ARTIS Project
Executive Summary Report

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GLOSSARY & ACRONYMS

ARTIS	Advanced Robotic Tele-echography Integrated Service
CNES	Centre National d'Etudes Spatiales
ESA	European Space Agency
SoW	Statement of Work
TTSA	Telemedicine Technologies SA
WP	Work Package

COMPOSITION OF THE ARTIS CONSORTIUM

MEDES - www.medes.fr

Project coordinator.

MAGELLIUM - www.magellium.fr

Design, development and manufacturing of the ARTIS system (Hardware and software)

TTSA (Telemedicine Technologies SA) - www.tentelemed.com

Technical evolution of the generic platform and deployment of the service at the pilot sites.

CERCOM / UNIVERSITY OF TOURS

Initiator of this concept, support to set up and evaluate the robotic tele-echography equipment and services from the medical point of view.

CNES - www.cnes.fr

Identification of the value chain elements for the end-to-end tele-echography service as well as a market study to build a sustainable economic model.

1. SCOPE OF THE DOCUMENT

The present document is the ARTIS Executive Summary Report of the activities performed under ESA contract ESA n° 21210/07/NL/HE.

2. BACKGROUND

In November 2007, ESA kicked off the "Advanced Robotic Tele-echography Integrated Service" (ARTIS) project, which was successfully concluded on October, 12th 2010. Led by the Institute for Space Physiology & Medicine (MEDES, France), this project aimed at validating a complete end-to-end tele-echography service. ARTIS combined know-how and technologies developed for human space flight activities and satellite communications.

2.1. Remotely Assisted Robotic echography

2.1.1. The need for echography and the related issues

Radiologists often use echography (or ultrasonography) is used by to get medical images as it offers several advantages compared to other medical imaging techniques. First, it is a non-invasive and harmless technique, which provides a wealth of anatomical and functional information. Then, from a practical point of view, ultrasound examination gives information in real-time and is simple to implement. In addition, ultrasound machines are compact and lightweight compared to other medical imaging tools (such as x-ray or computerised tomography systems). At last, ultrasonography is more affordable than other medical imaging techniques.

However echography has also a major drawback: skilled and experienced radiologists are required in its use to capture and interpret the dynamic images produced and this hinders the access to this technique in some circumstances where echography is needed or would be helpful. Some population, regional hospitals and isolated healthcare centres do not have access to echography because of their geographical isolation (e.g. in French Guiana or on some islands) or the lack of qualified radiologists or their uneven geographical distribution. Isolation and the absence of radiologist in crews also leads to the same issue in human spaceflights, in stays on the International Space Station, and future manned exploration missions where echography amongst other medical tools is essential in order to diagnose crews' health problems.

2.1.2. Remotely assisted echography

To overcome the above problems, alternatives to classical ultrasonography methods are necessary. One solution, commonly called "tele-echography", consists in enabling a radiologist to remotely perform the ultrasound examination, guide a medical doctor during the examination or give her/him a second opinion using Information and Communication Technologies (ICT). Adding to its medical benefits, tele-echography can also have economic interest since it may enable to save subjects' transport costs and may optimise radiologists' workload.

Assisted echography or sonography has been developed in different forms depending on whether scanning is transmitted in real-time, consultations are carried out live or videoconferencing is used. In the most commonly-used type, the radiologist gives instructions to an operator to position and move the ultrasound probe on the patient's body and visualizes in real-time the images from the remote ultrasound scanner and the operator's movements. However, this type of tele-echography is not an optimal solution: in particular, the "expert" radiologist may give instructions describing intuitively the movements that he would personally perform and the "remote" operator may inadequately interpret those instructions leading to approximations and slowness in performing the medical act.

2.1.3. Robotic tele-echography

Taking these limitations into account, the idea of robotic tele-echography, where the radiologist handles the probe through a remotely controlled robotic probe holder, has arisen (see Figure 1). Pr. Philippe Arbeille from University of Tours has advocated this concept for several years and has published this principle and its evaluation in clinical tests in several scientific and medical journals.

