DRONES IN MEDICAL LOGISTICS

White Paper

July 2019

Cerba HealthCare

THEDRONEOFFICE

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FOREWORD

BY CERBA HEALTHCARE

70% of medical decisions in general medical practice and 80% of decisions in hospitals are supported by clinical pathology. Medical innovation through novel diagnosis tests, as well as innovation in the services offered to doctors and patients, have been essential to Cerba HealthCare's mission over the last 50 years . At every stage of patient care , from prevention to screening , diagnosis , prognosis , therapeutic decision and follow -up , breakthroughs in medical biology proved instrumental in improving every patient's health and care.

This innovation culture prevails amid a particularly demanding environment. Samples' traceability, integrity, and transport are subject to strict regulations. At the same time, pressure to drive public health expenditures down cause regular cost optimisation actions.

To meet these challenges, clinical pathology championed scientific and technical progress in its core business, but also in other disciplines. For example, automation of technical platforms enabled a significant increase in the number of daily analyses, while digital transformation secured greater samples' traceability.

Innovation in samples logistics is key to clinical pathology At Cerba' s specialised biology laboratory in Saint-Ouen-l'Aumône, no less than 10 million tubes are handled each year. This performance is achieved thanks to thorough logistics processes integrating the best international innovation practices.

Looking ahead, autonomous vehicles are emerging. They may eventually transform transport and logistics. Google cars, Hyperloop trains, Amazon Prime Air, Google Wings, flying taxis are often hitting the headlines… Experiments of medical delivery by aerial drones are already ongoing.

With this in mind, we have developed a collaborative approach with The Drone to gain insight into:

- How advanced is the autonomous drone revolution? What is the state of the art in aerial drone transport? When should we be ready for it?
- Which use cases can make a difference to the benefit of patients and doctors?
- What are the challenges in terms of technology, regulations and business model?

BY THE DRONE OFFICE

Innovation is part of aeronautics' DNA. It has supported the extraordinary growth in air transport. Did you know that 3.5 billion passengers travelled by plane in 2017, safely? Could the aviation pioneers have imagined that within a few decades, air transport would be acclaimed as the safest means of mass transportation?

Today the sky is on the verge of new transformations. A new kind of aircraft is gradually taking its fair share of our skies, the aerial drone. Commercial drones first emerged as toys, or leisure drones. At the same time, drones were used in the professional audio-visual sector, for wedding photography or video shootage of wildlife documentaries. Gradually, embedded sensors and image processing software became more and more sophisticated, and professional drones became relevant in agriculture, infrastructure inspection, construction, emergency services ... the benefits of drones as professional tools apply to a wide array of business fields.

However, these applications are about sourcing images or information from the sky, and not transport. Tomorrow, as the autonomous vehicles revolution develops, autonomous drones will be able to transport goods over long distances.

Yet in terms of aeronautical safety, there is a big gap between on one hand a drone of a few hundred grams evolving within line of sight under the control of a remote pilot, and on the other hand a heavier aircraft evolving automatically over long distances, beyond visual line of sight. The technological challenge is tremendous and exciting.

Also, what's the purpose and benefit of drone delivery? Deliver pizzas within 30 minutes? How could disruptive technologies serve the common good and truly bring value for everyone?

Giving or improving access to medical diagnosis meets these aspirations. Several experiments are already in progress. Unicef supports drone delivery projects for blood units and vaccines in countries where infrastructure is weak or non-existent.

With this in mind, we have developed a collaborative approach with Cerba HealthCare, with a view to better understand:

- How advanced is the autonomous drone revolution? What is the state of the art in aerial drone transport? When should we be ready for it?
- Which use cases can make a difference to the benefit of patients and doctors?
- What are the challenges in terms of technology, regulations and business model?

EXECUTIVE SUMMARY

ONGOING EXPERIMENTS WITH MEDICAL DRONES

INTRODUCTION

The use of drones to transport goods, even of modest weight, is still at the experimental stage. Overall, the market opening currently applies to recreational drones and drones for professional use within line of sight, i.e. a few hundred metres away from the remote pilot.

Clearly, the ability to bypass ground infrastructure, either because it is too congested, or because it is deficient or non-existent, is a powerful lever for transformation. Several experiments are already underway around the planet, especially in the medical field. This White Paper introduces the most representative experiments in the medical sector.

VACCINES DRONE DELIVERY IN VANUATU

The Vanuatu Government has been implementing in 2019 a pilot programme of vaccine deliveries by drone for children in remote villages. This project was the subject of an international tender won by Swoop Aero and Wingcopter receiving support from UNICEF.

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Vanuatu is an island country in the Pacific, an archipelago of 83 islands that covers 1,600 kilometres. About one-third of the inhabited islands have airfields and established roads, which creates considerable logistical challenges to reach, engage with, and support remote communities.

"UNICEF is proud to partner with the Vanuatu Government in such an innovative initiative to trial drones for delivering a reliable supply of vaccines to children living in remote communities, the challenges of reaching children in the remote islands of Vanuatu are immense, nurses often walk several hours to deliver vaccines to health clinics in these communities. Every child in the world has the right to lifesaving vaccines and this technology is a step towards reaching those children most at risk", said UNICEF Pacific Representative, Sheldon Yett.

BLOOD UNITS DELIVERY BY DRONE IN RWANDA AND IN GHANA

Rwanda started a programme to deliver blood units using drones with California-based start-up Zipline as early as 2016. The logistics scheme comprises one distribution centre with 15 drones to deliver blood, plasma and platelets to 21 hospitals across the western half of the country. According to the company, since launching the service in Rwanda, Zipline's drones have flown over 300,000 km. Instant drone delivery has helped ensure that hospitals always have access to blood products, increasing the use of some blood products by 175% and reducing waste and spoilage by over 95% according to the teams.

