U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	**Date of Issuance:**
83734-1	4/27/23

Term of Issuance:
Conditional

Name of Pesticide Product:
Nocolyse

Julie Ownbey
Electronic Transmittal: julie.ownbey@tsgconsulting.com
Senior Consultant of Technology Sciences Group Inc. representing:
A.M.G. Medical Inc.
8505 Chemin Dalton
Montreal, Quebec H4T 1V5 Canada

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Steven Snyderman

Steven Snyderman, Product Manager 33
Regulatory Management Branch, Office of Pesticide Programs
Antimicrobials Division (7510M)

Date:
4/27/23

2. You are required to comply with the data requirements described in the DCI Order identified below:

    a. Hydrogen Peroxide: GDCI-000595-1127
    b. Silver Nitrate: GDCI-072503-1131

    You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Reevaluation Team Leader (Team 36): http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division

3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

4. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 83734-1."

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 04/13/2022

The alternate brand name, Nocotech, has also been approved and entered into the Agency's records. If you have any questions, please contact Joseph Williams Jr. by phone at 202-566-0672, or via email at williams.joseph@epa.gov.

Enclosure: Stamped Final Label

Nocolyse

{Alternate Brand Name: Nocotech }

Disinfectant

ACTIVE INGREDIENTS:	
Hydrogen Peroxide	6.0000%
Silver Nitrate	0.0035%
OTHER INGREDIENTS:	93.9965%
TOTAL:	100.000%

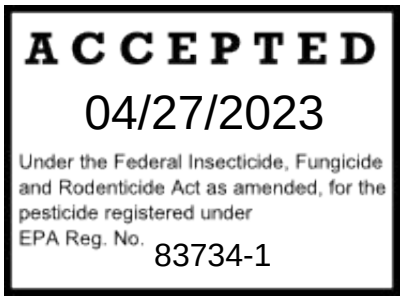
KEEP OUT OF REACH OF CHILDREN

CAUTION

{See [{left} {back} {side} {right} {insert} {panel} {of label} {below}] for {additional} precautionary statements} {and} {or} {first aid}.

*(**Note to Reviewer:** This referral statement may be organized in any order to be grammatically correct.)*
{{Consult} {See} {additional} {sheet} {insert} {inside} {outer container} {Product Information} {Bulletin} {for} {other} {directions for use} {and} {information} {claims} {organisms} {applications}.}

A.M.G. Medical Inc.
8505 Chemin Dalton
Montreal, Quebec H4T 1V5
Canada



EPA Reg. No. 83734-X
EPA Est. No.

Net Contents:
{{Batch} {Lot} No} {Manufacturing Date}:
{Product of USA} {Made in the USA}

(**Note to Reviewer**: Text in { } is optional. Brackets [ ] indicate that at least one option within the brackets must be used in the final label text. Parentheticals ( ) are meant to appear on final label. "This product" can be substituted with actual product name in the marketing and directions for use.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Avoid contact with eyes or on clothing. Wear protective eyewear {goggles} {or} {face shield}. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID

In case of emergency, call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

{For [{chemical} {and} {or} {medical} {and} {or} {environmental}] emergencies, call {*insert name and/or number of emergency contact*} {*hours of operation*} {24 hours a day} {7 days a week}}.

GENERAL INFORMATION: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For non-emergency and general information on product use, etc., information pertaining to this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday – Friday, 8:00 am – 12:00 pm Pacific Time; email: npic@ace.orst.edu; or web site: www.npic.orst.edu. For emergencies, call the poison control center 1-800-222-1222.

ORGANISM LIST

***(Note to Reviewer:** The list of organisms can be formatted into paragraph form using a comma to separate organisms.)*

This product is effective against the following organisms:

- Staphylococcus aureus (ATCC 6538)
- Pseudomonas aeruginosa (ATCC 15442)

◊ This product is effective against killing {eliminating} 99.999% the following organisms: Staphylococcus aureus (ATCC 6538), Pseudomonas aeruginosa (ATCC 15442)

MARKETING CLAIMS

*(**Note to Reviewer:** Marketing text is considered optional. Commas and the words "and" "or" can be added to phrases to make text grammatically correct.)*

{LOCATIONS**/SURFACES}

(**Note to Reviewer:** The locations/surfaces have been grouped for space purposes only; they can be used individually or grouped together in any order however at least **one** location/surface must appear on the label. In the case where one or more location/surface is chosen, an "and", "&", or "or" and appropriate punctuation may be used to link locations/surfaces.)

[This product is for use on hard, non-porous surfaces in *(insert location)**]

The use of this product is only intended to treat areas/locations where the environmental parameters don't exceed temperature 23±5°C , humidity ≤ 60%, a max room size of 28.5 m3 (1008 ft3), and max room height of 8 ft (244 cm).

[This product [{when used as directed} {can be used} {is formulated to [{disinfect} {clean} {deodorize}]} {is formulated for use}] {on} {{washable} hard, non-porous surfaces such as: *(insert location/surface)]*

[For use {in} {on} *(insert location/surface)]*
[For treatment of visibly clean, exposed hard non-porous *(insert location/surface)]*

(**Note to Reviewer**: Text in { } is optional. Brackets [ ] indicate that at least one option within the brackets must be used in the final label text. Parentheticals ( ) are meant to appear on final label. "This product" can be substituted with actual product name in the marketing and directions for use.)

*** The [area] [location]to be treated should meet the following environmental conditions before treatment; [{relative humidity} {RH}] of ≤ 60% and ambient [{temperature} {temp.}] between 18° and 28° Celsius {64° and 82° Fahrenheit}, a maximum room size of 28.5 m3 (1006 ft3), and max room height of 8ft (244 cm).*

± Whole Room is any visibly clean, exposed, hard, non-porous surfaces in a/the room, which is within the tested room parameters.

Environmental Parameters for Product Application

Temperature	23±5°C
Humidity	≤ 60%
Treated Room/Chamber size (Max room size)	28.5 m3 (1008 ft3)
Max room height	8 ft (244 cm)

LOCATIONS**

(Note to Reviewer: the specific locations used on the label will include the following footnote for all locations;)

*** The [area] [location]to be treated should meet the following environmental conditions before treatment; [{relative humidity} {RH}] of ≤ 60% and ambient [{temperature} {temp.}] between 18o and 28o Celsius {64o and 82o Fahrenheit}, a maximum room size of 28.5 m3 (1006 ft3), and max room height of 8ft (244 cm) area*

- Ambulances
- Medical aesthetic centers
- Ambulatory Surgical Centers (ASC)
- Anesthesia Rooms or Areas
- {Assisted Living} {or} {Full Care} Nursing Homes
- CAT Laboratories
- Central Service Areas
- Central Supply Rooms or Areas
- Critical Care Units or CCUs
- Dental surgery centers
- Dentist office
- Examination room{s}
- Dialysis Clinics {Facilities}
- Donation Centers {blood} {plasma} {semen} {milk} {apheresis}
- Emergency Rooms or ERs
- Eye Surgical Centers
- Health Care Settings or Facilities
- Hospital{s}, Hospices
- Intensive Care Units ICU{s} {areas}
- Infirmaries
- Isolation Areas
- Laundry Rooms
- Laboratories
- Long Term Care Facilities
- Medical Facilities
- Newborn or Neonatal {Nurseries} {Intensive Care} Units {NICU}
- Nursing or Nursing Stations
- Nursing Homes, Group Homes
- Operating Rooms or ORs
- Ophthalmic Offices
- Orthopedics
- Outpatient {Surgical Centers (OPSC)} {Clinics} {Facilities}
- Patient Areas
- Patient Restrooms

(**Note to Reviewer**: Text in { } is optional. Brackets [ ] indicate that at least one option within the brackets must be used in the final label text. Parentheticals ( ) are meant to appear on final label. "This product" can be substituted with actual product name in the marketing and directions for use.)