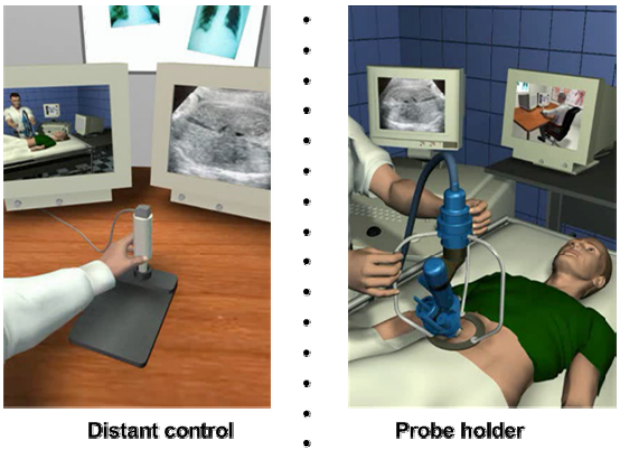


Figure 1: robotized tele-echography system

In collaboration with Pr. Philippe Arbeille, University of Orléans[1] has patented a concept working on the above principle a few years ago under the label "Robot for echographic and other medical investigations, comprises three motors able through gearing to drive an instrument along three axes which are concurrent at a point external to the robot" (publication number *FR2791294*). Since then, several projects funded by ESA and CNES have enabled the development and evaluation of the system. In particular, ESA funded the development of a first prototype through a MAP Programme[2] (reference: TERESA project, ESA MAP-023, 1999). More intuitive and comfortable for the radiologist, this technique creates conditions closer to those of a classical ultrasound examination. The developed solution is based on an "expert" station used by the radiologist and a "patient" station used by the site lacking the radiology expertise (see Figure 2). The two stations communicate with each other either by (ISDN) phone lines or any adequate communication means available such as

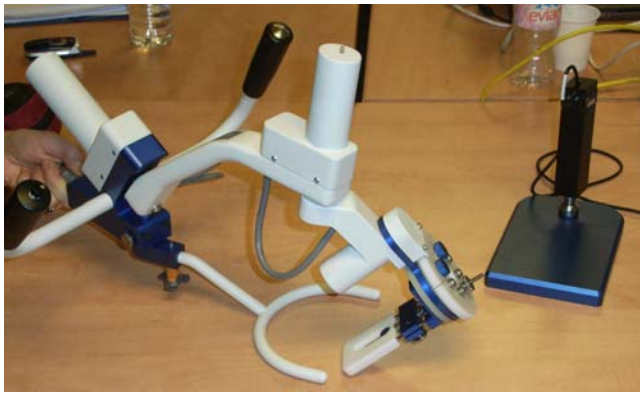
1 http://www.bourges.univ-orleans.fr/rech/lvr/presentation/presentation_index.html

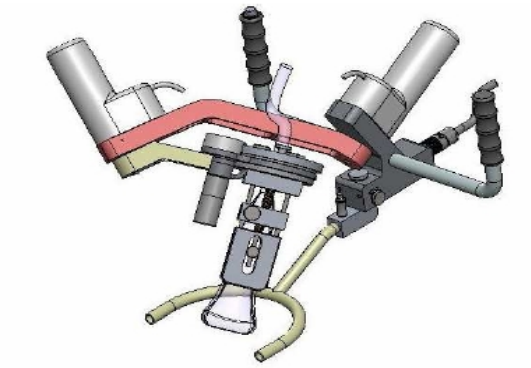
2 (http://www.spaceflight.esa.int/users/index.cfm?act=default.page&level=16&page=1096)

satellite communications. Short tests performed in local hospitals have proven the interest, the feasibility and the potential of this technique.

This concept was tested during an ESA parabolic flight campaign onboard the "Airbus A300 zero-g" (see Figure 3). The upgraded version of the tele-echography system is also currently used in the Tours hospital in France (see Figure 4).