REUTERS/James Akena - stock.adobe.com

In April 2019, the government of Ghana officially launched its first drone delivery service in cooperation with Zipline. The objective is to make national-scale, on-demand emergency delivery of 148 different vaccines, blood products and life-saving medications.

In addition, Zipline is setting up a site in Nevada, USA, to test service to hospitals.

PROJECT « DELIVER FUTURE » IN TANZANIA

In the framework of their common pilot project "Deliver Future", the logistics company DHL, the German international cooperation agency GIZ and the German drone manufacturer Wingcopter successfully completed a 6-month pilot project of medicine drone delivery to an island in Lake Victoria in Tanzania.

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During the trials, the drone completed the 60 km flight from the mainland to the island in 40 minutes on average. According to DHL, time savings are significant in a context of inadequate ground infrastructure and challenging geography: the same journey takes 4 hours by boat and 6 hours by road. A total of 2,200 km were flown and roughly 2,000 flight minutes recorded during the pilot project.

MEDICAL DELIVERY IN SWITZERLAND

REUTERS / Pierre Albouy - stock.adobe.com

Swiss Post first tested drone delivery in an urban environment between two hospitals in partnership with California-based Matternet in 2017. According to Swiss Post, since the launch of the project, around 100 autonomous test flights have been carried out in Lugano between two hospital locations, Ospedale Civico and Ospedale Italiano, approximately 3km away by road. The next stage is ongoing in the capital city of Berne between the Tiefenau hospital and University Hospital Insel.

In addition, Matternet announced a partnership agreement with UPS to transport medical samples via drone across hospitals in Raleigh, North Carolina.

FLYING HIGH CHALLENGE IN THE UNITED KINGDOM

NESTA Foundation

In July 2018, the global innovation foundation Nesta published the results of the first phase of Flying High, a collaborative engagement with five UK cities, UK government, the Civil Aviation Authority, industry, academia and public services to explore the potential uses of drones in urban environments, capture public sentiment, propose guidelines on drone use in the public realm and analyse the technical and economic feasibility of five socially beneficial use cases in real-world scenarios. Two of the five use cases were about medical transport via drone. The London case analysed the movement of pathology samples for post-kidney transplant monitoring between Guy's and St Thomas' hospitals, and the Southampton case focused on carrying blood products from NHS Blood and Transplant in Southampton to St Mary's Hospital on the Isle of Wight, as well as Portsmouth and Bournemouth.

The next phase in 2019 focuses on designing the testing capabilities and challenge prize specifications for socially beneficial, city-based use cases in the categories of medical transport, emergency response and infrastructure maintenance. These activities will support the design of an innovation challenge to accelerate development of urban drone services that bring public benefit to UK cities.

USE CASES WITH IMPACT IN CLINICAL PATHOLOGY

Ongoing experiments highlight drones' superior impact in specific instances. Drones will not replace existing logistics schemes, rather they will complement them, either because they are inadequate or costly. The teams at Cerba HealthCare and The Drone Office have identified 4 use cases in medical biology. They each fit under experimental scenarios considering current regulations and technology.

The first use case is about "on-demand" 24/7 emergency service in Europe. The 3 other use cases focus particularly on issues often encountered in Africa. Cerba HealthCare is present in Africa in 11 countries through a joint venture with its long-time partner Lancet Laboratories, through its central laboratory for clinical trials BARC , and trough specialised biology division , Cerba . The specialised biology activity of Cerba HealthCare , has been working with medical communities in many African countries for over 30 years and provides them with specialised biology and pathology anatomy and cytology services daily. Thanks to its mastery of sampling logistics and powerful digital tools, more than 600, 000 biology tests are conducted each year by Cerba for healthcare professionals in more than 15 African countries, with a turnaround time for results mostly below 48 hours.

By all means, drones are very well suited to the African continent where distances can be significant and road infrastructure inadequate. Drones could overcome these geographical constraints at a fraction of the cost.

Michal Jarmoluk/Pixabay.com

USE CASE #1: PROVIDE A 24/7 EMERGENCY SERVICE IN EUROPE

In Europe, health reforms, as well as the implementation of the ISO 15189 standard, have caused the concentration of technical resources into regional technical platforms serving peripheral sites. As a result, a clinic may be served by a specialised laboratory located tens of kilometres away.

Samples collection is organised through daily tours of sites, according to set schedules and itineraries. Typically, a patient visits his or her local laboratory in the morning for sample collection. The samples are then routed to the regional technical platform for analysis, and in most cases, results are made available to doctors and patients that same afternoon.

For example, the Normandy region within the Cerballiance network comprises 16 laboratories spread over 4 counties (Calvados, Eure, Orne, Seine-Maritime) while the regional technical platform is located in Lisieux. The region handles several thousands of patients every day, each file usually comprising 3 to 5 samples. 4 collection routines are performed daily by a team of 20 inhouse drivers.

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In contrast, emergency analysis requires exceptional therefore costly logistics resources and a flexible approach. The Normandy region manages several tens of such emergencies every week. These samples must be transported as soon as possible to the regional technical platform in Lisieux for immediate analysis and results by end of the day. If the inhouse drivers team is busy performing their routine journeys, an express courier is ordered. This requires a very flexible organisation to guarantee the timely transport service.

A drone could offer a flexible on-demand alternative transport service in an automated flight operating 24 hours a day, 7 days a week.

The planned routes cover tens of kilometres between two predetermined points, in a two-way itinerary between the technical platform and the local labs.

Schedule is not predetermined, flights are on-demand.

Most of Cerba HealthCare's labs and platforms are within city centres, part of the flightpath is over or near populated areas.

Emergency requests generally involve max 4 samples.

Emergency deliveries are currently performed at ambient temperature or in an air-conditioned vehicle.