- {Pediatric} Examination Rooms or Areas
- Pediatric Intensive Care Units {PICU}
- Pharmacies
- Physical Therapy Rooms or Areas
- Psychiatric Facilities
- Public {Care} Areas
- Radiology or X Ray Rooms or Areas
- Recovery Rooms
- Rehabilitation Centers
- Respiratory Therapy Rooms or Areas
- Restrooms
- Surgery Rooms or Operating Rooms or ORs
- Waiting Rooms or Areas
- Airplanes
- Classrooms
- {Computer} Clean Rooms, Server Rooms
- Cannabis [{Processing} {Growth Operation} {Drying} {Room}]
- Cars {police}, taxis, limousines
- Commercial, Institutional [{Rooms} {Spaces}]
- Correctional facilities, jails, prisons
- Cruise ship cabins
- Daycare centers
- Dormitories or barracks
- Elevators
- Food [{Processing} {Plant} {Packaging}] – Non-Processing Areas
- Fisheries
- Funeral [{homes} {parlors}]
- Gyms, {fitness} {and} {athletic} facilities
- Hotel{s} {rooms}, Convention Centers, Conference [{Centers} {Rooms}], Public Places
- Hatcheries
- Kitchens – non-food contact surfaces
- Locker rooms
- Mass transportation vehicles, buses, trains, subways
- Public bathrooms, restrooms
- {Fire} Trucks, Tractor Trailers, Tractors, Combine Harvesters, Animal transport vehicles
- Restaurants, Public Eating Places
- Veterinary facilities, Animal [{rescue,} {shelter,} {zoo,} {cages,} {stalls} {facilities}], Zoos

(**Note to Reviewer**: Text in { } is optional. Brackets [ ] indicate that at least one option within the brackets must be used in the final label text. Parentheticals ( ) are meant to appear on final label. "This product" can be substituted with actual product name in the marketing and directions for use.)

{SURFACES}

- Non-Food contact [{Countertops}, {counters,} {countertop laminates,}] exterior surfaces of [{stovetops,} {stoves,} {appliances,} {refrigerators,} {microwave ovens}]
- [{bathroom} {kitchen}] sinks, tub surfaces, shelves, racks, carts
- Floors, finished floors, high speed burnished floors, conductive flooring, walls, ceilings, fixtures
- Glass surfaces, aluminium, brass, copper, laminated surfaces, metal, plated steel, stainless steel, glazed porcelain, glazed {restroom} tile, glazed {restroom} ceramic, sealed granite, sealed marble, plastic {such as polycarbonate, polyvinylchloride, polystyrene or polypropylene}, sealed limestone, sealed slate, sealed stone, sealed terra cotta, sealed terrazzo, chrome, Plexiglas®, enameled surfaces, painted {finished} woodwork, Formica®, vinyl and plastic upholstery, washable wallpaper, windows, mirrors, painted surfaces
- Highchairs, baby cribs, diaper changing stations, infant bassinets/cribs/warmers/incubators/care equipment, folding tables, hampers, laundry pails, empty diaper pails
- Shower stalls, shower doors and curtains, bathtubs and glazed tiles, chrome plated intakes, toilets, toilet seats, toilet bowls, toilet bowl surfaces, urinals, portable and chemical toilets and latrine buckets, vanity tops, and restroom fixtures, bathroom fixtures, bathroom bowls, basins, tubs
- Tables, chairs, desks, folding tables, bed frames, lifts, washable walls, cabinets, doorknobs and garbage cans/pails, trash barrels, trash cans, trash containers, industrial waste receptacles and garbage handling equipment, shelves, racks and carts, doorknobs and handles
- Computers, Computer Screens
- Sealed foundations, steps, plumbing fixtures, finished baseboards and windowsills
- And other hard, non-porous, non-food contact surfaces
- Hospital beds, bed railings, bedpans, gurneys, traction devices, MRI, CAT, examining tables, scales, paddles, wheelchairs, hard, non-porous surfaces of cervical collars and neck braces, spine backboards, stretchers, unit stools, CPR training mannequins, curing lights, light lens covers, slit lamps, operating room lights, operating tables, oxygen hoods, dental chairs/countertops, examination tables, x-ray tables, ambulance equipment/surfaces, medical equipment surfaces

DISINFECTION MARKETING CLAIMS

(Note to Reviewer: *The following marketing claims may be used with the prefix "This product" {is} {a} {an}.)*

± Whole Room is any visibly clean, exposed, hard, non-porous surfaces in a/the room, which is within the tested room parameters.

- A Disinfectant that effectively eliminates 99.999% bacteria◊ on hard, non-porous surfaces.
- An effective disinfection {solution} {method} {system} for use in {ambulances} {healthcare} {medical} {Long term care} {LTC} {Laboratories} {clinics} environments
- An efficient and effective disinfection {solution} {method} {product} {system} for use in {hospitals} {healthcare} {medical} {long term care} {LTC} {ambulance} {classroom} {bathroom} environments for whole room± room surface disinfection {disinfecting} on hard, non-porous surfaces+
- An effective Disinfectant {system/solution /method} for cleans of hard, non-porous surfaces when used according to the direction for use
- An effective disinfection {system/solution /method} for isolation {rooms/wards/environments} on hard, non-porous surfaces+
- An efficient and effective {versatile} disinfection {system/method} for all hard non-porous surfaces in a room.
- An effective Disinfectant {solution} {formula} {product} for use in healthcare facilities for whole room± room for hard, nonporous surface disinfection {disinfecting}
- An effective Disinfectant {solution} {formula} {product} for use in {hospitals} {healthcare} {medical} {long term care} {nursing home} {rehabilitation {rehab}} environments
- Appropriate for disinfection {between patients}, isolation {areas/rooms/wards/departments} on hard, non-porous surfaces+
- Controls odors caused by bacteria
- Deodorizes by killing bacteria that causes odor{s}
- Deodorizing by killing odor-causing {bacteria} at their source
- {Daily} {Disinfection} of {all} hard non-porous surfaces
- {Multi-purpose} {Multi-room} hard non-porous surface {Disinfectant} {Disinfection}

(**Note to Reviewer**: Text in { } is optional. Brackets [ ] indicate that at least one option within the brackets must be used in the final label text. Parentheticals ( ) are meant to appear on final label. "This product" can be substituted with actual product name in the marketing and directions for use.)

