AMIE

(Advanced Multimedia Integrated Environment)

Esprit Project 8610

AI 5.2 Field Trial Report
(draft)

St. James's Hospital

November 1996

1. Introduction:

This document describes the field trial of EU Esprit project AMIE (Advanced Multimedia Integrated Environment), Project number 8610, which was conducted in St. James's Hospital, Dublin between 4th June and 17th September 1996.

2. Background:

The mission of the project was to research, develop and demonstrate an advanced environment for co-operative and distributed multimedia applications which would be integrated into as enterprise wide information technology system. The health care environment was chosen as an excellent demonstration of the capabilities of such a system as it offered a demanding environment with an abundance of data modalities. The refined medical requirement, as outlined in AMIE deliverable AD2.1 - Requirements for the Hospital Demonstrator[1], was in the creation of a multimedia conferencing toolkit for Cardio-Thoracic case conferencing in the Department of Cardiology, St. James's Hospital.

3. Department of Cardiology:

The Department of Cardiology, St. James's Hospital, is described in detail in AMIE deliverable, AD2.2 - Field Trial Scenario[2]. In summary, cardiac patients may undergo a range of diagnostic examinations including Angiography, Echocardiography (Ultrasound), Nuclear Medicine, X-ray, Electrocardiography (ECG) and / or Blood Pressure (BP) monitoring.

Each cardiac examinations has a specific role as outlined in table 1 below:

Examination:	**Role:**
Angiography	Visualisation of Coronary Artery, Left ventricular and Aortic structure via X-ray screening (fluoroscopy) of contrast injection.
Echocardiography	Visualisation of valvular and wall motion using 2D and M-Mode ultrasound. Identification of blood flow patterns using false colour.
Nuclear Medicine	Identification of myocardial perfusion by gamma camera detection of an injected radionuclide (Tc99m.)
X-ray	Visualisation of cardiac chamber size and lung fields.
ECG	Detection of variation in electric potential during the cardiac cycle.
Blood Pressure	Measurement of systolic and diastolic blood pressure. This may be invasive when measured during angiography or non-invasive ambulatory when recorded over a 24 hour period.

Table 1

The patient history and results of all examinations are recorded in the patient notes.

Each examination is conducted on a dedicated system with specific requirements for acquisition and storage. The storage media and system requirements are summarised in table 2, section 6. Currently patient examinations are reported upon by individual specialists at or soon after the time of the examination, resulting in a 'segmented' approach taken to cardiac diagnosis.

Cardiac Angiography is the 'gold' standard in the detection of coronary artery disease with other imaging modalities acting as secondary investigation procedures in the detection of this condition. St. James's Hospital provide an Angiography service to inpatients and to patients referred from other hospitals.

4. Cardio-Thoracic Case Conference:

A case conference takes place in the Department of Cardiology on a weekly basis to discuss the treatment and management of non-normal or difficult cardiac angiography cases. Approximately one third of all the weekly angiography patient cases are discussed at this conference, with patients being highlighted for inclusion at the time of the procedure by the doctor conducting the examination. The list of patients to be discussed at the conference is compiled by the Cardiac Secretary prior to the meeting. These patients are grouped according to the Consultant under whose care the patient has been admitted.

The conference is attended by up to 20 staff including two Cardio-Thoracic surgeons, three Cardiology Consultants and six Cardiac Registrars who attend regularly. House Officers and Interns also attend on a less frequent basis. The main objective is the determination of whether the patient can be treated medically, Surgically (Coronary by-pass surgery) or treated interventionally using balloon angioplasty or 'stent' insertion. Balloon Angioplasty (PTCA - Percutaneous Transluminal Coronary Angioplasty) is a procedure whereby an uninflated balloon on a guide wire is passed into a narrowed artery in a patients heart. The balloon is then inflated with a saline solution, widening the stenosed lesion. The balloon is then deflated and removed and the narrowed artery remains open. 'Stent' insertion involves the insertion of a metal 'stent' into the lesion, which is expanded and remains in place, keeping the vessel patent.

Cardiac Angiography images are stored on 35mm cine film. Prior to the weekly conference, the on-call Registrar collates the patient notes and cine films of each patient highlighted for discussion. Typically 20-30 cases are discussed at the conference and angiography films are reviewed by all present on a large screen using a 35mm cine-film projector. The cases are discussed in the order dictated by the patient list. Each case is introduced by the on-call registrar who delivers the background to the case, reads the reports of previous examinations and loads the cine-film for viewing. Although the cine-film is loaded by the Registrar, it is controlled and manipulated by the attending surgeons. This will involve playing the sequence at different speeds and freezing the image frames.

The duration of the conference is approx. 90 minutes. Due to timing constraints and the incompatibility of cardiac examination display media, the cine angiograms are typically the only images to be reviewed, with patient notes at hand. On occasion the ECG traces in paper format are passed around the attendees and infrequently the Echocardiographic studies are reviewed on a video recorder.

The resulting decision for each patient is documented on a dedicated form by the Cardio-Thoracic surgeons. A copy of this form is inserted in to the patients notes and another copy is and passed to the Cardiac secretary for filing. The Cardiac Secretary records the clinical decision made for each patient.

A flow diagram of the Cardiac Case Conference proceedings is given in figure 1 below:

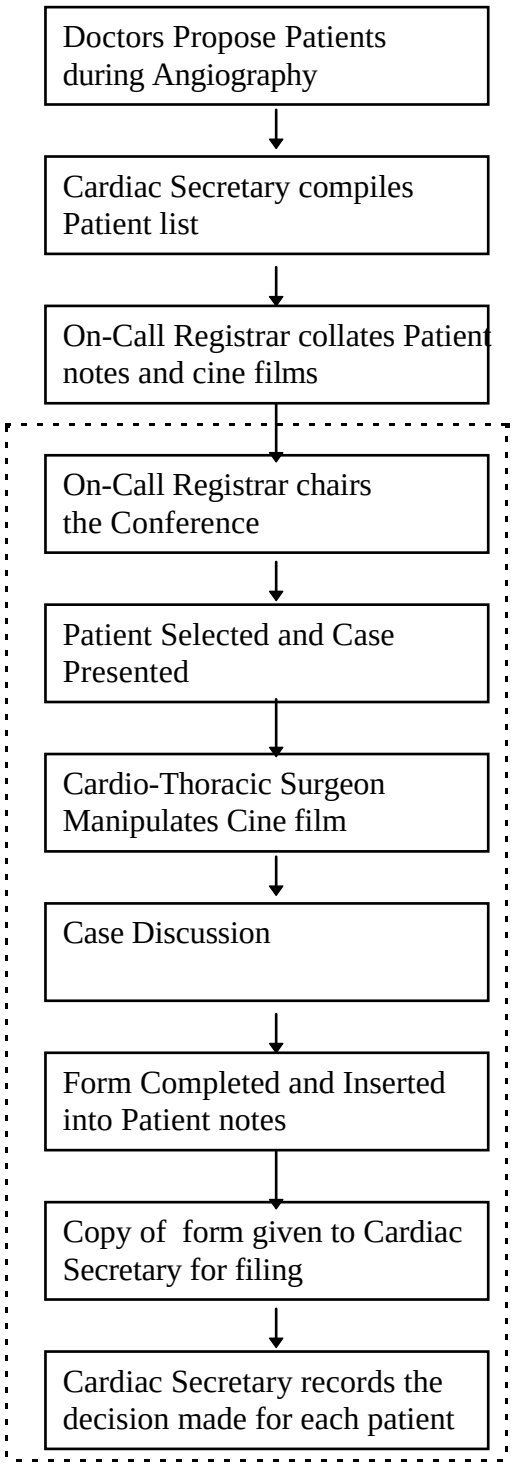


Figure 1: Flow Diagram of Cardiac Case Conferencing.

5. AMIE Application:

The objective of the AMIE application demonstrator was to provide facilities for the Cardio-Thoracic conference to enable all data types, including patient notes, to be reviewed and manipulated (using functionality available on current systems) in a uniform manner on a large screen display. The user interface is operated via hand held mobile pen computers incorporating hand writing recognition functionality and operating over a radio network. A remote station in the Coronary Care Unit (CCU) enables staff in that location to remotely participate in the conference using audio and video conferencing. The AMIE system results in a more 'holistic' approach to cardiac diagnosis, as every examination can be reviewed by the entire team.

The system requirements, as documented in deliverable AD2.1 'Requirements of the Hospital Demonstrator', were divided into four sections as follows:

1) *Baseline Requirements*:
   The requirements and functionality available with the existing system.
2) *Additional Requirements*:
   Those requirements which are not available with the existing system but considered necessary.
3) *Desirable requirements*:
   Those which are envisaged as probably giving added value to the applications.
4) *Research requirements*:
   Those whose necessity cannot be determined without further research.

The specific system requirements were documented as follows:

Baseline Requirements:

- All data relating to a patient should be present on the system.
- At least one person can interact with the screen display.
- The ability to display image and trace data using methodology currently available at the conference. In particular the replaying of image sequences at user adjustable speeds and the display in colour of doppler ultrasound images.
- The displayed data must be clearly identified as being associated with the selected patient.
- A simple, quick and easy to use user interface which does not require the user to have a good understanding of a windows-like environment.
- The ability to edit and amend patient notes, reports.

Additional Requirements:

- The ability to interface to the range of diagnostic modalities required by the Cardiac Department.
- The ability to manipulate the data using methods already present on the examination equipment. Including:
  a. The adjustment of brightness and contrast on all images.
  b. Magnification and edge enhancement facilities.
  c. The display in colour of certain image modalities.

- The facility to display the following data types simultaneously:
    a. Several ECG traces (pre- & post- stress)
    b. Two Angiography image sequences (Anterior-Posterior & Lateral)
    c. Two ultrasound image sequences (Past & Present)
    d. Two Nuclear Medicine image sets (Stress & Rest)
- The ability to obtain hard-copies of reports etc.

Desirable Requirements:

- Permit more then one person at the conference to interact with the system.
- Record reports or observations using voice input.
- Communicate with specialists at a remote location. This will involve the transmission of patient data to this location.
- Interface to the Hospital Patient Administration system for the retrieval of patient demographics or records.

Research Requirements:

- The ability to display simultaneously and combination of the current patient data types.
- The ability to display simultaneously any two similar data types from different patients.

These requirements serve as a guideline against which to assess the completed application.

6. Cardiac Data Types:

The data types required for the AMIE cardiac case conferencing system are indicated in table 2 below. Also indicated is the equipment on which the examination is performed, whether the data is acquired in an analogue or digital format and the data storage media.

Data Type	**Equipment**	**Analogue / Digital**	**Storage Media**
Angiography	Philips Digital Cardiac Imaging (DCI).	Analogue - permanent Digital - intermediate	35mm cine film
Echocardiography	Hewlett Packard Sonus 2500	Analogue	SVHS and VHS video
X-ray	General Philips and Shimadzu Equipment	Analogue	35” x 43” X-ray film
Nuclear Medicine	Link Medical Maps 10,000	Digital	Optical disk
ECG	Marquette MAC 12	Digital	Paper or 3.5” floppy
Invasive BP	Siemens Micor Mingograph	Digital	Paper - permanent Digital - Intermediate
Ambulatory BP	Spacelabs ABP	Digital	5.25” floppy
Patient Notes	Paper folder	Analog	Paper

Table 2

It is a requirement of the hospital that all patient data be stored for ten years. In the case of angiography, ECG and Blood pressure measurement examinations, the data may be stored on more than one medium as outlined below:

- The Philips DCI has the facility to simultaneously record the patient images on cine film and in digital format. The cine film is stored permanently however due to the limitations of the DCI system, the digital data is overwritten upon entry of the next patient case.

- ECG data is stored in on a permanent basis in paper format in the patient notes. The Marquette ECG system offers the facility to store this data digitally on OS/9 formatted 3.5” floppies. This is not done regularly due to the large number of patients being examined on a daily basis.

- Invasive blood pressure measurements which are recorded during the angiography procedure are temporarily stored on the system hard disk. This data is overwritten after a limited period and permanent data is recorded in paper format.

The required spatial, contrast and temporal properties of the image data types are listed in table 3 below. These requirements also serve as a guideline against which to assess the AMIE demonstrator.