Figure 2: test of the robotic tele-echography system in weightlessness (Picture credit: ESA)





Figures 3 & 4: tele-echography robot designed within the ARTIS project (Picture credit: ESA)

3. ADVANCED ROBOTIZED TELE-ECHOGRAPHY INTEGRATED SERVICE (ARTIS) PROJECT

The developed technology, supported by ESA, has been investigated both technically and clinically and has proven its added value. However, while the technology itself is ready, the supporting medical assistance service infrastructures do not exist as of today although they are indispensable for its operational use and commercialisation. As a result, the ARTIS project was initiated to develop the necessary elements of the value chain and carry out the validation of a complete end-to-end tele-echography service. The idea was to propose a proper remote diagnosis service adapted to users' needs and to see if it can become sustainable. In case of success, such a service could be extended to other medical diagnosis techniques such as magnetic resonance imagery (MRI) or computed-tomography scanner.

3.1. ARTIS Objectives

The main objectives of this activity were:

- to assess the feasibility and sustainability of tele-medical assistance services using multi modal imaging techniques. The implementation of such a service for a tele echography concept developed with the support of ESA will be used as a test case in ARTIS in different pilot sites;
- to assess the usefulness of satellite-based tele-medical assistance services, where such infrastructure is mandatory and/or can enhance multi modal imaging services.

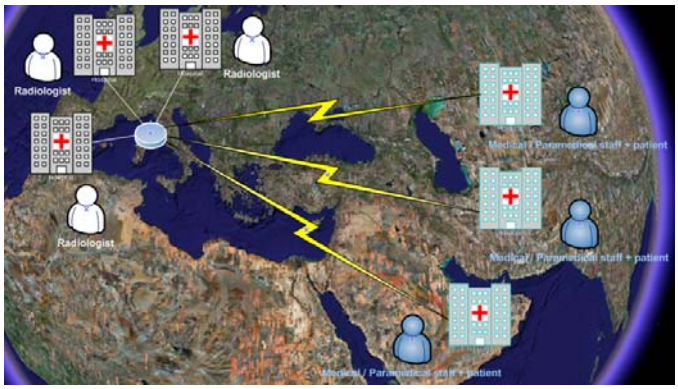


Figure 5: Schematic view of the service concept

3.2. ARTIS system Overview

The ARTIS Tele-Echography system relies on the provision to a radiologist/sonographer of an application to remotely perform an ultrasound examination. The system is divided in two stations:

- an Expert station
- an Operator station

At the Expert station, the radiologist/sonographer (Expert) remotely controls the orientation of an ultrasound probe on the patient's body using a joystick, and can visualize in real time the ultrasound images.

At the Operator station, an operator (e.g. nurse, radiology technician) prepares the Patient for the examination and holds a robotized probe holder on the Patient's body part that must be examined.

The system is available in two different configurations:

- the **Baseline configuration:** this default system configuration includes the remote robot control functionality,
- the **Integrated configuration:** this advanced system configuration includes the remote robot control functionality plus the videoconference functionality (ambient video and ultrasound video) and other advanced communication functionalities.

The communication between the two distant sites is performed over the Internet. The connection to the Internet can be done for instance through an ADSL connection or a satellite terminals network.

