The purpose of the collaborative project between ibex Healthdata Systems, Inc. and Johns Hopkins University is to prove the concept of a portable, voice-activated medical assist device that could be deployed and utilized in the space environment. The primary driving force for this initiative is to provide for a higher degree of autonomy for astronaut crews in order that they might provide "standard of care" emergency first-aid. As proposed, the device allows for easy input of algorithms and is expandable to allow for multiple, complex algorithms that will allow for the replacement of existing, cumbersome paper medical manuals. The majority of the work associated with Phase I involved the development of suitable software with which to power the device.

Over the course of our project, we have had regular meetings with all members of the team. Employees from ibex worked closely while developing the software and discussed progress of the project on a weekly basis throughout. The Johns Hopkins team met frequently (at least monthly and often weekly) and were in frequent contact via email, telephone and in person. In addition, the Johns Hopkins Emergency Medicine research administration staff provided regular advice and detailed reviews of all of the documents required for the Johns Hopkins research administration and institutional review board. Dr. Gabor Kelen, the Chair of Emergency Medicine at Johns Hopkins provided valuable feedback and the final review of all documents before submission to the university. The entire team met for conference calls monthly, the Hopkins team traveled to ibex during software development to review the application, and the ibex team visited Johns Hopkins at the completion of software development.

After the initial framework and demands of the system were explained to the programmers work began in selecting the speech recognition engine and the most versatile and effective programming language. IBM's ViaVoice speech engine was selected to interface with a Java application storing data in XML format. The program is wholly data driven, having no knowledge of content. It will work in any structured problem solving application. Given different

input the program will support other needs at NASA for self sustained expert knowledge. Similar use in other environments should be obvious: hard rock

mining, off shore oil platforms, ships at sea.

Once the application was written ibex employees recorded simple voice files to 'talk' the user through algorithms provided by the medical experts at Johns Hopkins. Stock images were used for both still and video images. In house testing of multiple microphones and speech engines produced a very responsive system. The prototype met and exceeded specifications and expectations of both teams.

After the completion of the prototype by ibex, the collaborators at Johns Hopkins convened a panel including the primary investigators to evaluate the usability. Shortly after the completion of the initial alpha version of the software, we met to review our findings. A dedicated laptop was purchased to house the device and software. Owing to the limitations inherent in Phase I we were forced to utilize an off-the-shelf laptop, which was dedicated to this purpose, containing the standard installation of Windows 2000 Professional. As the algorithms are extended markup language (XML) files, modification of the user views was possible immediately at the time of discussion. Both ibex and the Johns Hopkins staff tested the alpha version of the software and were trained to enter the algorithm data into the device. To complete this phase I of the project, we carried out two separate projects.

First, we converted the existing NASA Airway Management Algorithm for use with the device. With the assistance of the ibex programmers, we entered the modified algorithm into the device. Because the application supports branching logic, it is suitable for the adaptation of large, complex algorithms. As currently written, the only limitation of the application is the hard drive space of the host device. Each page exists as an XML document and is loaded only as needed. Each of us then ran a simulated airway emergency using the device and the NASA algorithm. At the end of this simulation, it was apparent to us that the voice-activated system was able to match the performance of that on paper. The primary advantage of the device is that it is able to ensure

that the standard of care is met, while providing for a higher degree of autonomy to the layperson, without the need to consult multiple pages in a manual. In the case of the NASA Medical Checklist manual, this may represent a major time saving as the document is large and cumbersome.

The second project was to validate the device in a setting unrelated to the needs of the Space Program. The purpose of this project was to test the usability of the device with healthcare practitioners and to test the ease of modification of the algorithm to suit different needs. The algorithm that we used is based on the Advanced Cardiac Life Support (ACLS) guidelines published by the American Heart Association. We tested the Basic Life Support (BLS) portions of the textbook along with the initial portion of the advanced provider sections and reprogrammed the device to use this algorithm. The device was then tested in an unblended, crossover study. Each participant performed a pre-scripted scenario using their existing medical knowledge. They then repeated the process with the assistance of the device.

Our objectives have been met in the following areas: software development, algorithm development and concept proof. In addition, we showed that the device is able to display both static and moving images, in real time and in response to queried prompts. The one area that has not been completed is a broader test of the device by the lay public
(Phase II).