Imaging Modality	**Matrix Resolution**	**Contrast Resolution (bits/pixel)**	**Image Acquisition Rate (/s)**	**Approx. No. of images per study**
X-ray Film (chest)	2048 x 2048	12	< 0.01	1-20
Angiography	>= 512 x 512	8	12.5 - 50	~ 1000
Nuclear Medicine	64^2 - 256^2	<=16	5-10	4-60
Echocardiography	512 x 512	8,8,8	25	~ 4000

Table 3

The diagnostic equipment operating systems and the interfaces made for the purpose of the AMIE field trial are indicated in table 4 below:

Data Type	**Equipment**	**Equipment Type / OS**	**Interface Method**
Angiography	Philips DCI	Dedicated Philips Quintessence system	Video Framegrabber
Echocardiography	HP	Dedicated HP OS	Video Framegrabber
X-ray	General	Dedicated Systems	X-ray film digitiser
Nuclear Medicine	Link Medical Maps 10,000	UNIX Workstation	1. FTP Ethernet transfer 2. DOS formatted floppy
ECG	Marquette MAC 12	Dedicated OS/9 system	Serial transfer from RS232 port using MS-Windows 'Terminal'.
Invasive BP	Siemens Micor Mingograph	PDP - 11	Serial transfer from RS232 port using Kermit
Ambulatory BP	Spacelabs ABP	DOS based system	DOS formatted floppy
Patient Notes	Paper Folder	Paper	Entered using MS-Paint

Table 4

- An acquisition system [166 MHz Pentium PC, 128 MB Ram, 2 GB hard disk] was provided by CAPTEC for procurement of angiography and echocardiography data during the course of the field trial. The acquisition station incorporated a video framegrabber and associated software. Image processing routines were also available for manipulation of the acquired data.

- A film digitiser, VSCAN with associated acquisition software was used for the digitisation of plain film X-rays.

- ECG, Blood pressure and Patient Notes were acquired using a 486 PC which was available in the hospital.

7. Pre Field Trail Evaluation:

Prior to the commencement of the field trial a number of studies were conducted to determine the optimum methods of data acquisition and the equipment settings required.

- *Angiography Acquisition:*

The Philips DCI offers the facility to download patient images onto a UNIX based cardiac workstation for post processing. The time taken to download an entire sequence of patient images is approx. 90 minutes, during which time the DCI cannot be used. This method of data transfer was used in the initial stages of the project development however it was deemed to be impractical and unacceptable for use during the field trial. The alternative solution used was to replay the image sequences on the DCI between patient procedures and framegrab the sequences using the video framegrabber outlined in section 6 above.

The DCI offers the facility to redisplay image sequences at varied rates. If a slow rate is chosen the system will display one frame several times before advancing the next frame. If a fast rate is chosen, the system will skip frames. Several studies were conducted, as outlined below, to determine the rate at which the angiography image sequences should be replayed for acquisition using the video framegrabber.

The DCI facilitates the display of an ECG signal on top of the image data. A marker on the ECG signal advances along the trace one step per image frame. Using this marker as a guide, an optimal replay rate was chosen whereby the AMIE acquisition framegrabber would acquire all image frames without skipping or duplicating any. This selected replay rate, 12.5 frames per second, was used for the duration of the field trial.

Cine film replay of angio. images permits display of one image sequence at time, either Anterior-Posterior (AP) or Lateral. These sequences are acquired simultaneously on the DCI, and one of the 'additional' requirements of the AMIE system (Section 5 above), was to facilitate dual display of AP and Lateral images. The acquisition system provided by CAPTEC permits the dual acquisition and thus dual display of angiography sequences. The acquisition system also provides the facility to adjust image matrix size. An optimal matrix size of 384 x 476 (768 x 476 for dual acquisition) was chosen as it permits acquisition of all relevant image data and facilitates longer sequence lengths than a matrix size of 512 x 512.

- *Plain film X-ray Digitising:*

The VSCAN digitiser and associated acquisition software, offered the facility of scanning X-ray films using a variety of matrix and contrast resolutions. The options available are as follows:

Matrix Resolution	Contrast Resolution (bits / pixel)
1K x 1K	8
1K x 1K	12
2K x 2K	8
2K x 2K	12
4K x 4K	8

Table 5

A number of international large scale studies have been performed to determine optimal film digitisation parameters. Some studies found that low resolution digital images were adequate[3-5.] Hayrapetian et al[6], showed that 2K x 2K, 8 bits was comparable in diagnostic performance to analogue film for chest images, however Dawood et al[7], have stated that pixel sizes larger than 210-μm are unsuitable for primary diagnosis. It is suggested in the literature[9] that opting for large matrix sizes and number of grey levels may result in better image quality. As the maximum resolution afforded by the highest resolution video projector available (section 8) was 2K x 2K, and as it is desirable to view the entire X-ray image on one page, all X-ray films were digitised at the highest contrast resolution available with this spatial resolution, 2K x 2K, 12 bits.

The quoted maximum resolution of the VSCAN digitiser is 4 lp/mm. A high resolution mammography film incorporating a Huttner resolution test object (see section 11) was digitised at 4k x 4k x 8 bits for verification of this claim. The system was found to be capable of attaining the quoted specification.

- *Patient Notes Acquisition:*

Prior to the commencement of the field trial, patient notes were scanned into the system using a commercially available document scanner, Apple Macintosh OFOTO. This was demonstrated to the users who found that this presented too much information which could not be read during the limited time available for each patient case. As an alternative, a one page summary describing the patient case was documented in a standard format using Microsoft Paint.

- *Monitor Settings:*

Various monitor resolutions, bits per pixel and refresh rates were evaluated prior to the commencement field trial. Those available on the delivered system (Section 8) are documented in the table 6 below:

Monitor Resolution	Contrast Resolution (bits / pixel)	Refresh Rate
640 x 480	16 Colour	No Indication
1280 x 1024	256 Colour	60 Hz
1280 x 1024	High Colour (16 bit)	60 Hz
1600 x 1200	High Colour (16 bit)	60 Hz
1280 x 1024	True Colour (24 bit)	43 Hz
1280 x 1024	True Colour (32 bit)	60 Hz

Table 6

Each monitor setting was selected and a digitised test film displayed. The test film was a radiograph of the Leeds N3 test object (section 11.1.2.). A monitor setting of 1280 x 1024, High Colour (16 bit), 60 Hz, was selected at the optimum setting as it provided the optimum image quality at an appropriate resolution to enable visualisation of image data and text by all present in the meeting room.