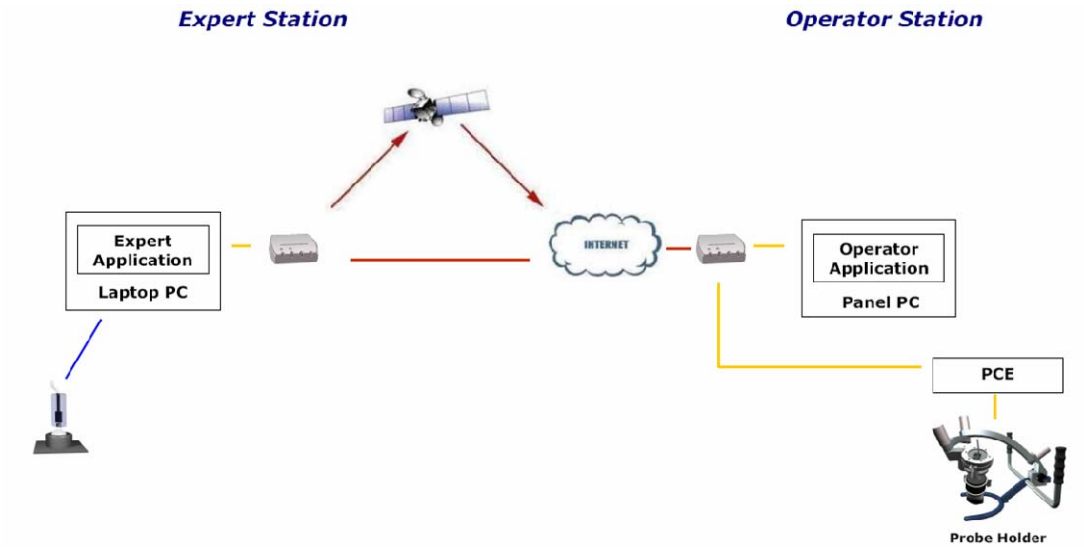


Figure 6: ARTIS System Overview

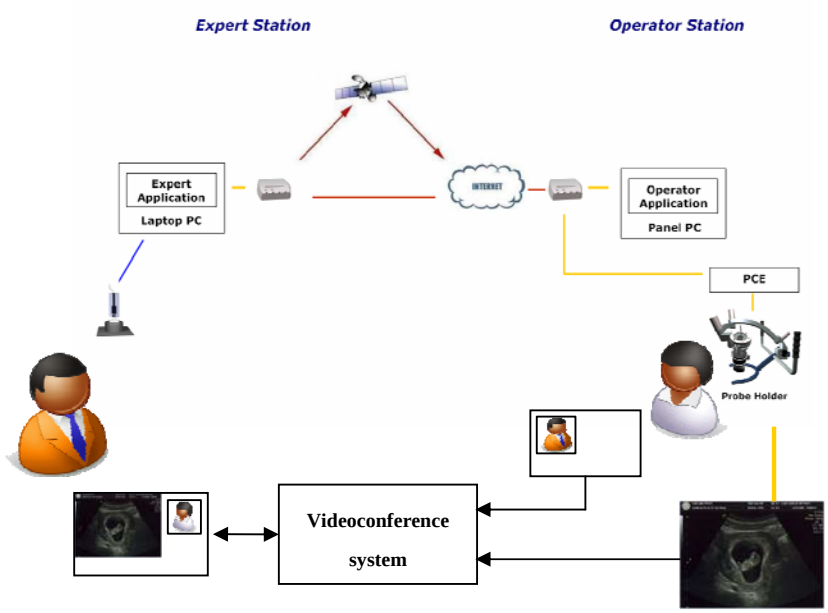


Figure 7: ARTIS Integrated Configuration

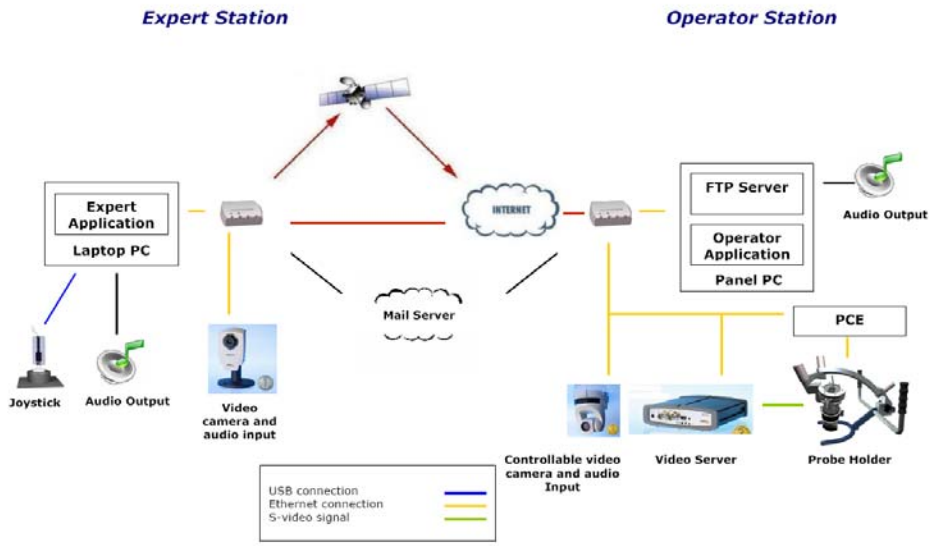


Figure 8: The necessary networks to operate ARTIS system

3.3. The ARTIS robot

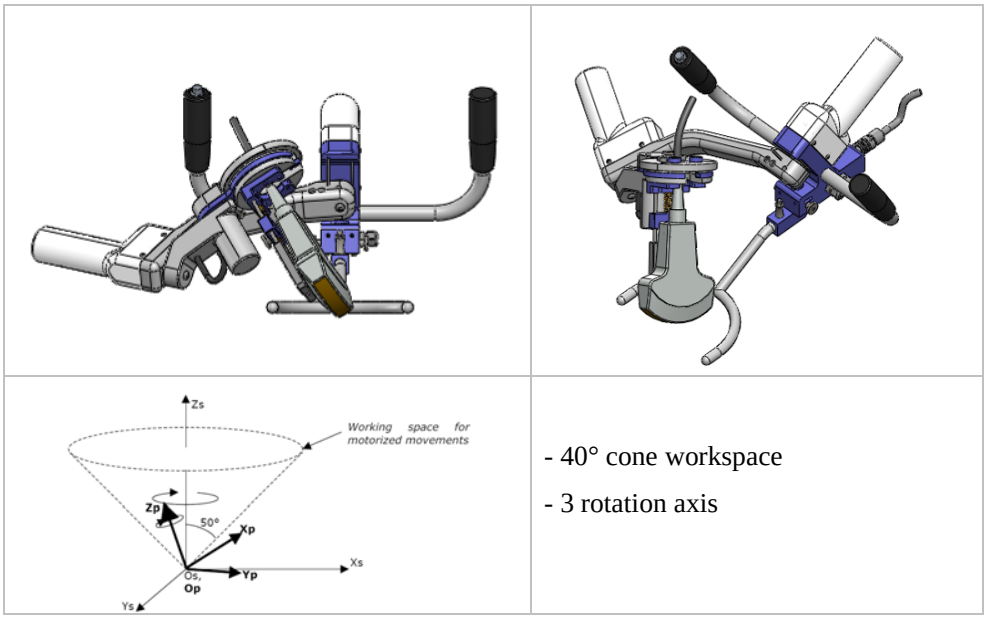


Figure 9: The schema of the robot / probe holder principle

Figure 10: Picture of the probe holder used on a patient post

4. PILOT FOR CLINICAL ASSESSMENT OF THE ARTIS SYSTEM

4.1. Context for pilot site selection

The selected pilot site, Hospital of Galate in Romania has an emergency and radiology department open 24h a day with several sonographers and paramedics on duty (approximately 10000 patient and 5000 echographies per year).

This hospital is surrounded by 10 small medical centres in the Danube delta approximately located between 20 to 80km from Spitalu, and in which it is difficult for patients to have access to basic imaging such as echography needed most of the time immediately after the clinical examination.

In fact, due to the lack of radiologists in the area, there is no sonographer on duty in these centres several days per week.

The sonographers and paramedics of the Galate Hospital were very motivated for testing the ARTIS tele-echography system between Tours and Galate Hospital as they plan to use it in the near future between their hospital (Expert centre) and some of the isolated medial centre in their surrounding (Remote centre).