- {Disinfects} {Daily} {Multiple} hard non-porous surfaces
- Disinfects hard pre-cleaned, non-porous non-food contact surfaces in: {industrial kitchens, cafeterias} use sites}
- Easy to use, Effective, Efficient {disinfection}
- Effective [alternative] broad-spectrum hard, non-porous surface disinfectantEffective [alternative] Disinfectant for hard, non-porous surfaces
- Eliminates {removes} 99.999% bacteria that causes odors◊
- For use in the [{NocoTech} {Nocospray}] Disinfection System{s}
- [{Gets to} {Goes to}] all exposed areas and disinfects pre-cleaned, hard, non-porous surfaces
- Gets rid of odors by killing the {bacteria} {that cause them}
- Great {suitable} for whole room± {disinfecting} {disinfection} on hard, non-porous surfaces
- Hard, Non-Porous Surface Disinfectant
- Hospital Disinfectant
- Intended for use in all medical, healthcare, ambulances, laboratories, hospital, clinic and long term care {LTC} {nursing home} {school} {laboratory} {vehicle} {dormitory} environments.
- Kills {eliminates} 99.999% {both} gram-positive and gram-negative bacteria◊
- Kills {eliminates} 99.999% of Pseudomonas aeruginosa◊
- Kills {eliminates} 99.999% of Staphylococcus aureus◊
- Kills {eliminates} bacteria {odors} and deodorizes
- Kills {eliminates} {destroys} 99.999% bacteria◊ on hard, non-porous surfaces
- Leaves [room's] hard, non-porous surfaces disinfected
- Makes room disinfecting easier {feasible}, {attainable}, {practical} {efficient} effective}
- Part of the effective, easy to use and versatile {{NocoTech} {Nocospray}]{Room} Disinfection System
- Reaches nooks, crevices and corners of exposed hard non-porous surfaces once visibly cleaned. Disinfects {a room/surfaces/ patient environment/ operating room (OR)/ laboratory/ bathroom/ dining room/ waiting room/ exam room/ Ambulances/ Classrooms/ Jails/ Infirmaries/ hatcheries/ dormitories/ hotel rooms / cabins} on hard, non-porous surfaces+
- Solution used as a {hospital} [{disinfectant}, {and} {bactericidal}].
- The NocoTech {Nocospray} {disinfection} system helps {staff} {nurses} {infection control} {environmental services} {housekeeping} address grey zones {like shared equipment} {like IV poles} {like commodes and wheelchairs}
- This {solution} {product} {formulation} is approved as a healthcare- {ready-to-use} Disinfectant {disinfecting} {solution} {formula} {product} and can be used in the following setting *(choose locations from list)* on hard, non-porous surfaces+.
- This product reduces the risk of cross contamination of bacteria◊ between treated surfaces on hard, pre-cleaned, non-porous surfaces
- This product [helps] [aids] in the reduction of cross contamination of bacteria◊ on hard, pre-cleaned, non-porous surfaces
- This {product} {system} {method} kills {eliminates} 99.999% bacteria◊ on hard, pre-cleaned, non-porous, non-food contact surfaces.
- This product helps reduce the spread of bacteria◊ on pre-cleaned, hard non-porous non-food contact surfaces
- Treats, does not cover up {no residue} {no need to rinse after use} as a disinfectant
- Whole room± Room {hard} Surface Disinfectant on hard, non-porous surfaces
- Whole room± Room Disinfection {Disinfecting} System on hard, non-porous surfaces
- {You can} {Use} this product {in places} {in areas} to be {disinfected} {treated} {addressed} {such as the} {with} exposed hard non-porous surfaces of nooks and crannies.

GENERAL MARKETING CLAIMS

***(Note to Reviewer:** The following marketing claims may be used with the prefix "This product" or "This product is {a} {an}".)*

(**Note to Reviewer**: Text in { } is optional. Brackets [ ] indicate that at least one option within the brackets must be used in the final label text. Parentheticals ( ) are meant to appear on final label. "This product" can be substituted with actual product name in the marketing and directions for use.)

- [{Meets}{Helps to meet}] [{the} {your} {hard non-porous surface}] disinfection needs [{of your facility}]
- Advanced, Patented system
- Can be used every day without endangering equipment
- For use with the {{NocoTech} {Nocospray}] Machine{s}
- For {hospital} {healthcare} {medical} {long term care} {nursing home} {ambulances} {laboratories} {transport} environments**
- For use in {hospitals} {healthcare} {medical} {long term care} environments as a disinfectant
- For use on hard, pre-cleaned, non-porous surfaces located in: {use sites}
- Great {suitable} {ideal} for frequent {daily} use.
- New (this claim will only be used for the first six month after commercial introduction)
- No {mixing} {or} {dilution} {diluting} {labor} required, ready to use {RTU} formula
- No Wiping, No rinsing, Non-corrosive, dry gas
- Effective in even the smallest spaces in a room to treat hard, non-porous surfaces where {people/staff /hands / wipes other manual systems} cannot reach {see}
- Effective on all hard-to-reach {small} {forgotten} {easily missed} {ignored} surfaces {areas} }
- The [{NocoTech {Nocospray}] system is not influenced by {human} {visual} bias {limitation}
- Ready-to-use {formula} {No mixing required}
- Reduce{s} labor costs
- Solution is ready to use, designed for use with one of the [{Nocospray®,} {NocoTech®,}] machines.
- The [{Nocospray®,} {NocoTech} {System}] can [effectively] disinfect a room, including hard, non-porous surfaces [{on} {in}] hard-to-reach areas+ [{staff} {environmental}{services} {cleaning} {housekeeping} {teams}] cannot [{treat} {reach}] but are [{accessible to} {available to} {open to} {visible to}] [{the Nocospray} {the system}] [{if they used}{using}] only manual disinfection methods.
- Use this product in {use sites- hospital, nursing homes/long term care/ ambulances/veterinary hospitals / schools / research laboratories /dormitories}**

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

{Please read entire label and use strictly in accordance with precautionary statements and directions.}

Before use of this product, ensure the environmental parameters for the area/location to be treated fall within the following parameters; temperature 23±5°C , humidity ≤ 60%, treated Room/Chamber size (Max room size) 28.5 m3 (1008 ft3), and max room height 8 ft (244 cm).

Consult {Safety Data Sheet} {and} machine instruction manual prior to use.

Do not deviate from standard cleaning regimes when using {Nocospray} {Nocotech}. Use product only with {Nocospray} {Nocotech} {dispensing device} {machine} following detailed instructions provided in the {Nocospray} {Nocotech} User Manual. Read and follow directions in user manual on room preparation, room set up and treatment protocol, and equipment operating procedures for the {Nocospray} {Nocotech} device.

Prior to initiating room disinfection with Nocolyse ensure that a manual clean of all hard surfaces has been performed to remove dust, debris and visible soil. Address all items that need to be disinfected by other means including porous surfaces according to the facility's protocol. Make sure all hard non-porous surfaces that are meant to be disinfected during this process, are exposed. {For example, open the door to adjoining bathrooms.} Make sure all openings out of the rooms are closed including windows and electrical outlets.

{Take the volume measurement of the space including all adjoining spaces to be disinfected, such as a bathroom. Multiply the volume of the space in m^3 (cubic meters) by 7 to obtain the correct setting for the [{Nocospray} {Nocotech Machine}]. The space should have [{relative humidity} {RH}] of ≤ 60% and ambient [{temperature} {temp.}] between 18° and 28° Celsius {64° and 82° Fahrenheit}, max room height 8 ft (244 cm) and a maximum room size of 28.5 m^3 (1008 ft^3) .

(**Note to Reviewer**: Text in { } is optional. Brackets [ ] indicate that at least one option within the brackets must be used in the final label text. Parentheticals ( ) are meant to appear on final label. "This product" can be substituted with actual product name in the marketing and directions for use.)