- *Echocardiography Acquisition:*

Echocardiography image sequences utilise only a section of the available image field, with the remainder presenting as a black surround in which no medical information is contained. An optimal image matrix size of 610 x 470 was chosen (as opposed to the initial requirement of 512 x 512) which enabled capture of all the medical information and removal of the surround. As with the angiography image sequences, the acquisition of smaller matrix sizes permits the accumulation of longer image sequence lengths.

- *Electromagnetic Interference:*

There is a large literature on the susceptibility of medical electronic equipment to electromagnetic radiation. The conference room is located in the Diagnostic Imaging Department, in which a substantial amount of electronic equipment is located. There was a concern that this equipment could be adversely affected by the Sixtel DECT radio network. The literature was critically reviewed and in particular reference was made to a large scale study conducted by the British National Health Service using the DECT radio networking protocol. This study recommended that the sensitive area surrounding DECT radio transmitters and receivers was less than 0.2m and recommended that sensitive electro-medical equipment should not be used within 1m of a radio transmitting or receiving device. The hospital wall and floor plans were obtained which revealed that no sensitive equipment would be operational within this range.

8. Equipment Installation:

The AMIE system is based on pentium 166 MHz PC's with one PC located in the conference room and the other in the CCU. Each PC is configured with 128 MB Ram, a 2 GB hard disk and a 4GB external SCSI disk. The application software runs on Windows 95. The large screen display in the conference room is operated via a ceiling mounted high resolution (2k x 2k) Electrohome video projector.

The initial system configuration delivered to the hospital consisted of three dual pentium PCs running Windows NT 3.51. This configuration was demonstrated to the system users on May 1st 1996, where it was found to be incapable of replaying image sequences at the required speed. This resulted in the AMIE application dropping image frames in an attempt to sustain the required replay rate. A study was conducted whereby a typical angiography sequence of 100 frames was replayed at 12.5 frames per second. Of the 100 image frames, only 10% were displayed using this system configuration with the remaining 90% being dropped. The dual pentium machines were replaced by the single pentium machines outlined above for the remainder of the trial. The new machines were evaluated and found to be capable of reproducing the necessary replay rates.

The system is controlled via a hand held pen computer (Toshiba T200) operating over the Sixtel DECT radio network. A second mobile pen computer (Fujitsu Stylistic 1000) is available for note taking during the meeting using Philips hand writing recogniser. This is used by the conference secretary to record the resulting decision on each patient. The Sixtel radio base station is located in the conference room enabling radio networking to the Toshiba T200 and the Fujitsu Stylistic 1000 is Ethernet linked.

The remote station in the Coronary Care Unit (CCU), facilitating full audio and video conferencing, replicates the patient data on a high resolution 21" monitor and enables staff in that location to remotely participate in the conference. ORL audio and video bricks and the required microphones and loudspeakers are located in both the CCU and the conference room.

Patient data is stored on ORL disk bricks in a machine room in a separate location. Typically 600 MB storage is required per patient for the storage of uncompressed data. A fibre optic network infrastructure was installed in the hospital to enable communication between the three required locations: the conference room, the CCU and the machine room. This infrastructure, which was built around existing fibre backbone installations in the X-ray Reception and the Intensive care unit (ICU) is outlined in figure 2 below. Also indicated in figure 2 are the locations of individual system components.

9. Field Trial Data Acquisition:

The acquisition of patient data used during the field trial was a very time consuming process. Patient cases for inclusion in the field trial were required to adhere to the following two criteria:

- They must possess a large number of data types
- They must have been identified for discussion at the conference by the doctor conducting the angiography examination.

Typically those cases adhering to the above criteria were right and left heart study cases (examinations involving the visualisation of right and left chambers of the heart).

At the start of the day, the list of patients undergoing angiography procedures was examined and those patients having previous multimodal examinations were identified. As St. James's Hospital provides an angiography service for other Irish hospitals, some patients were not suitable for the purposes of demonstrating the system as their previous examination data was located in other hospitals and unavailable for use with the project.

Angiography cases for inclusion in the case conference were highlighted, as usual, during the procedure by the doctor conducting the examination. This data would remain in digital format on the DCI system only until the next patient case was entered (approx. 10 minutes later), at which time the data was overwritten. Patient cases fulfilling the two criteria were identified and the angiography sequences immediately framegrabbed.

Patient angiography images are performed in a number of runs. Each run, consisting of AP and Lateral images, views an individual artery, the ventricle or the aorta at a specific orientation. Typically 5 - 8 runs are performed per patient, each containing a variable number of frames [usually 100 - 150]. Individual runs were framegrabbed into separate files which then required post processing to ensure that the correct number of frames had been acquired.

Immediately after the angiography procedure, an ECG examination was performed on the patient to ensure capture of ECG digital data. This was necessary as previous ECG traces, which may have been performed several months in advance of the angiography examination, were not stored in digital format. The ECG examination is non-invasive and presents no risk to the patient.

Prior to the conference patient X-rays were retrieved and digitised; Nuclear Medicine images were transferred from the dedicated imaging workstation. ECG traces were uncompressed using an algorithm which was made available from the manufacturer and Blood pressure traces were downloaded from the Siemens Micor Mingograph. The Micor Mingograph is based on old technology (PDP-11) and the time required to transfer trace data was approx. 90 mins. per patient.

Echocardiography sequences are typically very long, up to 5 minutes of image data per patient may be recorded onto video tape. Due to time limitations at the conference, it was not acceptable to present the entire run. It was therefore necessary to identify short sub-sequences with the aid of cardiology registrars for framegrabbing and inclusion in the conference. A one page summary of the patient history was compiled by the Cardiac Registrars and entered in a dedicated format into Microsoft Paint for display by the application during the conference. In general, approx. 6 hours was required per patient to collate all the required data onto the AMIE system.

10. KAVAS Evaluation Methodology:

"The evaluation of a system serves two main purposes. Firstly to guide the design of the system and secondly to quantify various performance aspects to verify the acceptability of the system." (O' Moore, 1995).

The purpose of an evaluation methodology is not to devise methods to debug a system but rather to assess its quality. The KAVAS evaluation methodology was adopted by the AMIE project to assess its quality in such a manner. (AD 2.2 Appendix).