For this validation, the hospital provided the paramedics to manage the ARTIS robotic arm on the patient, the technician to install the set up and restart the system when necessary, and the sonographer to perform after the tele-echography, the conventional echography to which the tele-echography diagnosis was compared The MD and sonographer from Galate Hospital provided a huge contribution to run the present project and make it successful.

The patients were those already planned to have an echography exam at the Galate Hospital. They were informed orally by the Galate doctor about the study and free not to accept to have both the echography tele-operated from TOURS and the conventional echography performed by the sonographer of Galate Hospital

4.2. Result of the clinical assessment on the Pilot site

47 patients from Galate Hospital were investigated both by tele-operated Echography and by conventional echography over a period of 8 weeks. Several organs were assessed with each patient because each clinical hypothesis requests to investigate approximately 1 to 5 organs.

A total of 141 organs (liver, kidney, spleen, uterus+ovarys) were investigated and 139 correctly visualized in various incidences (e.g. long and short axis, scan of the entire organ by self rotation of the probe on top of the organ). The medical validation of the system required as a technical performance of the robot to see all the organs of a "group of organs" as only the assessment of this group of organ can allow the clinician to make the diagnosis. Thus as 139 organs among the 141 investigated were visualized (99%), we can state that medically the ARTIS Tele operated Robotic arm enabled to access 99% of the organs.