Make sure that there is sufficient liquid in the bottle [{for the space} {for disinfection} {for the treatment}] (0.24oz/ft^3/7ml/m^3). If using a new bottle note the date of opening on the bottle where indicated. If the bottle is opened ensure that the contents are not more than 2 months old, if [{they are} {it is}] discard {the liquid}. Attach the bottle of Nocolyse {to the machine} {to the Nocospray} {the Nocotech machine}. [{See Instruction Manual.} {See Operator's Manual}].

Keep the room closed during treatment and contact time. No one should be in the room throughout the disinfection process.

*(**Note to Reviewer:** For labels that list medical devices and/or stainless-steel surfaces, one of the following FDA/EPA Memorandum of Understanding statements must be used.)*

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. {This product can be used to pre-clean or decontaminate critical medical devices prior to sterilization or high-level disinfection.}

(OR)

This product is not for use on medical device surfaces.

For Use as a {Hospital} Disinfectant:
This product [or product name] is designed specifically to be used in conjunction with [as part] of the [{NocoTech®} {Nocospray®,}] Disinfecting System [with the [{NocoTech} [Nocospray} Machine] [according to the disinfection directions in the {NocoTech} {Nocospray} User Manual] in the following settings of 50 ft^3 up to 1008 ft^3 {(1.42 m^3 up to 28.5 m^3)}.

Before use of this product, ensure the environmental parameters for the area/location to be treated fall within the following parameters; Temperature 23±5°C , Humidity ≤ 60%, treated Room/Chamber size (Max room size) 28.5 m3 (1008 ft3), max room height 8 ft (244 cm).

When used as a hospital disinfectant or bactericide, use 0.24 fl. Oz./35 ft^3 {(7 ml/m^3)} {(or equivalent use dilution)} with a 30-minute contact time.

Prior to fogging, all hard non-porous surfaces with visible or non-visible soils must be cleaned. Food products and open packaging material must be removed from the room or carefully protected. Fog desired areas using 0.24 [{fluid ounces, oz}] per 35.3 [{cubic feet, ft^3}] of room volume [alternatively 7 [{millilitres, ml}] [{per, /}] [{cubic meter, m^3}]] of the [{ready-to-use, RTU, premixed, prepared}] [{solution, liquid, disinfectant}] [{or equivalent use dilution]}. Wear [{medical, exam, medical exam}] gloves when attaching the container of [{product, liquid, Nocolyse, disinfectant}] to the fogging [{apparatus, device, machine}]. Vacate the area of all personnel during fogging and for a minimum of 30 minutes after fogging until the parts per million [ppm] of hydrogen peroxide detected is below 2ppm using a portable gas detector, such as a PortaSens II or a Dragger PAC Ill. Do not breathe spray mist.

Note: The fog generated is irritating to the eyes and mucous membranes. Under no circumstances must a [{space, building, room}] be entered by anyone within [{thirty, 30}] [{minutes, min}] of the actual fogging or when the [{PPM, ppm, parts per million}] of [{hydrogen peroxide, H_2O_2}] is [{2, two}] or above. If the [{space} {building} {room}] must be entered, then the individuals entering the [{building, room, space}} must wear a minimum of a filtering face piece NIOSH approved respirator [TC-84A] with any N, R, or P filter, and goggles. Higher level respirators that are NIOSH approved for particulates can also be used.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

(**Note to Reviewer**: Text in { } is optional. Brackets [ ] indicate that at least one option within the brackets must be used in the final label text. Parentheticals ( ) are meant to appear on final label. "This product" can be substituted with actual product name in the marketing and directions for use.)

{PESTICIDE} STORAGE: Store only in original container. Keep this product under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:
*(**Note to Reviewer:** One or more of the following paragraphs for Container Handling will be selected, depending on packaging use/type.)*

{For non-refillable containers equal to or less than 5 gal.}

Non-Refillable Container. Do not reuse or refill this container. Triple rinse container {(or equivalent)} promptly after emptying. Triple rinse as follows: Fill the container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

{For non-refillable containers greater than 5 gal.}

Non-Refillable Container. Do not reuse or refill this container. Triple rinse container {(or equivalent)} promptly after emptying. Triple rinse as follows: Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip back and forth several times. Turn the container over onto its other end and tip back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

{For non-refillable sealed containers}

*(**Note to Reviewer:** sealed containers are designed to reduce worker exposure to the concentrate. None of these types of containers can be triple rinsed because they are closed, welded, sealed containers.)*

Non-Refillable Container. Do not reuse or refill this container. {Wrap empty container and} Put in trash or offer for recycling.

MedPro DEFENSE®

nocospray®

enhanced disinfection: simplified

user manual

I. INTRODUCTION

I.1. General information

This user manual describes the functioning of the NOCOSPRAY® diffuser and includes essential information to ensure the safe use of the machine.
The documentation applies to Nocospray® diffusers in their original manufacturer's condition and which have not been altered.

Review this manual before using the NOCOSPRAY® diffuser. It was written to ensure you master all functionalities.

Product to be used according to the conditions described in the 'Technical Characteristics' section.

I.2. Classification / Regulation

Electric classification : Class I
Compliant to CEM requirements according to standard 60601-1-2 (2007)

I.2.1. Warranty purpose

The warranty consists of the free replacement of parts recognized as defective by our technical services.
Damage due to abuse, misuse, negligence or overload of the device, as well as those due to customer's electrical network, power surges or faulty equipment, etc… are not covered by this warranty.
In addition, the use of products (liquids) not approved by the manufacturer makes this warranty null and void.

I.2.2. Transport

The device must be transported in its original packaging and stored in a secure, dry place.
The device travels at risk of the user: in case of damage during transport, the recipient must file a claim with the carrier before accepting delivery of the device.

I.2.3. Warranty duration

This warranty remains in effect for 1 year from the date of invoice to the original owner.

I.3. Technical characteristics

Power:	850VA
Tension:	120V mono
Frequency:	50 à 60 Hertz
Nominal intensity:	4,5A
Maximum intensity:	10A
Compatible bottle:	1 Litre
Weight:	6,2Kg Package weight: 8,3Kg
Maximum room volume to be treated:	1000m^3
Average flow of the liquid:	1000 ml/h

Environmental conditions:

System should be used in the environmental conditions listed below;

- In condition of use:
  - Temperature between 18°C to 28°C
  - Ambient humidity between <= to 60%
  - Atmospheric pressure of 800 to 1060 hPa
- Transport and storage conditions :
  - Temperature between 0°C and 70°C
  - Ambient humidity between 10% and 95%
  - Atmospheric pressure of 700 to 1060 hPa

-

II. PRECAUTIONS FOR USE

The manufacturer cannot be held responsible for any material or bodily harm resulting from the abnormal or faulty use of the device, or the disregard for guidance below:

Use only with Nocospray® product

- **Modifying the machine is forbidden.**
- To avoid risk of electric shock, this device must only be connected to a supply main with protective earth.
- Make sure that electric power meets regular standards.
- Hand-held radio frequency communication devices (use of remote control) may affect other electrical equipment and devices.
- This device may only be used by professionals. According to requirements of norm NF EN 60601-1, it may cause radio interference and disturb operation of devices located close to the equipment.