The KAVAS Evaluation Methodology is based upon the division of the project lifecycle into four highly interacting phases as follows:

Phase I - Preliminary Exploration
Phase II - Validity
Phase III - Functionality
Phase IV - Impact

Due to the short evaluation period afforded in the AMIE project, the main emphasis in the evaluation of the system was in Phase II and Phase III, the validity and functionality phases.

- *Phase II - The Validity Phase:*

Assessment in the validity phase corresponds to the technical verification and validation of the system during and / or after its implementation. The focus is on the technical quality characteristics of the system.

- *Phase III- The functionality Phase:*

Assessment in the functionality phase focuses on the functionality and usefulness of the system in clinical practice. Included in this phase are the interaction of the system with the work process and the human-computer interaction.

The KAVAS Quality Assurance Framework dictates that initially a set of quality concepts must be identified. A strategy is then established to ensure the fulfilment of the quality needs in a goal oriented and structured way. For each identified quality concept there is a methodology for establishing and interpreting its value by means of methods and metrics.

As indicated in AD 2.2 Appendix, the proposed methods and metrics for the evaluation of AMIE were as follows:

Phase II: The Validity Phase:

Purpose:
Analysis of the following:

- Technical and Scientific accuracy of digitised data (Image quality)
- Technical validity of system components (Radio link, network, storage, display size, pen input)
- Correctness and completeness of the system as compared to the requirements specification and design strategies
- System performance
- Reliability of data
- Accuracy of system calibration
- Mechanical electrical and ergonomic aspects.

Responsible Personnel:
The Department of Medical Physics and Bio-Engineering, St. James's Hospital.

Frame of Reference, methodology and metrics:
The frames of reference are:

- The stated functionality from the requirements and design documentation.
- Standards on image quality and information technology in general.

The evaluation methodology will include the use of commercially available phantoms (dedicated test objects for the assessment of quality in imaging systems) to assess the quality of the digitised images.

Phase III - The functionality Phase:

Purpose:
To address the following issues:

- Usefulness of the system.
- Does the system meet the user requirements ?
- Concurrency of the system with existing work practices.
- Appropriateness of the system hardware in the clinical environment.
- Presentation of data and user interface.
- System functionality. (usefulness and usage)
- Clinical accuracy of digitised data.
- Completeness of data.
- System performance and efficiency.

Responsible Personnel:
The system users with the aid of the Department of Medial Physics and Bio-Engineering.

Frames of Reference, methodology and metrics:
The frames of reference are:

- The current work processes and requirements documentation.

The evaluation methodology includes the use of questionnaires. Clinical accuracy is assessed using blind testing of patient data and standard reporting formats. (American Heart Association.)

11. Field Trial Evaluation:

A two phased approach was taken to the AMIE field trial. In the first phase, a basic system consisting of the meeting room display station, the video projector and the control pad was evaluated. This permitted the users to gain familiarity with the base system before the addition of more sophisticated components. In the second phase, the remote video conferencing link to the CCU, the note takers pen pad and the handwriting facility were added.

In AMIE deliverable AD 2. Field Trial Scenario, it was documented that the trial must comply with the following requirements:

- It must not interfere with the existing system.
- It must not interfere with patient management.
- Data transfer must not interfere with the existing hospital network or monitoring devices.
- The system must not interfere with the existing running of the Cardiac Department.

Throughout the field trial it was ensured that these pre-conditions were adhered to.

It was also documented in AD 2.2 Field Trial Scenario, that during the course of the trial the AMIE system would be used at the weekly Cardio-Thoracic conferences. It was the initial arrangement that all patients would be discussed using the traditional methodology and at the end of the conference, 2 - 3 cases which would have been discussed several weeks previously, would be re-reported using the AMIE system. A comparison could then be made between the results of the two discussions.

This was the methodology used for the first conference, however interest in the system was very high and the Doctors requested to view current patient cases on the AMIE system. Throughout the duration of the field trial, 30 patients were reviewed on the AMIE system at 17 conferences. These cases were reviewed at a rate of approx. two per week. As outlined in section 4, patients are discussed in the order of the list compiled by the Cardiac secretary. As a result, AMIE cases were not left to the end of the conference where interest may have been low, but were discussed according to their position on the list.

As the users gained familiarity and confidence in the system they were satisfied to report on patient cases using the AMIE system only. Of the 28 current patient cases reviewed in the field trial, (the two cases used in the first session had previously been reported), reference was made to the original cine film in only 2 cases. 93% of patient cases were reported on using the AMIE system only. In the two cases where reference was made to the cine film, patient diagnosis was not altered after cine review.

As outlined in section 4, the on-call Cardiac Registrar chairs the conference, loads the cine film and presents the patient history. As it was the policy of the field trial to adhere to the current conference proceedings, the on-call Cardiac Registrar opened the AMIE patient folder when control passed to the AMIE system during the field trial. The Registrar also operated the control pad, playing the image sequences and utilising the system functionality. The Cardiac Registrars work on a six week rota and continual user training was therefore required throughout the course of the trial. System users were monitored constantly throughout the trial to observe for difficulties with the system and for frequency of use of system functionality.

11.1 KAVAS Phase II - The Validity Phase:

The results of the Phase II Validity study are analysed under the headings (I- VII) below, as outlined in section 10 above.

(I) Technical and Scientific Accuracy of digitised data:

Each modality is taken individually below and the phase II evaluation described. The methodology used for the evaluation in each case are current methods of assessing diagnostic systems in the clinical environment. The frames of reference used are the published and recommended tolerance guidelines.

- *Angiography:*

The DCI angiography suite is a bi-plane fluoroscopy system. The term fluoroscopy or screening refers to live X-ray imaging. Bi-plane refers to the ability of the system to simultaneously acquire images in two directions, Anterior-Posterior (AP) and Lateral, using individual imaging chains.

Routine commissioning, performance testing and quality control of such systems is well documented. There are two important sources of image degradation: unsharpness or blurring and noise. Unsharpness can be described by the Line Spread Function (LSF) or by its fourier transform, the Modulation Transfer Function (MTF). These functions can only be easily measured in the laboratory and are not useful in routine quality control testing. The spatial resolution limit, as measured by a radiological line phantom (Huttner Phantom), provides a useful practical measure of image unsharpness in terms of line pairs per mm (lp/mm) visible. In a similar manner, a test object containing discs of decreasing image contrast, can give a practical measurement of image noise.

