

Submission form

Innovative technologies that address global health concerns

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1. Applicant Information¹

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1.8. Title of innovative technology	Ambient Gas Plasma for Antisepsis	

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¹ The applicant refers to the person responsible for submitting the application as an individual or on behalf of a company, institution, university, government or non-profit organization.

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Certification

Signature of the applicant or the organization's authorized representative to confirm that:

The applicant accepts that the use of the WHO logo and/or name is only allowed with prior written permission from WHO.

All of the information in the application is current and correct.

The applicant certifies that it owns all the intellectual property rights of the product disclosed and related to its use.

Name: David B. Graves Title: Professor

Signature:  Date: Jan. 19, 2010

The application form should be completed in English and e-mailed as a PDF document to:

medicaldevices@who.int

Receipt of applications will be confirmed by e-mail.

The deadline for submission is 31 January 2010.

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2. Summary of application

2.2 Please provide a summary of the health problem to be addressed and the proposed solution. Please do not disclose your or your institution's identity. (2000 characters maximum)

Bacterial, fungal and viral infections are serious health problems throughout the developing world. Lower respiratory infections, diarrheal disease, neonatal infections and infant/child mortality are linked to such infections. In hospitals and crowded situations, infection transmission occurs through personal and/or object-mediated contact. Antibiotic resistant bacteria are prevalent and virulent and anti-microbial resistance is implicated in infectious disease mortality. The cost and logistics of combating these infections with conventional means are sometimes prohibitive, particularly where refrigeration and reliable supply chains are absent. Recently, a set of antiseptics, disinfection and wound healing technologies have been demonstrated which utilize ambient gas plasmas (AGP). Ionized gas plasmas are well established in plasma displays and etching silicon microchips. Plasmas used for antiseptics/disinfection/wound healing applications operate near room temperature in air. AGP create a mixture of chemically active species that rapidly destroy microbial targets without harming mammalian cells/tissues. When AGP are sustained in air, a small fraction of molecules are converted to charged and neutral reactive oxygen species (ROS) and reactive nitrogen species (RNS) that are thought to be the dominant anti-microbial agents. Exposure to AGP can achieve bacterial reduction of 10^5 in < 10 seconds and 10^7 in 30 seconds (in vitro) for E. coli (typical Gram-negative bacterium), Enterococcus (Gram-positive bacterium), and Candida albicans (a commensal yeast). The technology offers significant potential advantages over soap and water, alcohol-based or antibiotic based skin hygiene approaches. No evidence of bacterial resistance was observed. AGP has also been shown to promote blood clotting and wound healing. AGP require only electricity in small amounts, so the need for refrigeration or a logistics chain for re-supply is eliminated.

2.2 Please provide a generic summary of the health problem to be addressed and the proposed solution that may be made public. Please do not disclose your or your institution's identity or any confidential information in this section. (800 characters maximum)

Bacterial, fungal and viral infections are a serious health problem throughout the developing world. Ambient (air) gas plasmas create a mixture of active chemical species that have been shown to rapidly destroy microbial targets in a way that does not harm skin or other mammalian cells and tissues. In addition to killing bacteria on skin and surfaces, the technology has been shown to promote blood clotting and wound healing. Hand-held plasma devices are inexpensive, effective, use very little electricity and no consumable chemicals. The technology is well suited to low- and middle-income country needs.

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3. Project characterization

3.1. Please select the appropriate product category.

- Instruments
- Medical equipment
- Implants
- Disposables
- Software
- Assistive devices
- Other: Please describe

3.2. Please check which of the following applies.

- The product concept is novel.
- The product is an adaptation of an existing medical device for the low- and middle-income setting.
- The product is an adaptation of an existing non-health product for a health purpose.
- Other: Please describe

3.3. To which health concern(s) does your project relate (check all that apply)?

- Lower respiratory infections
- Diarrhoeal diseases
- HIV/AIDS
- Malaria
- Premature birth and low birth weight
- Neonatal infections
- Birth asphyxia and birth trauma
- Unipolar depressive disorders
- Ischemic heart disease
- Cerebrovascular disease
- Tuberculosis
- Road traffic accidents
- Chronic obstructive pulmonary disease
- Alcohol use disorders
- Refractive errors
- Maternal morbidity and mortality
- Infant and child (Under 5) mortality
- Cancer
- Disability

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3.4. Please indicate the development stage of your submission.