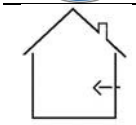
- The use of accessories, transducers and parts, other than those supplied by A.M.G. Medical Inc. for internal components, may result in increased emissions or decreased performance and robustness of the device.
- The device should not be stacked on or under other equipment. In case this is not possible, check the performance of the system in the desired configuration prior to treatment.
- Only A.M.G Medical products and liquids can be used with the Nocospray®.
- Do not introduce any object or liquid in the nozzle of NOCOSPRAY®.
- Check presence of nozzle and nozzle holder (cf. n°2 §III.1) prior to use.
- **Remove the bottle of Nocolyse from NOCOSPRAY® for transportation.**
- **Any intervention must be carried out by staff trained on the system.**

II.1. Safety instructions

The device diffuses a chemical substance and makes noticeable sound, therefore it is necessary to pay attention to following recommendations.

IMPORTANT RECOMMENDATIONS

- Always consult the accompanying documents



- For indoor use only.

- Do not inhale the product

- Do not direct the spray toward an incandescent source

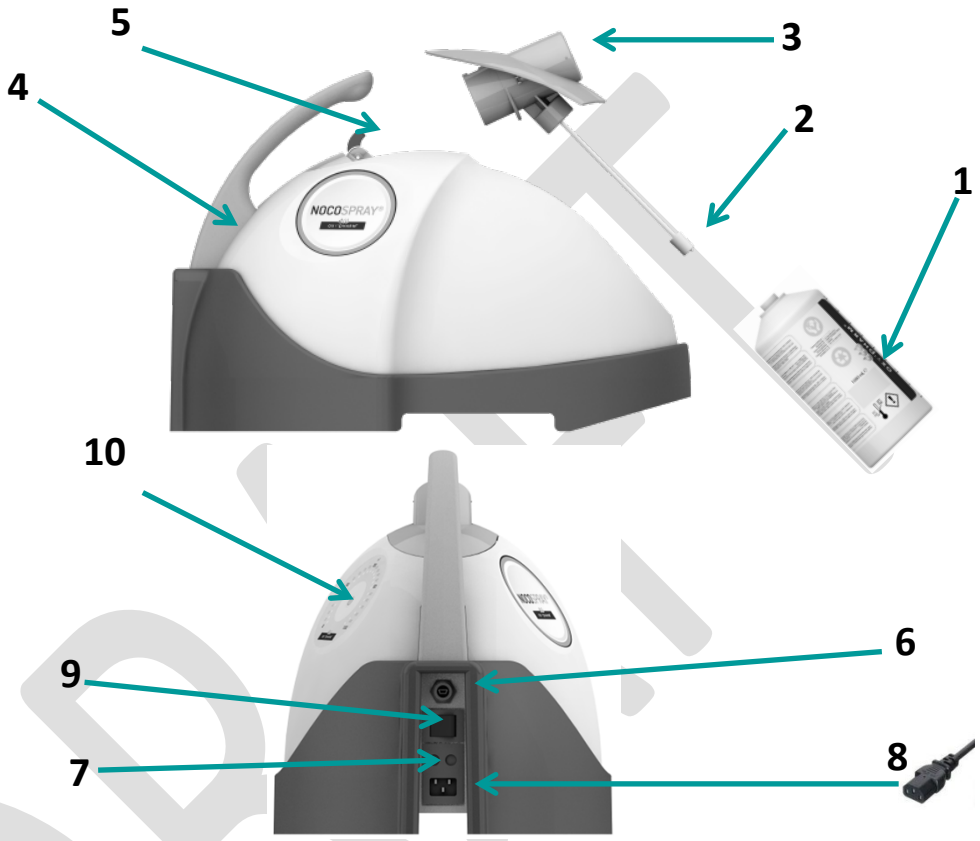
- Do not smoke close to the device

- Grounded connection only

- No one should be in the room while the machine is operating
- Do not use in the presence of a flammable liquids
- Handle the machine and bottle with care
- If a person must enter the room while the machine is running or during the required contact time, they must be equipped with individual protection equipment :
- Noise-cancelling headphones.
- Independent respirator.
- Personal protective equipment.
The individual should exit the room and seal it again as soon as possible.

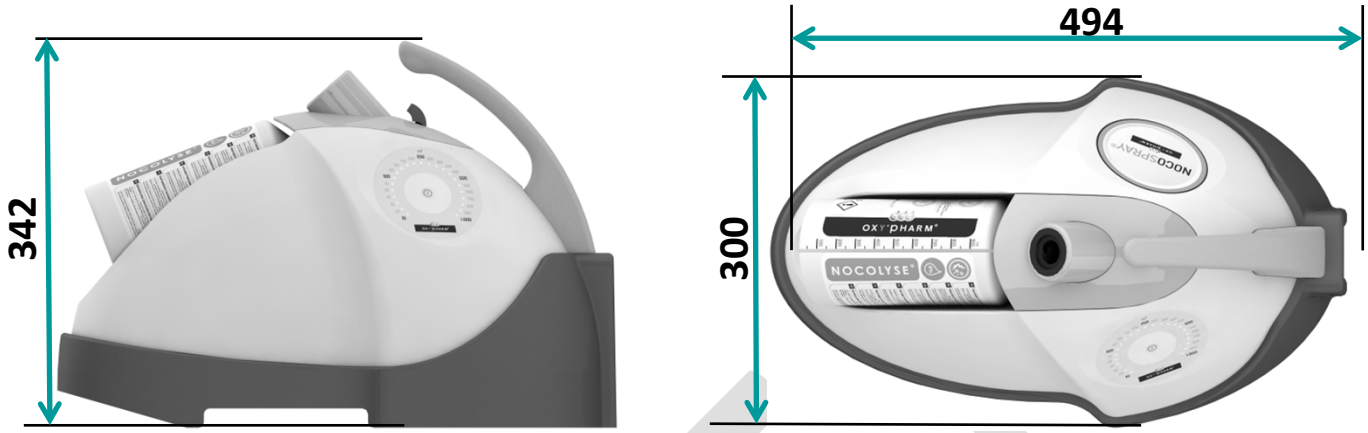
III. DESCRIPTION

III.1. NOCOSPRAY® description



1	Bottle	6	Mini USB port
2	Nozzle and nozzle holder	7	Fuses (5x20 10A T)
3	Nose of the diffuser (venturi)	8	Power cable
4	Handle	9	Power switch
5	Nozzle release button	10	Control touch pad

III.2. NOCOSPRAY® dimensions



IV. Instructions for USE

IV.1. Positioning of the device

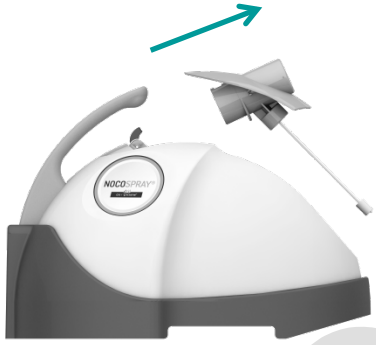
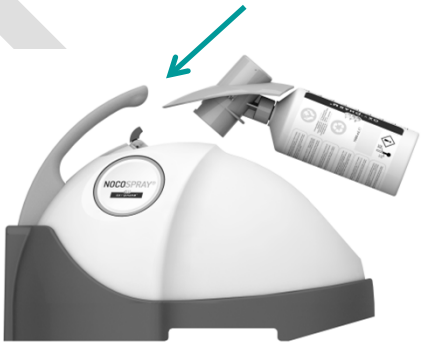
The NOCOSPRAY® must be placed on a hard and flat surface and if possible in a corner of the room to treat.
Tested to ceiling height of 8 ft (244 cm).