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USE CASE #2: IMPROVE THE DETECTION OF CERVICAL CANCER IN SUB-SAHARAN AFRICA

Adam Jan Figel/shutterstock.com

In 2017 the magazine Médecine et Santé Tropicales published: "This emerging cancer is constantly increasing in sub-Saharan Africa, with more than 75,000 new cases and nearly 50,000 deaths a year, further promoted by HIV infection. According to the World Health Organization, cervical cancer will kill more than 443,000 women worldwide by 2030, nearly 90% of them in sub-Saharan Africa. Yet cervical cancer is a non-communicable disease that can easily be prevented. Indeed, this disease can be avoided by vaccination and secondarily by the early diagnosis of risk situations ". According to the Inca, the French National Cancer Institute, regular smear testing can prevent cervical cancer in 9 out of 10 cases.

However, by lack of adequate road infrastructures, large populations may be deprived of access to clinical pathology diagnosis and are excluded from prevention campaigns for frequent pathologies.

Closer to home, islands, mountains but also accident scenes can face a temporary close or chronic insufficiency in their transport services.

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The planned routes cover several tens of kilometres between two predetermined points, in a two-way itinerary between a logistics node or the specialised platform, and the isolated collection points.

The schedule is a routine at predetermined times.

Flying over populated areas can be avoided.

Each routine flight can mutualise the collection of tens of samples on the return flight back to the logistics node while the outbound leg could be made available to pharmaceutical companies, NGOs, hospitals and other health organisations to deliver vaccines or medicines to those isolated populations. Such sharing approach would not only minimize costs but also CO_2 and greenhouse gases emission and would offer a global service to patients.

Subject to testing by experimentation, transport may be carried out at ambient temperature, if necessary, in an insulated box with cool packs.

USE CASE #3: BETTER SERVE REMOTE INDUSTRIAL SITES

In Africa many industrial sites are in remote areas and hardly accessible. This can be the case in mining, in oil and gas, in the Republic of Congo for example. To a certain extent these sites are designed like small towns, with small medical clinics, and they benefit from dedicated road infrastructures.

However, toxicology risks are higher, and Health and Safety regulations require that workers' health is routinely checked. Such tests are performed in specialised technical platforms that may be located hundreds of kilometres away. Also, these industrial sites can be relying on the logistics organised by the industrial operator of the site, and this can significantly affect logistics. Little room of manoeuvre is available for emergencies in tight operating schedules, and these emergencies can prove very expensive (aircraft, helicopter or specific land vehicle depending on the case). Performing all or part of the journey by drone could save significant time and render a highly valuable service.

The planned routes could cover up to hundreds of kilometres, between two predetermined points, between the isolated industrial or mining site and a logistics node or the specialised technical platform.

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The schedule is a routine at predetermined times.

Flying over populated areas can be avoided.

The payload would involve several tens of samples.

The return flight back to the industrial or mining site can be made available to transport medicines or vaccines in a mutualisation and sharing approach.

Subject to testing by experimentation, transport could be carried out in controlled temperature to secure samples' integrity.

USE CASE #4: OVERCOME TRAFFIC JAMS IN SATURATED MEGACITIES

Population in megacities, particularly in growing countries, is expanding at a rapid pace, much faster than road infrastructure and public transport. The traffic becomes chaotic and random.

For instance, the traffic jams in Lagos, Nigeria's capital city and the largest city in Africa, are legendary, they are called the "go slow". According to the magazine Alternatives Economiques, from 5 a.m., tens of thousands of people are packed in the danfos, the yellow minibuses that connect to the business districts of Victoria Island and Ikoyi. The twelve kilometres of the Third Mainland Bridge are completely saturated, and many roads are obstructed at any time of the day.

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In such circumstances, delivering a predictable logistic routine, let alone providing emergency services, is a tremendous challenge. Cerba HealthCare for example had to set-up two distinct technical platforms on each side of the city since it can take 3 hours to simply cross the main bridge. Using a drone could solve that challenge, with a flightpath essentially above the water, a key safety risk mitigation factor in this populated environment.

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The planned routes cover a few kilometres, possibly up to twenty kilometres, between two predetermined points.

The schedule is a routine at predetermined times.

Part of the flight path is over or near populated areas.

Each routine can mutualise the collection of tens of samples.

Subject to testing by experimentation, transport may be carried out at ambient temperature, and if necessary, in an insulated box with cool packs.

CHALLENGES AND PREREQUISITES

DRONE REGULATIONS

The use of drones to transport goods, even of modest weight, is still at the experimental stage. Globally, the opening of the market cover leisure drones and commercial drones piloted within line of sight, meaning within maximum a few hundred meters from the remote pilot.

In September 2018, the mandate of the European Aviation Safety Agency, the EASA, was extended to include drones of less than 150kg. The first package of European regulation was published on 11th June 2019. In this first step, the regulation focuses on operations presenting the lowest risks, called the "open" category. These operations will not require prior authorisation from the competent authorities. The regulation also defines the guiding principles but not yet the details of the "specific" and "certified" categories for operations presenting greater risks. These operations will require a declaration or authorisation prior to flight. Such authorisation shall be granted after review of a robust safety operational risk assessment and risk mitigation plan.

Europe promotes the safe development of drones because it is a source of growth and new job creation. "This regulation will enable the free circulation of drones and a level playing field within the European Union, while also respecting the privacy and security of EU citizens, and allowing the drone industry to remain agile, to innovate and continue to grow", mentioned Patrick Ky, EASA Executive Director during the High-Level Conference on Drones organised by EASA in Amsterdam in November 2018.

For this reason, the regulatory framework will continue to evolve as relevant use cases are developed and mature technological solutions become available.