For 9 patients, lesions were found at the liver (angioma), kidney (size, cyst), ovarian cyst with conventional echography exams. Among all these lesions, 1 was not detected with the tele-operated echography system while it was detected at the conventional echo (small renal cyst or angioma of 2 cm diameter).

Thus the ARTIS tele-echography system delivered the right diagnosis in 7 out of the 9 pathological cases (78%) and did not detect the lesion for 2 other cases (22%). Nevertheless the lesion was not detected because the organ was not clearly visualized thus the expert considered that the tele-echography was not completed and that no diagnostic could be delivered. But these minor lesions were not clinically of high interest as the failure in detecting them would not have impacted the medical management of the patient. By the end, all lesions found with the tele-echography system were confirmed by conventional methods. Thus Tele-echography never generated false positive observations as conclusions were made only when all the organs requested for the diagnosis were visualized.

The Tele-operated Echography session was 1.5 time longer than the conventional echography. Nevertheless, it should be noted that this increase of the exam duration is not perceived as a major constraint by medical centres not able to perform conventional ultrasound scans: tele-echography aims indeed at bringing ultrasound scanning knowledge where not available but not at replacing conventional echography where it exists.

5. PILOT TECHNICAL ASSESSMENT OF ARTIS SERVICE

2 interested users (ENI in May 2010 and Spanish Army in August-September 2010) have made a technical assessment of the ARTIS service;

- ENI has achieved an assessment on ADSL loops
- Spanish Army in double hops satellite links, with QoS and rate 512 Kbps up and 128 Kbps down (from Patient /Operator post).

The 2 users have suggested some improvements of the ARTIS system and have confirmed their will to become users of the service.

In addition, several other potential end users have confirmed their interest to use the ARTIS tele-echography systems within additional ESA projects (for instance, loan agreements, ARTES 20 and ARTES 3-4).

It is to be noted that tele-echography was selected as it is the most difficult device to tele-operate, at both technical and operational levels. Indeed, it requires the presence of a qualified radiologist and a real time interpretation of the data, which are dynamic images. Therefore, the ARTIS study enables to confirm that for other medical imaging modalities, the setup of telemedical services can be achieved, using ground or satellite communication means.

This is an important input for future ESA projects, in particular ARTES activities.

6. REGULATORY ASPECTS

Telemedicine and for instance tele-echography refers to the ability of providing patients with healthcare, based on the use of information and communication technologies. In fact, although medical science goes from strength to strength, it is hard in certain circumstances to have access to a competent medical doctor and, of course that may constitute a breach of duty on behalf of physicians and hospitals to not provide with a suitable healthcare as required at real time.

However, either in physical direct one-on-one contact with a patient, or by the use of information and communication technology (indirect contact), physicians' duty towards patients

does not change. In somewhat, medical doctors' duties are highly strengthened within healthcare provided from distance.

It is important to mention that there is nothing that prevents a physician to provide healthcare from distance when such provision is available. Notwithstanding, the recognition as the standard of a non physical contact healthcare provision, such as tele-echography, is matter of medical body.

Expert sonographers providing tele-echography, shall keep in mind to preserve patients' privacy and to have the more correct images as possible through the use of information and communication technology. Basically, they shall highly respect their duties set out in the code of medical deontology when carrying out a tele-echography.

Telehealth and consequently the tele-echography is a major subject for the different Ministers of Health of the European Community. However, today the regulatory environment has to be better defined and legislative mechanisms for the reimbursement of telemedicine healthcare are still missing in most of the European Community countries to impulse this innovative and promising medical practice.

Regulatory aspects were tackled in a dedicated technical note during the project.