IMPORTANT RECOMMENDATION

Before starting a cycle, check that there are no obstacles within 2 meters from the device.

IV.2. Installation of the bottle

Follow instructions below to install the bottle.

		
Remove the diffuser nose by pressing the button	Open the bottle and screw on the nozzle. When opening a new bottle make sure to write the date in the area provided Do not over-tighten to avoid damaging the seal.	Place the nozzle back on the device. And press gently until you hear the «click».

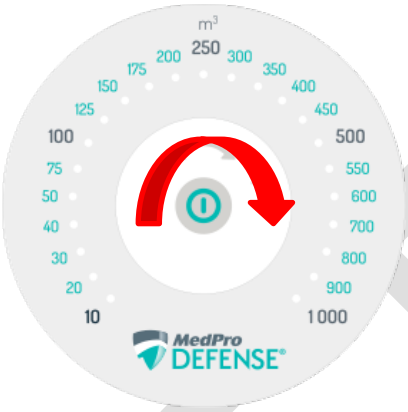
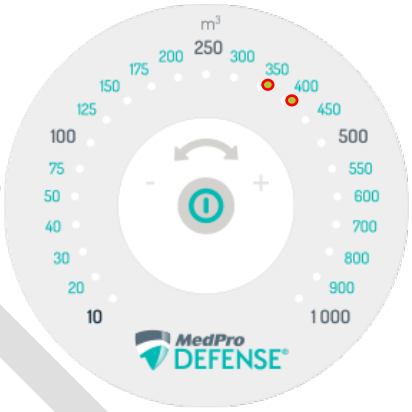
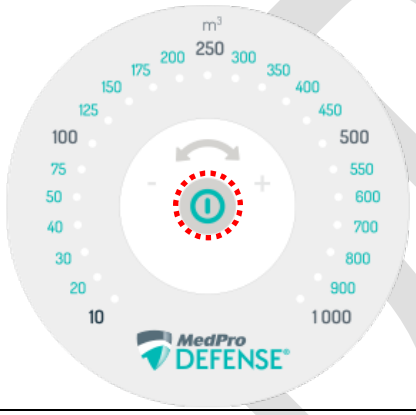
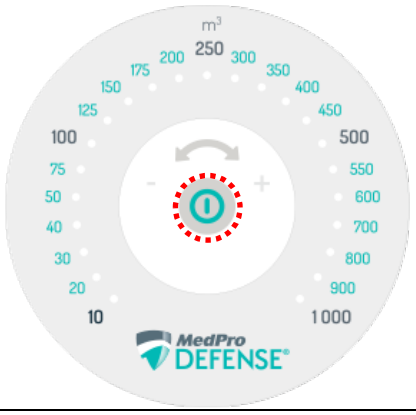
Always check if the bottle contains enough product for the treatment.
The device will not indicate whether there is sufficient liquid.
If the treatment stops due to insufficient liquid the lights on the machine will remain illuminated to indicate where the cycle stopped. If this occurs the treatment should be repeated with correct amount of liquid in the bottle.

IV.3. Diffusion duration and consumption*

Volume setting (m^3)	Consumption (ml)	Duration of diffusion
10	10	36 seconds
15	15	54 seconds
20	20	1 minute & 12 seconds
25	25	1 minute & 30 seconds
30	30	1 minute & 48 seconds
35	35	2 minutes & 6 seconds
40	40	2 minutes & 24 seconds
45	45	2 minutes & 42 seconds
50	50	3 minutes
62.5	62.5	3 minutes & 45 seconds
75	75	4 minutes & 30 seconds
87.5	87.5	5 minutes & 15 seconds
100	100	6 minutes
112.5	112.5	6 minutes & 45 seconds
125	125	7 minutes & 30 seconds
137.5	137.5	8 minutes & 15 seconds
150	150	9 minutes
162.5	162.5	9 minutes & 45 seconds
175	175	10 minutes & 30 seconds
187.5	187.5	11 minutes & 15 seconds
200	200	12 minutes

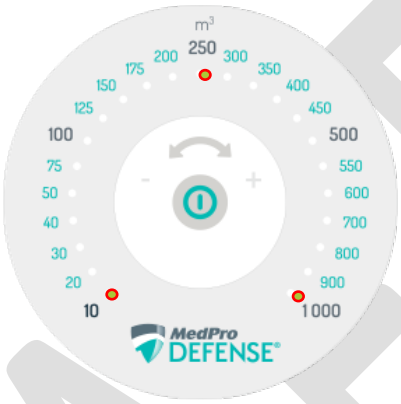
**Maximum room size of 28.5 m^3 (1006 ft^3) with 8ft ceiling.*

IV.4. Functioning in « standard » mode

		
Connect the power cable and put the main switch on « I »	Select the volume by dragging your finger on the clear part of the touchpad. (The range is between 10m³ and 1000m³)	The light indicates the volume chosen, if two lights are illuminated, the selected volume is the middle point between the two values.
		
After selecting the volume, press and hold the start button in the middle of the touchpad to start the diffusion cycle. A beeping sound will begin.	A beeping sound will continue for 15 seconds and then the diffusion will begin. Leave and close off the room before the end of these 15 seconds.	The device can be stopped by pressing the start button again (device beeps when treatment is stopped manually).

IV.5. Downloading usage data

A mini USB connector enables transferring the treatment history to a computer (see **installation of the traceability software**)

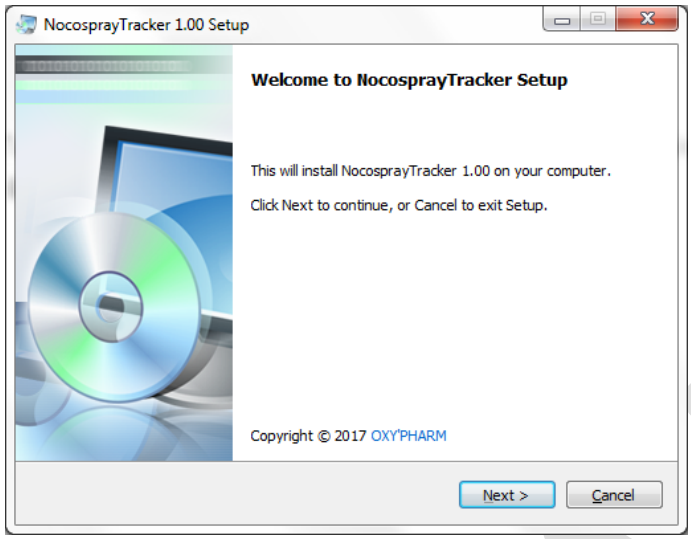
<table>
<tr>
<td>  </td>
<td> 
</td>
<td rowspan="2">The device will not diffuse when in USB mode.