REGULATIONS FOR THE TRANSPORT OF BIOLOGICAL SUBSTANCES

OMS https://www.who.int/fr

Biological substances category B are classified as hazardous substances classification 6.2 in international transport regulations (IATA/ADR, ...). As such, their transport is subject to specific international regulations. Processes and packaging are standardised, employees in the supply chain are specialised and trained for this purpose. The international air transport regulation by IATA mirrors the UN's recommendations, adapted to air transport.

Most samples collected for analysis at Cerba HealthCare are classified as UN 3373 biological substance category B. In the framework of the European drone regulation , transport of dangerous goods are operations in the certified category, due to sanitary risk.

Therefore, incremental experimentation, where appropriate in partnership with a medical player from the country or region involved, will be the preferred way forward.

AVAILABILITY OF SOLUTIONS MEETING THE SPECIFICATIONS

Transport by drone is at the experimental stage. As a result, very few solutions have been developed to achieve that mission, let alone solutions that have been approved by the relevant aviation safety authorities.

Could we consider using drones developed to address existing market segments and adapt them to transport missions? And if a transport-specific solution is required, which technologies should be selected?

The market volume today is driven by recreational or leisure drones. Solutions in this market segment benefit of significant return of experience on their safety and reliability. Also, they can leverage volume to scale costs down. However, manufacturers in this segment target the general public flying in visual line of sight, the future "open" category in the EU regulation, i.e. solutions unlikely to fit the project's use cases requirements.

Professional multi-rotor drones are more flexible by design and more powerful than recreational drones. However, their endurance is limited by their LiPo batteries to approximately 30 minutes flight time, and often by the range of their radio links, around 3 to 4 km under the European ETSI norm.

Fixed-wing drones, such as mapping drones, offer greater endurance, they can fly farther and longer. Return of experience on their safety and reliability in flight beyond visual line of sight has been accumulated through operations in Africa, Australia, Asia. On the other hand, the manoeuvrability of fixed wing drones can be challenging. Hovering is not possible therefore delivery at precise spots can prove difficult. Take-off and landing phases require minimum landing areas. Hybrid platforms called VTOLs for vertical take-off and landing, address that challenge.

Eventually, the nature of the mission (range, weight, payload, flight path over or close to populated areas …) will determine the best type of drone for each mission. Equally important, incremental experimentation will be essential to challenge and test the performance of selected solutions.

PROMOTING A SOCIALLY RESPONSIBLE INNOVATION

Cerba HealthCare and The Drone Office share the vision of innovation serving the common good. Besides, social acceptance of disruptive technologies will expand if they benefit everyone.

When it comes to drones, a socially responsible approach to innovation should strive to reduce existing nuisances and avoid creating new ones, for instance:

- reduce urban traffic jams;
- reduce pollution and target zero-emission-carbon transport;
- reduce noise and visual nuisance;
- respect people's privacy;
- comply with safety and security requirements.

IN SUMMARY

This White Paper summarizes the collaborative work of Cerba HealthCare and The Drone Office.

The use of aerial drones to transport goods, even of modest weight, is still at the experimental stage. Overall, the market opening currently applies to recreational drones and drones for professional use within line of sight, i.e. maximum a few hundred metres away from the remote pilot.

Clearly, the ability to bypass ground infrastructure, either because it is too congested, or because it is deficient or non-existent, is a powerful lever for transformation. Several experiments are already underway around the planet, especially in the medical field. The "Drones at Unicef" program contributes to raising awareness of drone benefits.

The teams at Cerba HealthCare and The Drone Office assessed the existing and future opportunities and benefits of using drones in biological samples logistics. They identified 4 use cases where drones would be a powerful alternative to existing logistics schemes.

- ✓ Case #1: Provide an emergency service in Europe, 24/7

And with a particular focus on challenges in Africa:

- ✓ Case #2: Improve the detection of cervical cancer in sub-Saharan Africa;
- ✓ Case #3: Serve large remote industrial sites;
- ✓ Case #4: Overcome traffic jams in saturated megacities.

The first package of drone regulations at the European level was published on 11^{th} June 2019. Within this European framework, the 4 use cases identified are classified in the "specific" or "certified" categories.

Air transport of biological samples is subject to specific United Nations and IATA regulations. Most samples collected within Cerba HealthCare are transported as biological substances category B UN 3373. In addition, ISO 15189 requires temperature management and traceability of biological samples.

Fernando Zhiminaicela/Pixabay.com

The Drone Office and Cerba HealthCare favour open innovation and promote a shared understanding and approach with stakeholders. They are open to dialogue and partnerships with a view to test and experiment the identified use cases.

APPENDICES

SAMPLE COLLECTION IN CLINICAL PATHOLOGY

A COMPLEX INDUSTRIAL PROCESS

Every day, within Cerba HealthCare, tens of thousands of samples are transported to technical platforms under rigorous transport conditions to ensure results' quality. Logistics is an industrial process supporting a significant volume of activity while meeting regulatory quality requirements.

With regards to specialised analyses, Cerba offers full logistical support for its clients whether they are laboratories, hospitals, private clinics, or industrial companies. Cerba provides the pick-up at the sampling laboratory, the supply of sampling equipment, and the transport of samples in accordance with pre-analytical conditions.

Cerba HealthCare

Outside of France, collection of samples is sub-contracted by Cerba to local partners. Local agents must obtain ISO certification demonstrating the respect of the most rigorous standards for the transport of biological samples from human origin. In particular, they must comply with ADR and IATA requirements for road and air transport respectively, if their country has signed those agreements. They must also adapt to additional specific rules set up by airline companies for transportation of biological samples.

Cerba enforces the use of thermochips by its agents. Those chips record and trace the temperature of the samples all along the transport process from the customer's laboratory to the technical centre. Used on a systematic basis, those chips provide optimal temperature management all along the pre-analytical phase.

PRE-ANALYTICAL PHASE REQUIREMENTS

Cerba HealthCare Group's customers benefit from a logistics solution perfectly adapted to the requirements of the NF EN ISO 15189 standard. With regards to the transport of biological substances category B, the standard has two major requirements: temperature management and traceability.