Overall image quality of fluoroscopy systems is assessed using a set of commercially available phantoms or test objects, the Leeds test objects. The Leeds test objects consist of 9 phantoms which assess various aspects of the X-ray system. The test objects and their measurement parameters are summarised in table 7 below.

Test Object	**Measurement Parameters**
Edge E1	System Sensitivity
Greyscale GS2	Grey Scale Linearity and Circular Geometry
Matrix M1	Rectangular Geometry and Image Field Diameters
Huttner type 18	Limiting Resolution
Mesh, MS1, MS3, MS4	Focal Homogeneity
Noise N3	Low-Contrast Sensitivity
'Leeds' TO10	Threshold Contrast Detail Detectability

Table 7

Frame of Reference:
Leeds test objects are imaged and graded subjectively. The limits of acceptability for fluoroscopy systems assessed using these test objects are well documented.

Methodology:
The Leeds test objects were imaged on the AP and Lateral chains of the Philips DCI. The images were simultaneously acquired digitally and on 35mm cine film. The resulting images were viewed and graded on the DCI system monitors (on which a clinical diagnosis is frequently made), on the projected cine film, on the framegrabbed image sequences displayed on the AMIE monitor and on the AMIE framegrabbed images projected using the Electrohome high resolution video projector. The results of the most important tests are summarised in tables 8a - 8b below. The AMIE displays were graded using black on white video with and without image processing (IP). Image processing functionality included Edge enhancement / sharpening, contrast and brightness enhancement and zooming.

Anterior-Posterior Chain	**Huttner Resolution**	**N3 Noise**	**GS2 - Grey scale Linearity**
DCI Monitors	7 groups [1.0 lp/mm]	11-12 discs [contrast 0.03]	10 steps
Cine Film	11groups [1.6 lp/mm]	10-11discs[contrast 0.036]	9 steps
AMIE Monitors - No IP	6 groups [0.9 lp / mm]	12 discs [contrast 0.027]	9.5 steps
AMIE Monitors - with IP	7 groups [1.0 lp/mm]	12 discs [contrast 0.027]	10 steps
AMIE Projector - No IP	6 groups [0.9 lp/mm]	11 discs [contrast 0.033]	9 steps
AMIE Projector - with IP	7 groups [1.0 lp/mm]	12 discs [contrast 0.027]	10 steps

Table 8a - Angiography AP Image Quality

Lateral Chain	**Huttner Resolution**	**N3 Noise**	**GS2 - Grey scale Linearity**
DCI Monitors	9 groups[1.25 lp/mm]	10-11discs[contrast 0.036]	10 steps
Cine Film	11-12 [1.7 lp/mm]	11-12 discs[contrast 0.03]	9.5 - 10 steps
AMIE Monitors - No IP	9 groups [1.25lp/mm]	11 discs [contrast 0.033]	10 steps
AMIE Monitors - with IP	9.5groups[1.3 lp/mm]	12 discs [contrast 0.027]	10 steps
AMIE Projector - No IP	8-9 [1.31 lp/mm]	11 discs [contrast 0.033]	9 steps
AMIE Projector - with IP	9.5groups[1.3 lp/mm]	11 discs [contrast 0.033]	10 steps

Table 8b - Angiography Lateral Image Quality

The tests were then repeated using inverse video (white on black) and image processing functionality The results are summarised in tables 9a - 9b below:

AP Chain	**Huttner Resolution (groups)**	**N3 Noise (discs)**	**GS2 - Grey scale Linearity**
AMIE monitor,B/W, no IP	6 [0.9 lp/mm]	12 [contrast 0.027]	9.5 steps
AMIE monitor, B/W, IP	7 [1.0 lp/mm]	12 [contrast 0.027]	10 steps
AMIE projector,B/W,no IP	6 [0.9 lp/mm]	11 [contrast 0.033]	9 steps
AMIE projector,B/W, IP	7 [1.0 lp/mm]	12 [contrast 0.027]	10 steps
AMIE monitor,W/B, no IP	5-6 [0.85 lp/mm]	11 [contrast 0.033]	10 steps
AMIE monitor, W/B, IP	7 [1.0 lp/mm]	12 [contrast 0.027]	10 steps
AMIE projector,W/B,no IP	6 [0.9 lp/mm]	11-12 [contrast 0.03]	10 steps
AMIE projector,W/B, IP	6.5 - 7 [0.95 lp/mm]	12 [contrast 0.027]	10 steps

Table 9a - Angiography AP Image Quality using AMIE functionality

Lateral Chain	**Huttner Resolution (groups)**	**N3 Noise (discs)**	**GS2 - Grey scale Linearity**
AMIE monitor,B/W, no IP	9 [1.25 lp/mm]	11 [contrast 0.033]	10 steps
AMIE monitor, B/W, IP	9.5 [1.3 lp/mm]	12 [contrast 0.027]	10 steps
AMIE projector,B/W,no IP	8-9 [1.2 lp/mm]	11 [contrast 0.033]	9 steps
AMIE projector,B/W, IP	9.5 [1.3 lp/mm]	11 [contrast 0.033]	10 steps
AMIE monitor,W/B, no IP	8 [1.12 lp/mm]	10 [contrast 0.039]	10 steps
AMIE monitor, W/B, IP	9 [1.25 lp/mm]	12 [contrast 0.033]	10 steps
AMIE projector,W/B,no IP	8 [1.12 lp/mm]	10 [contrast 0.039]	10 steps
AMIE projector,W/B, IP	9.5 [1.3 lp/mm]	10 [contrast 0.039]	10 steps

Table 9b - Angiography Lateral Image Quality using AMIE functionality

The recommended minimum acceptable values, for a system such as the DCI, in good adjustment are as follows:

GS2 Grey Scale Linearity	10 steps
N3 Noise	>= 9.5 discs [Contrast <= 0.04]
Huttner - Limiting Resolution	>= 11 groups [>= 1.6 lp/mm]

Table 10

Image sequence frame rate measurements were made at 12.5 frames per second, using the ECG marker as an individual image frame identifier as outlined in section 7. Test results show that the AMIE acquisition and display systems are capable of reproducing this frame rate.