To exit USB mode, unplug the cable from the computer</td>
</tr>
<tr>
<td>Plug the mini USB cable where indicated.</td>
<td>The 10m³ and 1000m³ LEDS flash and the 250m³ LED lights up.</td>
</tr>
</table>

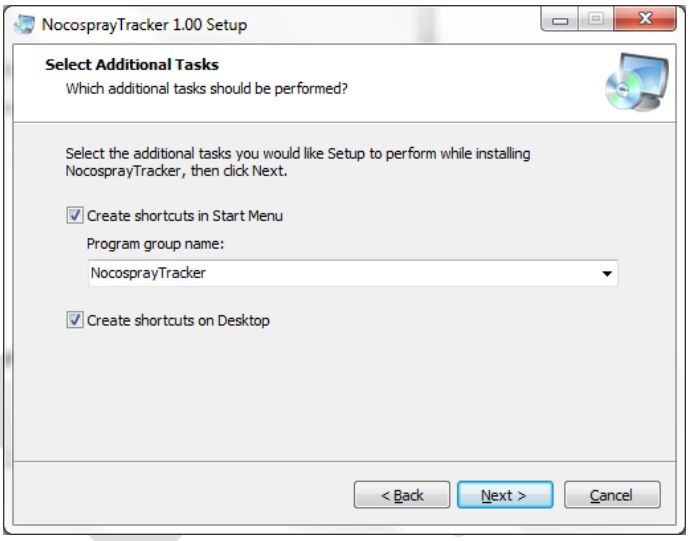
IV.5.1. Installation

Click on “NocoSprayTacker_Setup.exe” on the CD ROM or USB key supplied. Allow the program to install the software if Windows asks.

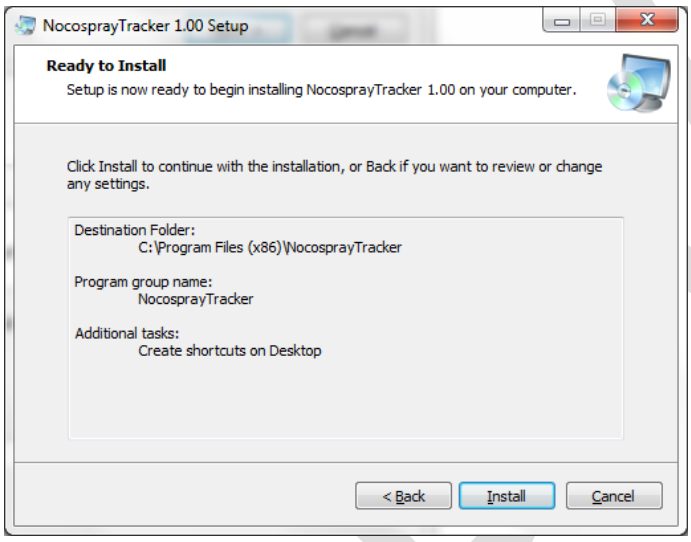
1°) Click on « Next »



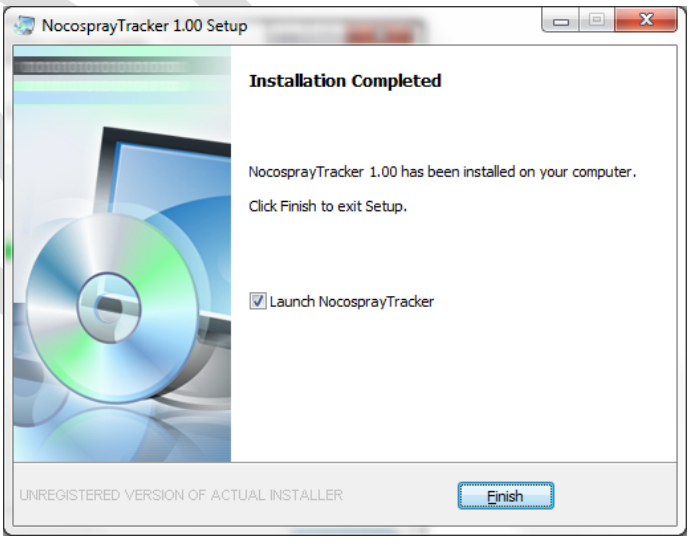
2°) Click again on « Next »



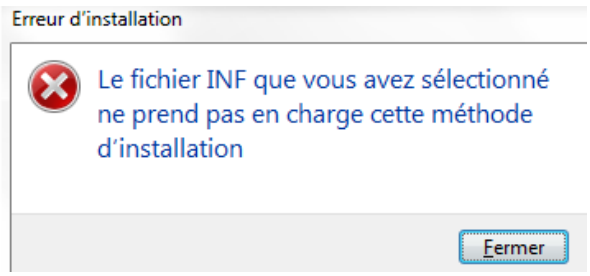
3°) Click on « Install »



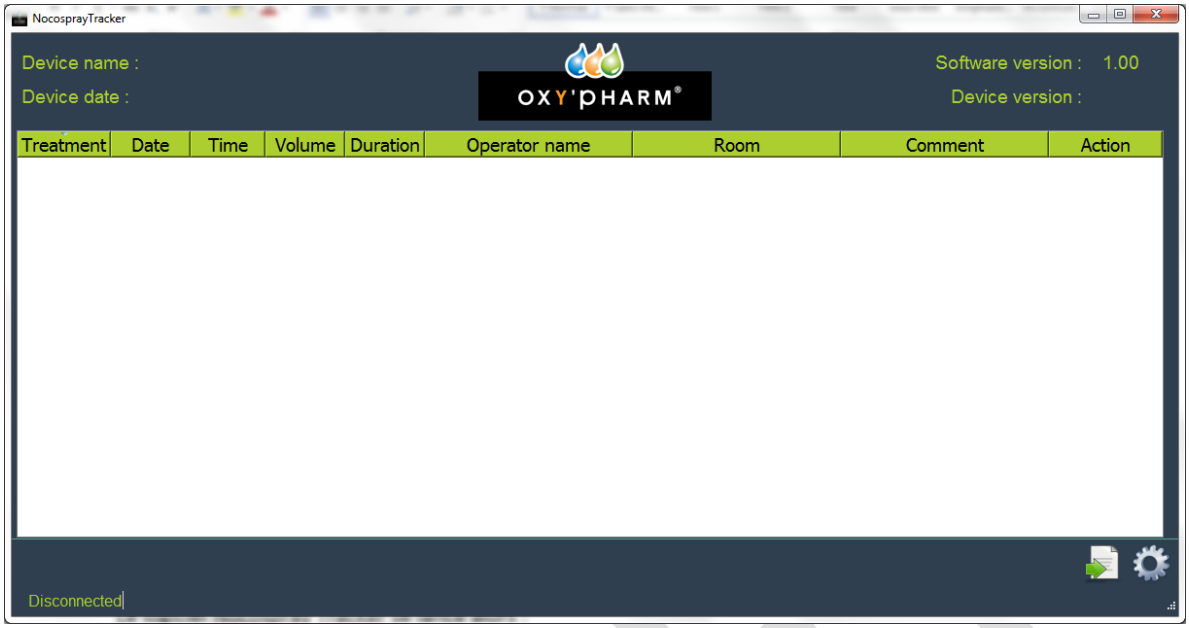
4°) Click on « Finish ».