- Commercialized (in high-income country/-ies)
- Ready to be commercialized
- Under development
- Proof-of-concept stage
- Other: Please describe

3.5. If your product is commercialized, please provide the following information.

a. When and where was it first commercialized?

Please provide a list of countries where is it currently commercially available in Annex A.

Information provided in Annex A.

b. Indicate in Annex B where regulatory conformity assessment has been undertaken if at all.

Information provided in Annex B.

c. Is a product manual available on the internet? Yes No

If yes, website address where manual can be found:

If no, could a manual be provided if requested? Yes No

If your product is not commercialized yet, please provide details on the stage of development (300 characters maximum). A diagram or drawing may be included as Annex.

Prototype devices exist in our laboratories and other laboratories around the world. Efficacy and toxicity results (*in vitro*) have been published.

Diagram or drawing provided as Annex E.

3.6. The application of the technology is:

- Preventive
- Screening
- Diagnostic
- Therapeutic
- Rehabilitative
- Assistive
- A support technology to health technologies
- Other: Please describe

3.7. The technology is intended to be used:

- By the users applying it to themselves
- In a health post or community center

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- In a health centre
- In a district/general/rural hospital (internal medicine, obgyn, paediatrics and general surgery)
- Provincial hospital (has more clinical specialties than the district or rural hospital, and also specialized diagnostic and treatment services)
- Regional, specialized, tertiary care, or research hospital
- Other: Please describe

3.8. Describe how the technology is innovative.

The handheld, portable ambient gas (air) plasma device for antiseptics, bleeding control and wound healing is a novel technology. It offers dramatic possibilities for reducing nosocomial infections; neonate cord infections; speeding wound healing; reducing excess bleeding after surgery; for burn wounds and other open-wound situations. The devices are inexpensive, simple, use no consumables and very small amounts of electrical power. Device manufacture and repair are simple and inexpensive. The technology is ideally suited to a developing world context.

3.9. Describe how the product is an improvement over existing technologies.

Ambient air plasma antiseptics devices work much more rapidly and replace alcohol-based hand hygiene products and skin antiseptics compounds, such as chlorhexidine. The plasmas act on antibiotic-resistant bacteria. Devices can be used as a general skin antiseptics, surgical scrub, and a pre-operative skin preparation, as well as prior to the use of hypodermic needles or catheters. It can be used to control bleeding and to promote wound healing.

3.10. Please select the appropriate statement(s).

- The technology has not previously existed.
- The technology has not previously been made available in low- and middle-income countries.
- The technology is safer, and/or simpler to use than earlier solutions.
- The technology is more cost effective than previous technologies.

3.11. Describe the ownership of intellectual property (IP) of the technology including the role of third parties by ticking the appropriate box(es).

- Patent(s) granted
- Patent(s) pending
- Registered Trade Mark
- Design Right(s)
- Copy right(s)

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- Licensed IP
- Business/trade secret
- Test data protection
- No protection applied for
- Other: Please describe

Please provide further information such as patent or application number if applicable:
MI (Max Planck Innovation, associated with the Max Planck Society, Germany) applications:
4063 WWT, PCT Patent Application; and 4073 WWT, EP Patent Application.

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4. Selection criteria information

In the following section answers are restricted to 200 characters.

4.1. Level of safety

Is the technology associated with any particular risks to patients, users and/or the environment?

Yes No

If yes, which?

The device amplifies low voltage (e.g., from batteries or line voltage) to high voltage, contained in the device. UV radiation and some possibly toxic compounds are created in low concentration.

Explain how these risks may be controlled.