TEMPERATURE MANAGEMENT

The temperature range assigned to a given sample for its optimal storage (frozen, refrigerated or ambient temperature) must be preserved from the sampling laboratory to the technical platform, without breaking the temperature chain. To achieve this, couriers are equipped with temperature-controlled bags. Vehicles are equipped with cooling units and local offices have storage containers that are also temperature controlled. Each bag and container used to carry a sample at one time or another in the process is equipped with an electronic chip that records its temperature and transmits it in real time to both the driver of the vehicle (who can act immediately in case of problem) and to a server that records this data. The next day, each sampling laboratory can consult the temperature curve of any sample throughout its transport. Transparency ensures verifiable compliance with the standard.

SAMPLE TRACABILITY

Michal Jarmoluk/Pixabay.com

Avoiding losses or exchanges of tubes, indicating to each sampling laboratory that all its samples have been correctly collected and have arrived at the technical platform: this is the objective of physical traceability. It is achieved by the pairing of the bar code of a tube and that of a location. Thus, during the collection, the courier flashes the bar code of the client laboratory and that of each of the specific bags containing the samples. The same process is applied at every step, from collection to arrival at Cerba where flashing of the barcode certifies delivery. The GPS position of each vehicle and the list of all the bags that the driver has flashed are transmitted to computer servers. That way, teams know the precise position of every sample throughout its routing from the client laboratory to the technical platform.

SAMPLE RECORDS

The department in charge of reception and record of samples has been especially engineered to comply with the requirements of NF EN ISO 15189 standard (N°8-0945 Medical analyses). Traceability is the keyword of a process involving automation each time it is possible, to minimize the risk of error and allow men and women to focus their attention and time on what they must do.

DRONES

INTRODUCTION

A drone is a robot that may be terrestrial, marine, submarine, spatial or aerial. In practice, the term relates to aerial drones, i.e. an "aircraft without a person on board", or "Unmanned Aircraft System" or simply "UAS".

There is a huge variety of drones in size, shape and mass, ranging from nano-drones such as the Black Hornet by Prox Dynamics, to large unmanned planes such as high altitude, long endurance "HALE "drones.

A drone is actually more than an aircraft, it is a global system consisting of the following primary elements:

- The aircraft, also referred to as the platform, the unmanned aircraft UA, or the unmanned air vehicle UAV;
- The ground station enabling the remote pilot to remotely control the aircraft;
- The GPS system (satellite-based Global Positioning System) for aircraft real-time geo-localisation;
- The communication uplink to transmit the remote pilot's commands to the aircraft;
- The communication downlink to transmit the video feed and the aircraft data back to the ground station.

CLASSIFICATION OF DRONES

By definition constraints induced by having a person onboard do not apply to drones. As a result, designers have developed novel architectures to meet the specific needs of each mission.

In general, drones are classified in 3 main categories:

- Fixed wings
- Rotating wings, especially multi-rotors
- Convertible or hybrid or VTOLs ("vertical take-off and landing")

FIXED WINGS

Fixed wings designed as airplanes

Drones designed like traditional aircrafts are generally composed of a fixed wing, a fuselage, a drift and a tail. This type of drone offers greater endurance, they can fly longer, over longer distances. They are well suited for inspection missions over railway lines, pipelines and maritime borders. On the other hand, they lack manoeuvrability compared to multi-rotors. Turning may require a relatively wide radius of action, taking-off may require launching by hand or catapult, and landing may require a certain landing area.

Fixed wings designed as « flying wings »

Flying wings are self-stabilised by virtue of their shape. Their manoeuvrability allows to follow a pre-determined flight plan, even in case of wind gusts. They are well suited for use cases such as agriculture, mines and quarries inspection and monitoring.

ROTARY WINGS

Multi-rotors

Rotary multi-rotors account for most of the recreational drone market and professional drone market.

The lift capability of a multi-rotor drone is produced by the rotating rotors and not by wings exerting a pressure on air like airplanes do. Instead, a multi-rotor stabilises and moves thanks to the speed modulation of its multiple rotors. A drone with 4 rotors is called a quadcopter or quad, with 6 rotors an hexacopter, with 8 rotors an octocopter.

The higher the number of rotors, the higher the power, the higher the payload and/or endurance capacity. In addition, rotor redundancy improves drone safety: with 6 rotors and more, in the event of one motor failure, the other engines can compensate and better support an emergency landing.

Limited autonomy induced by LiPo batteries

Multi-rotors operate with an electric propulsion system powered by lithium polymer or LiPo batteries, with high energy density and fast discharge. Their autonomy or flight time is therefore limited. Order of magnitude is 10 minutes for toys and 30 minutes for higher end leisure and professional drones. This constraint is acceptable in a visual line of sight operation, where a 30-minute flight is enough to collect the data and images required by the mission. However, it is challenging in the context of longer endurance or beyond visual line of sight flights.

Rotary wings designed as “helicopters”

Helicopters account for a marginal share of the current drone market. However, projects are under way for the transport of passengers, the so-called "flying taxis", and some designs are inspired by helicopters.

HYBRIDS OR « VTOL »

Fixed-wing aircraft such as airplanes or gliders take advantage of the lift, the force created by the wings and pushing them upwards. This allows them to fly over greater distances compared to multi-rotors. However, fixed wings must fly within their flight critical parameters in terms of angle of incidence and minimum speed, else they may lose their lift, stall and fall. As a result, changes in trajectory are performed in ample movements, and minimum areas are required for take-off and landing. This can prove complicated in a city environment, albeit an option is to land on large flat roofs.