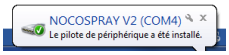
If the following window appears, click on « Fermer »



Nocospray Tracker software runs:

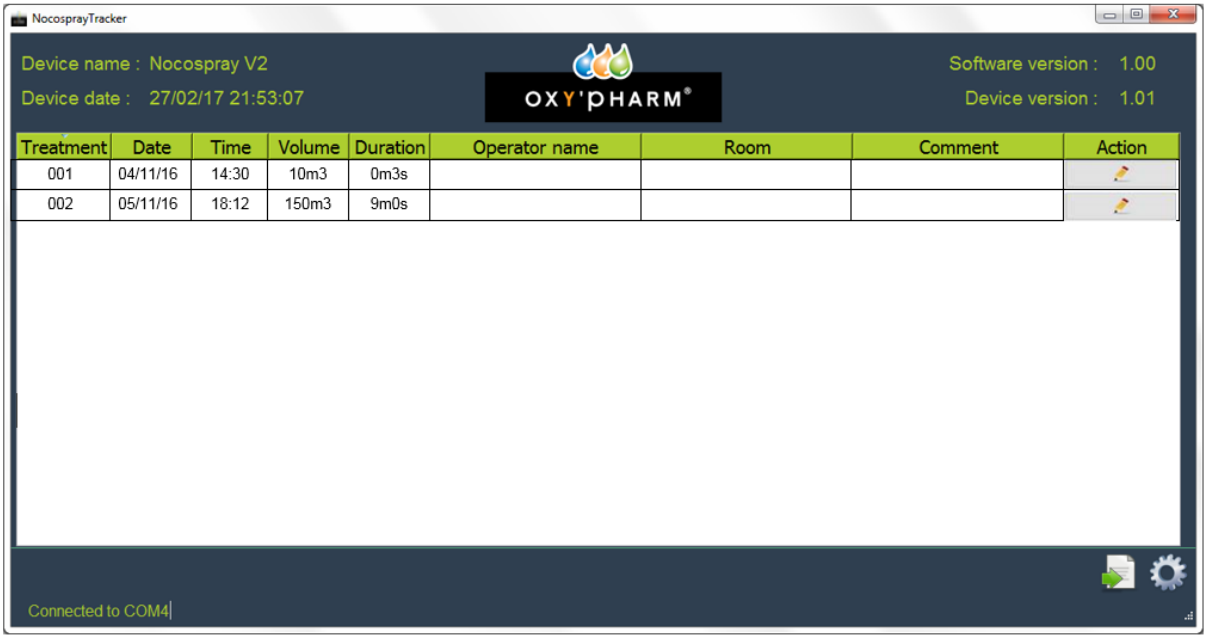


Connect Nocospray® on the USB port of your computer:
An icon on bottom right might appear to indicate that the device driver is running.



If your computer doesn't allow an automatic installation, the driver « .inf » is provided with the software, please contact your system manager.

The text "Connected to …" shows that the Nocospray® is correctly connected



IV.5.2. Use

a) General information

Nocospray tracker software will launch automatically once installed. If it does not, it can be initiated manually.

« Device Name »: Name of the device (editable parameter)
« Device date »: Date and time of the device (to be set the first time – it will automatically update afterwards)
« Software version »: Version of Nocospray Tracker software
« Device version »: Version of the intern software of Nocospray (motherboard)

Each line indicates each treatment. It is possible to organize each treatment following its number, date, time, volume, duration, room name, operator name or comment.

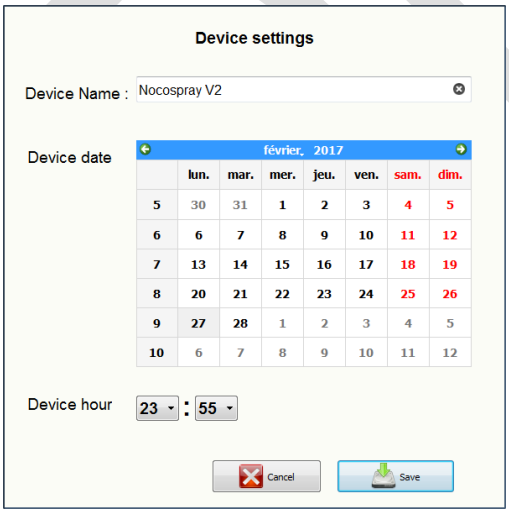
« Treatment »: treatment number
« Date »: Date of the treatment
« Time »: The time of the treatment
« Volume »: Volume setting of the Nocospray
« Duration »: Duration of the treatment (this parameter is automatically calculated)
« Operator name »: Name of the operator who made the treatment.
« Room »: Name/number of the room treated
« Comment »: Other comment

 : Enter parameters « Operator name », « Room » and « Comment »

WARNING: Once those parameters are saved, they cannot be modified

b) General settings modification :

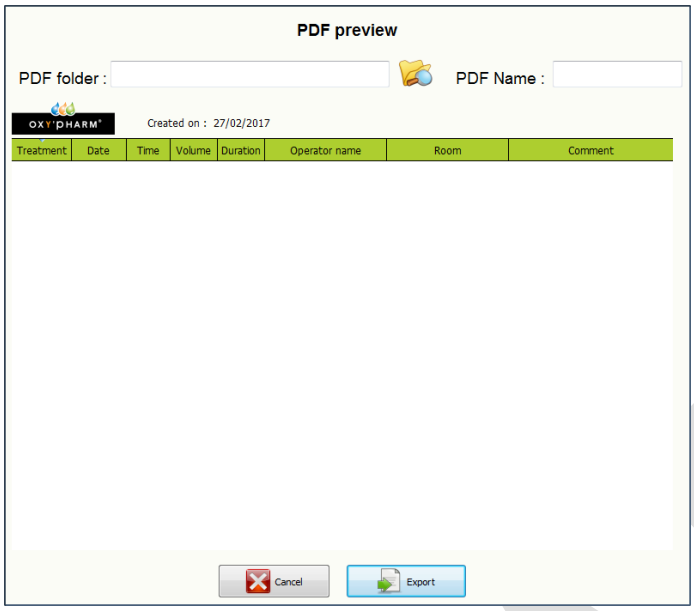
This icon gives you access to the following window:



On this window device name « Device Name », date and hour of the device can be modified.

c) Export records

This icon enables exporting the recorded treatments to a PDF.
It brings you to the following window:



Using this icon  , you can choose the folder where you want to save the data (PDF file).

« PDF Name »: enter the name of the record file.

Then, click to « Export » to record the file.

V. TROUBLESHOOTING

The table below shows a list of common problems and likely solutions. If the problem persists, contact you're A.M.G. Medical representative or our Customer Service Center.

Before any intervention, switch off the device and disconnect the power cord

Failure	Resolution
The device does not switch on	- Check the power cable connection - Check if the switch is in « I » position. Is the red light on? - Check fuses
The device works but the consumption is incorrect	- Check that nozzle is attached securely and not blocked - Check if the bottle contains enough liquid
The device has fallen and has a malfunction	Contact A.M.G. Medical Customer Service Center
At the end of the treatment several LED lights remain illuminated	There was insufficient liquid in the bottle when the cycle started. Repeat the treatment with the correct amount of liquid

VI. MAINTENANCE

The NOCOSPRAY® device requires regular maintenance.

- Switch off the device before any cleaning.
- Do not use abrasive products, bleach, acetone or solvents for maintenance or cleaning operations of the device. These aggressive agents may damage the surface materials (discoloration, tasks, drips, microcracks…)
- For the cleaning of external surfaces, use a slightly damp cloth or wipes.

VII. EMC COMPLIANCE BOARD

Recommended separation distances between portable and mobile RF communications equipment and the NOCOSPRAY®.

The **NOCOSPRAY®** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **NOCOSPRAY®** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **NOCOSPRAY® 2** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.737
1	1.167	1.167	2.330
10	3.690	3.690	7.368
100	11.67	11.67	23.300

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.