of 49% was determined, which essentially corresponds to an additional cleaning (KRINKO/RKI: cleaning efficiency 50–80%, 6).

Of course, the device cannot be loud in order to enable undisturbed sleep.

#### 4. Expert opinion on possible implementation of Novaerus

Although, varied to date, the exploratory results suggest that, through constant reduction of pathogens, the Novaerus technology maintains successfully cleaned and disinfected surfaces for longer, resulting in a sustained reduction in the bio-burden within rooms. Since, Novaerus technology is based on primarily a deactivation of pathogens and not filtering, it can be used in isolation rooms. Its use is therefore perfectly conceivable for patients isolated as a result of existing microbial colonisations or infections, as well as for patients in protective isolation due to a suppressed immune system. There is no limitation to the deactivation of pathogen spectrum with Novaerus technology case, so a reduction in infectious outbreaks, which often originate from contaminated surfaces, is also likely. As the studies show, the Novaerus technology represents a valuable addition to existing hygiene management tools .

If minor operations are carried out in procedure rooms in medical practices, but there is no ventilation technology at Room class 1b level in accordance with DIN 1946 part 4 and it is only possible to ventilate the room via the window, Novaerus technology will contribute to the prevention of infection by reducing the entry of pathogens into the wound and the area around the patient, including the instruments. This also applies in wound care centres.

Since a reduction in odours is repeatedly described and appears to be plausible on the basis of the mechanisms listed under Section 1, an implementation of Novaerus in unclean rooms, in palliative care and on tumour wards should also be obvious.

In the elderly care sector, use in soiled or dirty and laundry rooms or sluice rooms also seems sensible and obvious, as ventilation systems in such rooms often do not deal adequately with the odour problem particularly in older buildings.

It should be noted that efficiency of the technology can depend on the physical location of the units in the room (close to the ceiling where possible) as well existing ventilation systems. For example, strong ventilation may reduce the effectiveness of the technology as it may divert the flow of air away from the Novaerus units (Budapest study).

To mitigate this effect, smoke tests could be devised to study airflows in the room, and the optimal position of the devices thus determined. This procedure could then be repeated in warmer seasons as the air flows may differ due to varying thermic conditions.

The devices should be installed such that air supply inlets or exhaust shafts do not impair the desired circulation of air.

On the basis of the data recorded to date, the air exchange rate achieved by ventilation systems in the room should not exceed 5–6. This is precisely the case in rooms filled with 'standing air'. The lack of dilution effect means that in rooms of this type if pathogen counts and odour levels are higher, resulting in the possible uses above.

## 5. Further Investigations for validation

A distinction should be made between points which still need to be clarified by the manufacturer and those which need to be taken into account during installation in order to ensure the necessary efficiency.

### 5.1 Further data

In general, the data pool under field conditions needs to be increased. The following data would be of value

Data	Justification
Precise relationship between room size and required Novaerus capacity	As in all air circulation procedures, the air exchange rate is important. Appropriate air exchange protocols and which units should be used should be determined.
Statements on the effect depending on room temperature and air humidity	Although there are indications that these parameters do not play a role or only play a minimal role (7), clarity on this is needed.
Statements on the impact of air exchange rates determined by outside forces (fresh air supply)	The results of the investigation in Hungary suggest that a high air exchange rate with a fresh air supply has a negative impact on the performance of the units when places near to ventilation inlets. Upper limits must be determined for this.
Quantitative presentation of the reduction in odours	For the time being there are only episodic, subjective, sensory observations on this which need to be verified by quantitative measurements.



## 5.2 Individual facility validation

The following steps should be carried out during planning and installation:

- Determination of the rooms in which the Novaerus technology is to be used
- Determination of the device type (dimension, air exchange rate) depending on the number of cubic metres identified
- Determination of the installation location depending on the other ventilation outlets or exhaust shafts (generally near to the ceiling, as far from air outputs as possible)
- Definition of the cleaning interval for the housing in the hygiene plan (e.g. twice a year, in the intensive care ward and operating theatres every two months).
- Measurement of the effect using culture plates (there must be initial values for this), at least one measurement point should include areas which are rarely cleaned such as the top of a cupboard. The measurement should be repeated annually.

## **6. Conclusion**

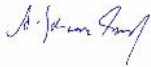
There is currently no practicable alternative to Novaerus technology for the purposes cited in Section 4. The technology therefore presents a most promising component in overall hygiene protocols for preventing infections in isolation rooms, high-risk areas, as well as operating theatres with insufficient ventilation technology, where filters are often covered with bacteria. The in-vitro data speaks for itself in this regard, while the few controlled field studies which have been carried out, lead to the conclusion that the reduction in pathogens in the air is of a magnitude of 80% (75–84%) and on surfaces it is of a magnitude of 50%. This will also result in a decrease in staff contamination, since it is accepted that when hand hygiene is inconsistent, many bacteria and viruses transfer from surfaces and fomites onto staff members' hands. These pathogens then infect other colleagues or patients, or lead to illness and infection in the staff member him/herself. It would therefore be sensible to collect further data, as described under 5.1 but it is already possible to state that use in Germany under the conditions mentioned completely complies with existing hygiene laws.

## **Literature**

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Yours sincerely,



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