The device is designed to shield patient from electrical hazard. UV/gas toxicity has been demonstrated to be minimal if device is not abused.

4.2. How does the technology address the health concern in question?

- What is the potential impact on the health problem?
Device is designed to rapidly and safely kill microbes on skin/wounds and objects/surfaces, reducing infections and infection transmission, promoting healing, and reducing bleeding.
- Indicate what kind of patient could benefit from the technology and how.
Carefully designed and applied ambient air plasmas prevent nosocomial infections; eliminate infections in umbilical cords; minimize infections at injection/wound/catheter sites; prevent bleeding; and promote wound healing.
- Which countries or specific regions could benefit from the technology at least in principle?
All.
- Does the technology have an impact on quality of life?
No negative impacts are anticipated.
- Indicate any data, articles or reports supporting the effectiveness of the proposed solution in Annex D.
 Information provided in Annex D.

4.3. How is the technology suited to local infrastructure in resource-limited settings?

- Describe the setting or the health care facility in which the technology can be used.
The technology can be used in any setting, including in the home.
- Describe features that may be of particular importance to low- and middle-income countries.

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Although the technology is in prototype stage so costs are estimated, we estimate capital cost of the device can be as low as ~\$100 USD for simple implementations either manufactured in large quantities or assembled locally by technicians to perhaps several \$1000 USD for more complex and larger versions. The device has simple operation requiring little specialized training. There are no moving parts and manufacture and repair are likely to be simple. There are no consumables other than electricity or possibly rechargeable batteries.

- c. Describe electric power, water supply, temperature conditions, information technology and/or other operational requirements.
Power use is minimal (~1-5W) for tens of seconds per application). No water is required. Temperature and humidity conditions appear to have minimal effects. There are no information technology requirements and no special operational requirements.
- d. Indicate whether, and in what way, existing infrastructure may need to change to accommodate the introduction of the technology.
None.

4.4. Use and maintenance

- a. Explain the operation of the device.
In the absence of available electricity, the device can operate off a battery. The battery powers a circuit to create a high voltage, low current waveform applied to an insulated electrode. The device creates an air plasma several mm deep that is placed near skin/wound/surface to be treated..
- b. What training or skill level is required for using the technology?
Minimal.
- c. Does the technology have any labor saving advantages? Explain.
No.
- d. What training or skill level is required for maintenance of the technology?
Elementary electrician skills, including soldering and circuit board repair.
- e. Describe the product in terms of weight and size. Is it portable?
Device is handheld, cylindrical, and ~0.2 kg.

4.5. Cost-effectiveness and affordability

- a. What costs are associated with the use of this technology (installation, consumables, maintenance)?
Device cost is likely to be low - we estimate the simplest devices to be ~\$100 USD if locally assembled. Power requirements are on the order of 1-5W. Rechargeable batteries may be required.
- b. Describe why this technology is cost-effective; for example does it provide greater health

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benefit than existing technologies at a reduced cost?

Replaces various chemical/drug approaches.

c. What is the estimated life-time of the device?

5-7 years.

4.6. Cultural and social acceptability

a. Describe the expected/known social and cultural acceptability of the technology.
Possible advantage in Muslim populations as the technology could replace alcohol-based antiseptics, and as it operates through fabric, could allow arm antisepsis without baring skin above wrists.

b. In Annex E, indicate any data, articles or reports supporting the social and cultural acceptability of the technology.

c. What are the possible barriers for acceptance of the technology?

No known barriers.

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5. Time to market

5.1. Is the product ready for commercialization in low- and middle-income countries?

Yes No

If no, how soon could it be commercialized and what product development would be necessary?

2-5 years estimated. The technology needs to go through standard regulatory certification.

5.2. What if any challenges are foreseen to make this technology available in low- and middle-income countries? Please tick the appropriate boxes and provide additional details where applicable. (300 characters maximum per ticked box)

Financing

Manufacturing partners

Ideally, devices should be manufactured in targeted low- and middle-income country. The device is constructed of relatively simple parts that are amenable to a cottage-industry model.