We have met with some hurdles along the way, owing to the large, complex and bureaucratic nature of an institution such as Johns Hopkins. Initially, our efforts were hampered by a possible conflict of interest, as Michael VanRooyen, MD is a board member of ibex and, as such, could not be listed as primary investigator at Johns Hopkins. In addition, Ron Elfenbein, MD could not be listed as PI because he completed his training program in June, 2003 and would no longer be officially affiliated with the institution (except in his current role on this project). As a result, Gary Zimmer, MD was recruited to be the lead investigator at Johns Hopkins. Once Dr.

Zimmer was identified, the research administration application was complete and the IRB approval was undertaken. This process is still ongoing and we expect formal IRB approval before the end of January, 2004. As soon as approval is obtained, we are prepared to move ahead with our formal study. While this limitation precludes us from publishing in the medical literature at this time, we are preparing manuscripts which will allow for a formal review of our work in the scientific community. Because the scope of this phase of our work was only to prove the concept of the device, our IRB-approved study, while necessary, will add little to the feasibility of the project.

Our plans for Phase II include the formal review of the software and its superiority to the paper equivalent in both the trained and lay populations. Additionally, we plan to undertake, at least the beginning steps of, the construction of a dedicated device, not off the shelf, capable of surviving the rigors of spaceflight.

Our preliminary work strongly supports moving to Phase II. In Phase II, we would perform several additional tasks. We have found that the existing, affordable microphone solutions are not acceptable for a loud environment (ambient noise >50 dB). Even during our initial tests, the microphone that we chose provided acceptable results only with limited background noise. Next, a more robust deployment installation application needs to be developed. That application would need to provide for the entry of future algorithms without requiring XML programming. In addition, an error check for the installation needs to be created. This feature would run an error check on algorithms once they have been entered to identify errors in logic without requiring a manual iteration of all algorithms. Finally, Phase II would provide adequate funds to produce appropriate still and moving images for NASA purposes. Existing images in the device were taken using volunteers and without the benefit of professional production facilities and equipment.

Total cumulative costs incurred as of the report date

COSTS FOR THIS PERIOD

- Johns Hopkins personnel costs

    o   Dr. Gary Zimmer: 10 hours   @ $50/hour   = $500.00

    o   Dr. Ron Elfenbien: 10 hours   @ $50/hour   = $500.00

- ibex Healthdata Systems, Inc. personnel costs

    o   John Epler: 2 hours   @$56.49/hour   = $112.98

    o   Eric Spencer: 4 hours   @$36.06/hour   = $144.24

    o   Brandon Brown: 5 hours   @$20/hour   = $100.00

TOTAL for this Period   = $1,357.22

TOTAL for Project   = $21,807.35

REPORT DOCUMENTATION PAGE

1. REPORT DATE (DD-MM-YYYY)	2. REPORT TYPE	3. DATES COVERED (From - To)
13-01-2004	Final Report	1/3/03 to 1/13/04

4. TITLE AND SUBTITLE
Intelligent Medical Systems for Aerospace Emergency Medical Services

5a. CONTRACT NUMBER
NAS2-03101

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
John Epler, ibex Healthdata Systems, Inc.
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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8. PERFORMING ORGANIZATION REPORT NUMBER
Final Report

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

10. SPONSORING/MONITOR'S ACRONYM(S)

11. SPONSORING/MONITORING REPORT NUMBER

12. DISTRIBUTION/AVAILABILITY STATEMENT

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of this project is to develop a portable, hands free device for emergency medical decision support to be used in remote or confined settings by non-physician providers. Phase I of the project will entail the development of a voice-activated device that will utilize an intelligent algorithm to provide guidance in establishing an airway in an emergency situation. The interactive, hands free software will process requests for assistance based on verbal prompts and algorithmic decision-making. The device will allow the CMO to attend to the patient while receiving verbal instruction. The software will also feature graphic representations where it is felt helpful in aiding in procedures. We will also develop a training program to orient users to the algorithmic approach, the use of the hardware and specific procedural considerations. We will validate the efficacy of this mode of technology application by testing in the Johns Hopkins Department of Emergency Medicine. Phase I of the project will focus on the validation of the proposed algorithm, testing and validation of the decision making tool and modifications of medical equipment. In Phase II, we will produce the first generation software for hands-free, interactive medical decision making for use in acute care environments.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19b. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			John Epler
				7	19b. TELEPHONE NUMBER (include area code) (847) 993-2200