Multi-rotors on the other hand offer greater manoeuvrability, they can perform stationary flights, and can effortlessly turn at 90, 180 or 360 degrees. However, since they do not glide, LiPo batteries limit their autonomy to about 30-minute flights for high-end leisure and professional drones.

Convertible, or hybrid, or VTOL for "vertical take-off and landing" drones strive to take advantage of the benefits and to compensate for the limits of both designs. These are aircraft that combine multi-rotors used in the landing and take-off phases and a fixed wing during flight.

NATURE OF MISSIONS AND LEVELS OF AUTONOMY

We often hear about "autonomous drones", but the reality of this autonomy should be carefully evaluated based on the actual degree of the machine's autonomy vs. the remote pilot ability to regain control of the aircraft at any time, especially in the case of an emergency.

THE REMOTE PILOTE

The remote pilot is the person in charge of the aircraft flight and operation, just like the pilot-in-command is in charge aboard a plane.

The European regulation refers to the following definition:

> **Remote pilot** means a natural **person responsible** for safely conducting the flight of a UA by operating its flight controls, either manually or, when the UA flies automatically, by monitoring its course and **remaining able to intervene** and change its course at any time.

FLIGHT WITHIN VISUAL LINE OF SIGHT (VLOS)

When flying within line of sight, the remote pilot always keeps visual contact with the aircraft and effectively pilots it and controls its trajectory. The pilot monitors the flight environment, identifies obstacles and modifies the trajectory accordingly ("see and avoid").

The European regulation refers to the following definition:

> Visual line of sight operation ('VLOS') means a type of UAS operation in which, the remote pilot maintain continuous unaided visual contact with the unmanned aircraft, allowing the remote pilot to control the flight path of the unmanned aircraft in relation to other aircraft, people and obstacles for the purpose of avoiding collisions.

FLIGHT BEYOND VISUAL LINE OF SIGHT (BVLOS)

The flight path extends beyond the remote pilot's visual field. The pilot defines the trajectory based on real-time information communicated by the drone back to the ground control station (live video feed, flight data such as altitude, GPS position, speed …). In practice, it is anticipated that these flights will be highly automated, i.e. the flight path is fully determined pre-flight and the aircraft executes the programmed flight.

The European regulation refers to the following definition:

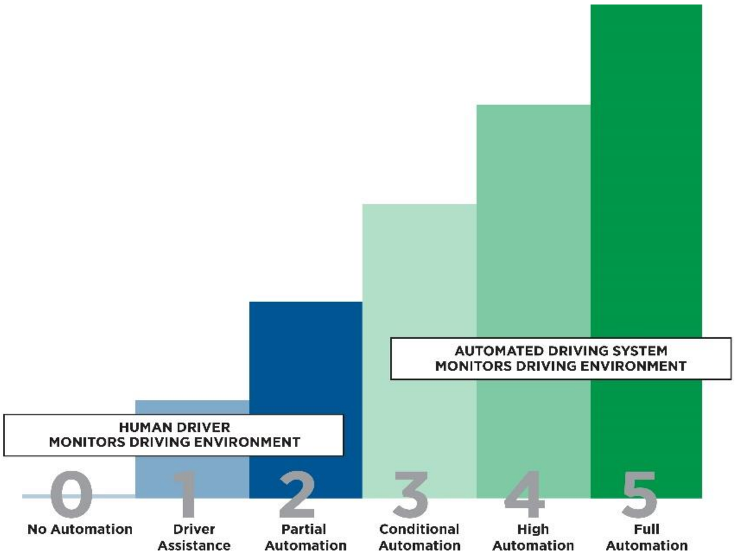
> Beyond visual line of sight operation ('BVLOS') means a type of UAS operation which is not conducted in VLOS.

AUTOMATED SYSTEM

The flight path is pre-programmed and is automatically executed by the aircraft, but the remote pilot remains the person in charge and can take control over the drone trajectory, for example in case of incident. Some missions require to accurately follow a very precise flight plan to collect the right data and reach the required precision level. For example, when conducting a diagnosis of an agricultural parcel or a mine, an automatic flight plan is often more rigorous than a human pilot.

AUTONOMOUS SYSTEM

What is autonomy? The automotive industry is a major contributor to thought leadership when it comes to autonomous vehicles. The SAE, the Society of Automotive Engineers, defines 5 degrees of automation (not autonomy).



Society of automotive engineers , standard J3016

The European regulation refers to the following definition:

> "autonomous operation means an operation during which an unmanned aircraft operates without the remote pilot being able to intervene."

Larousse dictionary refers to the term autonomy as:

> "Ability of someone to be autonomous, not to be dependent on others; character of something that works or evolves independently of something else. "

In this sense, automatic drones can be qualified as autonomous since they are pre-programmed, they execute their flight plan accordingly, and predefined emergency procedures in case of incidents. With this definition in mind, one could say that driverless metros such as line 1 in Paris and DLR in London that have been running for years, also qualify as autonomous vehicles.

However, if one refers to the concept of "decision-making capacity" as the true attribute of autonomy, and not merely to the capability of executing predefined commands, then the terminology proves inadequate and autonomous drones are better qualified as fully automated drones.

REGULATIONS

AERONAUTICAL RISKS ASSESSMENT

Two major risk families are considered:

Air Risk: risk that the aircraft hits another aircraft during flight (airplane, helicopter, ULM, drone, bird) damaging itself and/or the other aircraft

Ground Risk: risk that the aircraft falls and damages goods or injures people on the ground.

The ground risk level depends on many parameters such as population density on the ground (populated or congested areas vs. countryside), the aircraft mass, its altitude, speed, shape, the sensitivity of sites along its flight path such as airports, critical infrastructure, roads.

Simplified ground risk qualification:

The Drone Office

Risk matrix

The remote pilot performs a risk assessment prior to each flight. Weather conditions, temporary flight restrictions, anticipated flight of other aircrafts, presence of people in the vicinity ... are all part of the operational context reviewed and assessed by the remote pilot.