Distribution channels

The devices need to be distributed where they can be used.

Procurement

Intellectual property rights

Some patents exist and patent applications have been made for some versions of the device.

Other: Please specify

The technology should be introduced to low- and middle-income country medical schools and technical school/universities so the expertise for manufacture, use and repair are indigenous.

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6. References

For commercialized products:

Please provide 3 references from professionals in institutions where the product is used.

For non- commercialized products:

Please provide 3 professional references.

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Annex A

List of countries where the product is currently commercially available (please list in alphabetical order).

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Annex B

**List of countries where regulatory conformity assessment has been undertaken
(please list in alphabetical order)**

Germany
USA

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Annex C

Articles, data or reports supporting the effectiveness of the proposed solution

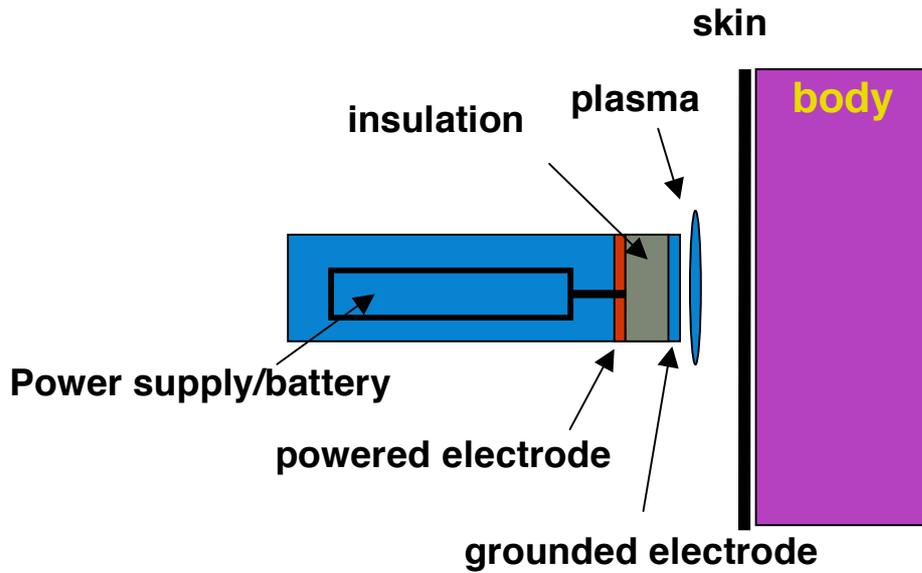
1. G. Fridman, G. Friedman, A. Gutsol, A.B. Shekhter, V.N. Vasilets and A. Fridman, Applied Plasma Medicine, Plasma Processes and Polymers, 5, 503-533, 2008.
2. M. Laroussi, Low Temperature Plasmas for Medicine?, IEEE Trans. Plasma Science, 37(6), 714-725, 2009.
3. G. E. Morfill, T. Shimizu, B. Steffes and H.-U. Schmidt, Nosocomial infections - a new approach towards preventive medicine using plasmas, New J. Physics, 11, 115019, 2009.
4. G.E. Morfill, M.G. Kong, J.L. Zimmerman, Focus on Plasma Medicine, New J. Physics, 11, 115011, 2009.
5. M.G. Kong, G. Kroesen, T. Nosenko, T. Shimizu, J. Van Dijk, and J.L. Zimmerman, Plasma medicine: an introductory review, New J. Physics, 11, 115012, 2009.

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Annex D
Data, articles or reports that support the social and cultural acceptability of the technology

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Annex E.



Simplified sketch of prototype handheld ambient gas plasma antiseptic device. Ambient temperature, ionized air ('plasma') region ~ 2-5 mm deep. Designed to be held near skin/wound/device to be disinfected. Typical exposure ~ 10-30 seconds.

Length ~ 25 cm; diameter ~ 8 cm; weight ~ 0.2 kg. Battery rechargeable. Power ~ 1-5W. On-off switch operation.

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