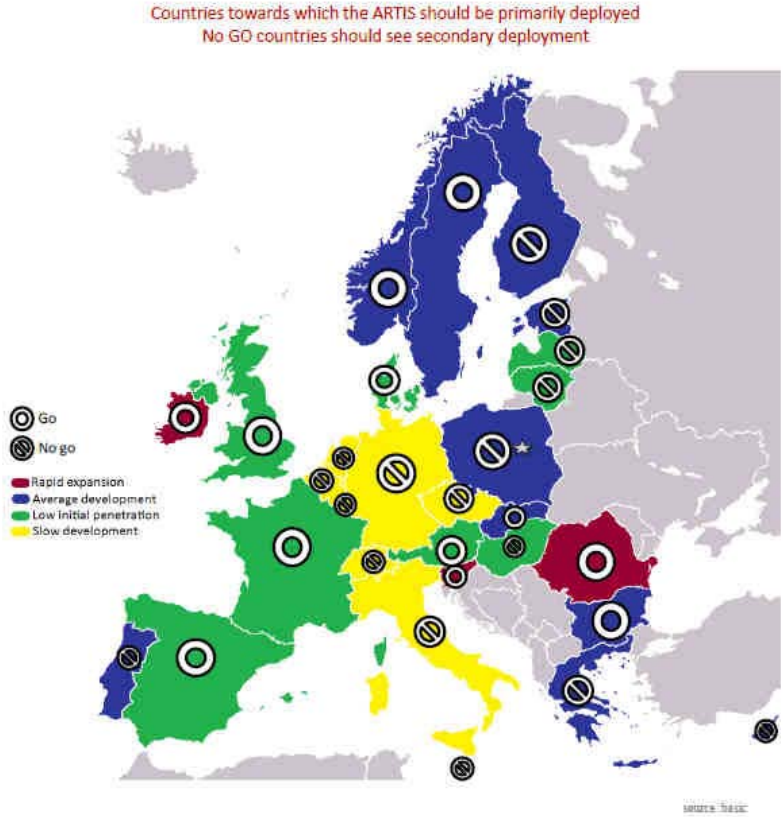
7. FIRST MARKET ANALYSIS FOR ARTIS SYSTEM

The main outputs of the market analysis achieved indicate:

- Market acceptance of the service depends on many factors, of which **health regulation and reimbursement schemes** are the most important. It appears that, unless radical changes happen in the short term horizon, these reimbursement schemes are not favourable to telemedicine at large and even more so to tele-echography.
- The private sector seems more likely to adopt the new service, mainly to use it to expand its customer base or maximise return on expertise. However, public institutions could also be interested, first on case by case basis (e.g. at the TSS 2010, a representative of the French Government considered the system as very useful to be used in the newly French Mayotte region.)
- The market perception of the service may be summarized as a **"nice-to-have" service** rather than a "must-have" one: apart from a couple of rare occasions, the service does not meet unsatisfied critical needs, which may be a severe drawback in a scientific environment.
- The adoption profile varies significantly from one country to another with mostly limited sales which will not make a distribution scheme easy to implement either directly or via partnerships.
- **Some key features of the service may be questionable** such as:
    - The value of the integrated video conferencing system
    - The value added by the robotic probe
    - The remote control of scan parameters is a must (not provided on the current prototype)
- The **given price for the system1 is acceptable** although perceived as rather high and would require some financial engineering and support to ease the service acceptance and implementation.

- The rather **high financial risk profile of the project is more of an issue**: the pay back is uncertain

The recommendations GO or Not GO (see definitions) among the EC countries are:



In the GO countries for the period up to 2020 the anticipated mean value of the number of the services sold are in total is 67 (minimum 12 and maximum 250). The foreseen market is therefore a niche market.

8. RECOMMENDATIONS AND CONCLUSIONS

8.1. Recommendations

Some easy improvements of the ARTIS system (SW and HW) can be implemented by Magellium. A complete list was provided to ESA in view of future utilisations and upgrades of ARTIS systems.

In particular, when using satellite service, it is required to book sufficient bandwidth for the uplink from the patient site 800 Kbps with a right QoS activated, for the uplink from the expert site is 120 Kbps with a right QoS activated.

8.2. Conclusions

Despite many difficulties the ARTIS project has been conducted to his achievement with a limited delay of 10-11 months. Objectives have been fulfilled and study outcomes can provide interesting inputs in view of future ESA activities including tele-echography systems.

All the requested activities with their deliverables have been fulfilled.

Thanks to ESA for its active support throughout the study.

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