In a simplified schematic way, the risk analysis is based on the following methodology:

- Identification of all possible failures (motor failure, loss of communication link ...)
- Identification of all possible causes (bird hit, mechanical failure, weather conditions...)
- Identification of all possible outcomes in terms of damage to property and/or people
- Calculation or estimation of each probability

- Mitigation plan for each of the risks identified to reduce the occurrence or the consequence of each occurrence.

Risk level = probability of incident occurrence x severity of damage

This calculated risk is compared to the acceptable risk, which is the level of risk that society is willing to tolerate. This tolerance to risk may vary from one country to another.

Risk probability		Risk severity				
		Catastrophic A	Hazardous B	Major C	Minor D	Negligible E
Frequent	5	5A	5B	5C	5D	5E
Occasional	4	4A	4B	4C	4D	4E
Remote	3	3A	3B	3C	3D	3E
Improbable	2	2A	2B	2C	2D	2E
Extremely improbable	1	1A	1B	1C	1D	1E

Figure 2-13. Safety risk assessment matrix

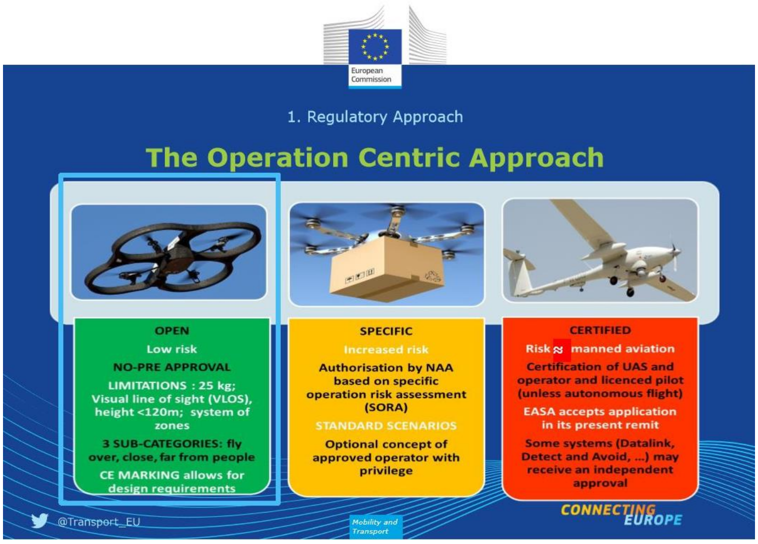
Safety Management Manual, 2013 edition, International Civil Aviation Organisation ICAO

DRONE REGULATION AT THE EUROPEAN LEVEL

On 11th September 2018 the mandate of EASA, the European Aviation Safety Agency, was officially extended to cover drones under 150kg. Previously, each member state was responsible of its airspace in relation to drones below that 150 kg threshold.

EASA has been working extensively for several years on defining the future European regulation together with a panel of experts and national authorities from member states. Opinion No. 01-2018 published in February 2018 summarised the results, and laid out a regulatory scheme. On 11th June 2019, the "Commission delegated regulation on unmanned aircraft systems and on third-country operators of unmanned aircraft systems" dated 12th March 2019, and the "Commission implementing regulation on the rules and procedures for the operation of unmanned aircraft dated 24th May 2019 were published at the Official Journal of the European Union.

EASA defines 3 categories called Open / Specific / Certified depending on the level of operational risk:



European commission, DG Move, Octobre 2018

« Open » category

Operations in the Open category present the lowest risk. They are not subject to any prior authorisation, nor to an operational declaration by the UAS operator before the operation takes place. They are all in visual line of sight at a maximum height of 120m.

Open sub-categories

Three sub-categories have been defined in order to gradually increase restrictions for flights over or close to people depending on the risk level, including the drone's mass. On one side, drones under 900g may fly over people, under certain conditions of course. On the other end of the spectrum, drones of up to 25kg may fly over non-populated areas far away from people, also under certain conditions.

European Aviation Safety Agency | ***Opinion No 01/2018*** | *2. In summary — why and what*

Operation		Remote pilot competency (age according to MS legislation)	UAS				UAS operator registration
Subcategory	**Area of operation (far from aerodromes, maximum height 120 m)**		**class**	**MTOM/ Joule (J)**	**Main technical requirements (CE marking)**	**Electronic ID/ geo awareness**	
A1 Fly over people	You can fly over uninvolved people (not over crowds)	Read consumer info	Privately built	< 250 g	N/a	No	no
			C0		Consumer information, Toy Directive or <19 m/s, no sharp edges, selectable height limit		
		• Consumer info • online training • online test	C1	< 80 J or <900 g	Consumer information, <19m/s, kinetic energy, mechanical strength, lost-link management, no sharp edges, selectable height limit.		
A2 Fly close to people	You can fly at a safe distance from uninvolved people	• Consumer info • online training • online test • theoretical test in a centre recognised by the aviation authority	C2	< 4 kg	Consumer information, mechanical strength, no sharp edges, lost-link management, selectable height limit, frangibility, low-speed mode.	Yes + unique SN for identification	yes
A3 Fly far from people	You should: • fly in an area where it is reasonably expected that no uninvolved people will be endangered • keep a safety distance from urban areas	• Consumer info • online training • online test	C3	< 25 kg	Consumer information, lost-link management, selectable height limit, frangibility.		
			C4		Consumer information, no automatic flight	if required by zone of operations	
			Privately built		N/a		

European Aviation Safety Agency (EASA), Opinion N° 01/2018

« Specific » category

The specific category refers to operations that are neither "open" nor "certified". These operations will require either prior authorisation from the competent authorities based on a thorough risk assessment and mitigation plan, or a prior declaration to the extent that these operations meet criteria of pre-determined standard scenarios (currently under definition).