Discussion:
As can be determined from tables 8 - 9 above, in terms of contrast resolution the AMIE monitors and projected display, without any image processing, are capable of producing comparable results to traditional cine film and the DCI system monitors. There is a small loss in contrast resolution evident on the AMIE projected display as compared to the AMIE system monitor however results of all contrast resolution tests are within the recommended tolerance levels for angiography systems.

In terms of grey scale linearity, the DCI monitors were found to be superior to the traditional cine film. The AMIE monitors were capable of producing results comparable with the cine film readings however some loss was again evident on the projected display. Using image processing functionality the AMIE monitors and projected display were capable of producing results comparable to the DCI monitors and within the required tolerance limits for angiography systems.

In terms of limiting resolution, there was a notable difference between the cine film readings and the AMIE readings. Cine film is capable of producing very high spatial resolution and the results were 1.6 lp/mm for the AP chain and 1.7 lp/mm for the lateral chain. The recommended limiting resolution for an angiography system in good adjustment is >=1.6 lp/mm. At the time the tests were performed, the limiting resolution of the DCI monitors was 1.0 lp/mm and 1.25 lp/mm for the AP and Lateral chains respectively. Work is currently being conducted by the equipment suppliers to improve this resolution. Using image processing functionality, the AMIE monitor and Projected display were capable of reproducing the same spatial resolution as the DCI monitors from which patient diagnosis is frequently made. As with previous tests, the AMIE monitor was found to be superior to the projected display.

From table 9 it can be seen that in all cases, use of image processing functionality improves image quality measurements. In terms of spatial and contrast resolution, the subjective measurements made using black on white video gave superior results to inverse video. In terms of grey scale linearity, inverse video measurements produced superior results.

In general, through the use of image processing functionality, the AMIE projected display was found to be capable of reproducing the comparable image quality to the DCI system monitors which are used for primary patient diagnosis. The reproduced image frame replay rate was also found to be satisfactory.

- *X-ray:*

As with fluoroscopy systems, the image quality of general X-ray systems may be assessed using the Leeds test objects as outlined above.

Frame of Reference:
There are currently no published tolerance limits in terms of limiting resolution however many studies have been conducted on the evaluation of digital systems. The current X-ray systems may be used as a guideline against which to assess the AMIE system.

Methodology:
Plain film radiographs were made of the Leeds Test objects outlined in table 7 and the films digitised using the optimal VSCAN digitiser settings (section 7). Table 11 below documents the results obtained by evaluation of the plain film radiographs, the default images displayed on the AMIE monitor and projected display, images displayed using the 'fit to page' (ftp) function and images displayed after image processing (IP) manipulation using Magnification, contrast and brightness enhancement, video inversion and edge enhancement.

Anterior-Posterior Chain	**Huttner Resolution (groups)**	**N3 Noise (discs)**	**GS2 - Grey scale Linearity**
Plain film X-ray	>21 [>5.0 lp/mm]	19 [contrast 0.007]	7 steps
AMIE monitor, default, No IP	13-14 [2.14 lp/mm]	18 [contrast 0.009]	7 steps
AMIE monitor, ftp, No IP	8 [1.12 lp / mm]	18 [contrast 0.009]	7 steps
AMIE monitor - with IP	17 [3.15 lp/mm]	19 [contrast 0.007]	7 steps
AMIE projector,default,NoIP	13 [2.0 lp/mm]	18 [contrast 0.009]	7 steps
AMIE projector, ftp, No IP	7-8 [1.1 lp/mm]	18 [contrast 0.009]	7 steps
AMIE projector - with IP	17 [3.15 lp/mm]	19 [contrast 0.007]	7 steps

Table 11

Discussion:
In terms of grey scale linearity and contrast resolution, the AMIE system, using image processing functionality, is capable of producing the same results as the radiographic film. Black on white video was found to give the same results as inverted video imagery.

In terms of spatial resolution, the high resolution afforded by the silver halide crystals of the radiographic film is superior to the digital imagery. The spatial resolution of the AMIE monitors was also found to be superior to that measured on the projected AMIE images. Using the AMIE system, chest X-rays are viewed using the 'fit to page' option to enable visualisation of the entire thorax. The spatial resolution using this option is less than one third of that afforded by the plain film radiograph. In order to evaluate the clinical consequences of this spatial resolution degradation, a large scale study is being conducted in the hospital. Fifty X-ray films have been digitised and reported from the AMIE system by five independent radiology specialists. The plain film X-rays will be re-reported after several months and a comparison made using ROC (Receiver Operator Characteristics) analysis. Several months are required between reportings to obtain an accurate result as radiologists can frequently remember cases.

- *Nuclear Medicine:*

The limiting resolution of Nuclear Medicine gamma camera systems is approximately 3mm[8] which is significantly lower than that of conventional X-ray and Angiography systems. Image quality may be determined by visualisation of test patterns.

Frame of Reference:
The conventional system parameters and published guidelines were used as a frame of reference against which to assess the AMIE application.

Methodology:
A test pattern from the Nuclear Medicine system was transferred to the AMIE system for image quality evaluation purposes. The test pattern consisted of horizontal and vertical bar patterns, contrast resolution scales, an image geometry matrix and a very fine resolution mesh.

The test pattern was evaluated on the AMIE monitor and projected display. All bar patterns and contrast resolution scales were clearly visible. The image geometry demonstrated no distortion. Although the fine resolution mesh was visible on the Link Medical Maps 1000 Nuclear Medicine system monitor, it was not possible to visualise it on either the AMIE monitor or the projected display. This is because the Nuclear Medicine system monitor has been configured with a higher resolution then the AMIE system. The resolution of this fine mesh however is far higher than the limiting resolution of the gamma camera imaging systems and the AMIE system can easily obtain the required spatial resolutions.

Discussion:
The AMIE system is of sufficient quality to be able to produce the spatial and contrast resolutions required for Nuclear Medicine image display.

- *Echocardiography:*

Echocardiography image sequences may be reported from the dedicated Hewlett Packard system, S-VHS video tape or VHS video tape. As with Nuclear Medicine imagery, the spatial resolution required is significantly lower than that required for conventional X-ray and Angiography systems.