« Certified » category

Operations in the certified category should, as a principle, be subject to rules on certification of the operator, the licensing of remote pilots and the certification of the aircraft. Considering the level of risk of damage to property and/or people, safety requirements are similar to manned aviation, all proportions being considered of course. The following operations shall be classified as "certified":

- flying over assemblies of people;
- transporting people;
- carrying dangerous goods, that may result in high risk for third parties in case of accident.

Entry into force and application

Both Implementing Regulation and Delegated Regulation were published in June 2019 and will become gradually applicable starting 1st July 2020.

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KEY DEFINITIONS OF THE EUROPEAN DRONE REGULATION

Unmanned aircraft ('UA') means any aircraft operating or designed to operate autonomously or to be piloted remotely without a pilot on board.

Unmanned aircraft system ('UAS') means an unmanned aircraft and the equipment to control it remotely.

Remote pilot means a natural person responsible for safely conducting the flight of a UA by operating its flight controls, either manually or, when the UA flies automatically, by monitoring its course and remaining able to intervene and change its course at any time.

Unmanned aircraft system operator ('UAS operator') means any legal or natural person operating or intending to operate one or more UAS

Open category: operations shall be classified as UAS operations in the 'open' category only where the following requirements are met:

(a) the UAS belongs to one of the classes set out in Delegated Regulation (EU) 2019/945 or is privately built or meets the conditions defined in Article 20.

(b) the unmanned aircraft has a maximum take-off mass of less than 25 kg.

(c) the remote pilot ensures that the unmanned aircraft is kept at a safe distance from people and that it is not flown over assemblies of people.

(d) the remote pilot keeps the unmanned aircraft in VLOS at all times except when flying in follow-me mode or when using an unmanned aircraft observer as specified in Part A of the Annex.

(e) during flight, the unmanned aircraft is maintained within 120 metres from the closest point of the surface of the earth, except when overflying an obstacle, as specified in Part A of the Annex (f) during flight, the unmanned aircraft does not carry dangerous goods and does not drop any material.

Specific category: operations in the 'specific' category should cover other types of operations presenting a higher risk and for which a thorough risk assessment should be conducted to indicate which requirements are necessary to keep the operation safe.

Specific category, standard scenario means a type of UAS operation in the 'specific' category, as defined in Appendix 1 of the Annex, for which a precise list of mitigating measures has been identified in such a way that the competent authority can be satisfied with declarations in which operators declare that they will apply the mitigating measures when executing this type of operation.

Certified category: operations shall be classified as UAS operations in the 'certified' category only where the following requirements are met:

(a) the UAS is certified pursuant to points (a), (b) and

(c) of paragraph 1 of Article 40 of Delegated Regulation (EU) 2019/945; and

(b) the operation is conducted in any of the following conditions:

i. over assemblies of people;

ii. involves the transport of people;

iii. involves the carriage of dangerous goods, that may result in high risk for third parties in case of accident.

In addition, UAS operations shall be classified as UAS operations in the 'certified' category where the competent authority, based on the risk assessment provided for in Article 11, considers that the risk of the operation cannot be adequately mitigated without the certification of the UAS and of the UAS operator and, where applicable, without the licensing of the remote pilot.

Visual line of sight operation ('VLOS') means a type of UAS operation in which, the remote pilot is able to maintain continuous unaided visual contact with the unmanned aircraft, allowing the remote pilot to control the flight path of the unmanned aircraft in relation to other aircraft, people and obstacles for the purpose of avoiding collisions.

Beyond visual line of sight operation ('BVLOS') means a type of UAS operation which is not conducted in VLOS.

Autonomous operation means an operation during which an unmanned aircraft operates without the remote pilot being able to intervene.

Payload means instrument, mechanism, equipment, part, apparatus, appurtenance, or accessory, including communications equipment, that is installed in or attached to the aircraft and is not used or intended to be used in operating or controlling an aircraft in flight, and is not part of an airframe, engine, or propeller;

Dangerous goods articles or substances, which are capable of posing a hazard to health, safety, property or the environment in the case of an incident or accident, that the unmanned aircraft is carrying as its payload, including in particular:

(a) explosives (mass explosion hazard, blast projection hazard, minor blast hazard, major fire hazard, blasting agents, extremely insensitive explosives);

(b) gases (flammable gas, non-flammable gas, poisonous gas, oxygen, inhalation hazard);

(c) flammable liquids (flammable liquids; combustible, fuel oil, gasoline);

(d) flammable solids (flammable solids, spontaneously combustible solids, dangerous when wet);

(e) oxidising agents and organic peroxides;

(f) toxic and infectious substances (poison, biohazard);

(g) radioactive substances;

(h) corrosive substances;

Direct remote identification means a system that ensures the local broadcast of information about an unmanned aircraft in operation, including the marking of the unmanned aircraft, so that this information can be obtained without physical access to the unmanned aircraft.

Geo-awareness means a function that, based on the data provided by Member States, detects a potential breach of airspace limitations.

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- Veterinary biology and genetics with two laboratories near Paris and Lyon
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- Biology of diagnostic tests with a dedicated technical platform within Cerba.

8 000	650	27 million
Employees	Laboratories	Patients /year

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- Headquartered in Paris
- + 650 laboratories
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- 27 million patients a year
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ABOUT THE DRONE OFFICE

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THE DRONE OFFICE is a consulting and services company specialising in drones & robots, based in London and Paris. We offer public and private clients independent, solution-agnostic expertise.

Drones are part of the autonomous vehicle transformation and our first objective is to help clients develop a safe and innovative drone roadmap.

Drones are also part of the digital transformation. So, beyond safety, our objective is to help clients transform disruption into a competitive advantage and value creation.

Equally important, we share with clients a vision of technology with a sense of purpose, that truly adds value for everyone.

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