Frame of Reference:
The frame of reference used was the conventional ultrasound image quality.

Methodology:
Dedicated phantom test objects are commercially available for the evaluation of ultrasound systems. A Nuclear Associates Multi-Purpose Tissue-Equivalent phantom, No.:84-317, was used for the technical evaluation of ultrasound imagery. The Phantom permits determination of spatial resolution and image contrast. The phantom was imaged and the video output signal captured directly by the CAPTEC acquisition system. The phantom images were then transferred to the AMIE system.

Table 12 below documents the spatial and contrast resolution details visible on the HP ultrasound system, the CAPTEC acquisition system, the AMIE monitor with and without image processing and the AMIE projected display, with and without image processing. Image processing functionality used included Magnification, edge enhancement, contrast and brightness enhancement.

	HP Sonus 2500	Acquisition System	AMIE monitor no IP	AMIE monitor with IP	AMIE proj. no IP	AMIE proj. with IP
Lateral Resolution 28cm	5	5	5	5	5	5
Vertical Res. 28-43 cm	6	6	6	6	6	6
Lateral Resolution 75cm	5	5	5	5	5	5
Vertical Res. 75-90 cm	5	5	5	5	5	5
Lateral Res. 132 cm	5	5	5	5	5	5
Vertical Res.117-132cm	5	5	5	5	5	5
Lateral Res. 179 cm	4	4	4	4	4	4
Vertical Res. 164-179cm	5	5	5	5	5	5
Low Contrast-near field	4	4	4	4	4	4
Low Contrast-far field	4	4	3.5	4	3	4
High Contrast-near field	3	3	3	3	2.5	3
High Contrast-far field	3	3	2.5-3	3	1	3

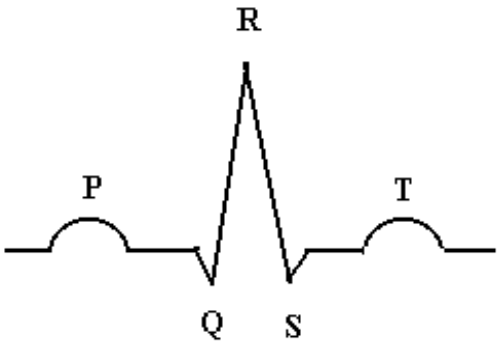
Table 12

Discussion:
The above results indicate that in terms of spatial resolution there is no significant image degradation incurred in acquiring echocardiographic images. In terms of contrast resolution, the AMIE displays are darker than the HP system displays resulting in a loss of image contrast. By adjusting the AMIE brightness and contrast controls, results obtained were consistent with the those obtained on the conventional HP system which is used on a routine basis for patient diagnosis.

Ultrasound images and captured and displayed at a rate of 25 frames per second (fps). Due to technical limitations, these sequences were captured and displayed at 12.5 fps for the purpose of the field trial. The users were questioned on the image display rates and

- *ECG:*

The spacing of the measurement grid on ECG traces is critical in the reporting of the electrocardiogram. The ECG trace is labelled by P,Q,R,S,T, identifiers as outlined below:



Typical measurements made on a routine basis are as follows: Signal width (Q-S interval), Signal height (Q-R height), Time between signals (R-R interval), calibration pulse height and calibration pulse width.

Frame of Reference:
The original paper ECG traces acted as the frame of reference in the AMIE trace evaluation.

Methodology:
123 measurements were made on 25 ECG paper traces. The ECGs were transferred to the AMIE system and the measurements repeated. The readings in agreement and disagreement are summarised in table 13 below:

Agreement	Disagreement
114/123 [92.7%]	9/123 [7.3%]
Total : 123	

Table 13

Discussion:
The results above indicate that the system reproduces the ECG traces with approx. 93% accuracy.

- *Blood Pressure:*

As with the ECG tracings, the spacing of the measurement grid on the Blood Pressure traces is critical.

Frame of Reference:
The frame of reference against which to assess the AMIE application is the conventional paper trace system.

Methodology:
20 Blood Pressure traces were identified and transferred to the AMIE system. Signal measurements were made on the paper traces and on the AMIE projected traces. The measurements in agreement and disagreement are listed in table 14 below:

Agreement	Disagreement
20	0
Total : 20	

Table 14

Discussion:
The sample number of traces used in this study was very small however it would appear that the correlation between the traditional system and the AMIE system is very high.

(II) Technical validity of system components:

- *Hand writing recogniser:*

The Philips handwriting recogniser was incorporated into the note takers pen pad for note taking by the cardiac secretary during the cardiac conference.

Frame of Reference:
The frame of reference against which to evaluate the hand writing recogniser was the user aspirations which was 100% work accuracy.

Methodology:
The hand writing recogniser was evaluated by two groups of personnel. The first group, consisting of 5 people, were trained as to how they should write in order for the system to recognise their handwriting. The second group of people were untrained. Both groups were required to enter 100 words into the system. The words were those which would be used frequently at the conferences, all of which had been entered into the system dictionary. The list of words is given in the appendix.

The results obtained in terms of percentage of words accurately identified, are listed in table 15 below. The third column contains the percentage of words correctly identified when the trained users were permitted a second attempt at entering the word.

Trained Users	**Untrained Users**	**Trained Users - 2 attempts**
69%	36%	90%
88%	36%	95%
90%	53%	96%
84%	48%	94%
78%	34%	92%
Mean = 82%	Mean = 41%	Mean = 93%

Table 15

Discussion:
The above results indicate that the system had a high word recognition rate when the users were instructed as to how they should write. When users were permitted a second attempt at entering the words, the success rate increased. The recognition success rate was relatively low when the users were untrained. The users found the handwriting trainer on the system to be unhelpful in improving the success rate and found that the success rate was more likely to improve by modification of their handwriting.

(III) Correctness and completeness of system as compared to the Requirements Specification:

Frame of reference:
The frame of references against which to assess the completeness and correctness of the system are the system requirements as documented in AMIE deliverable AD 2.1 and summarised in section 5 above.

Methodology:
The system baseline, additional and desirable requirements are documented in table 16 below, alongside an indicator as to whether the requirements have been achieved. The research requirements are not listed as these are seen to be additional to the AMIE system development.

System Requirements:	**Achieved ?**
Baseline requirements:	
All data relating to a patient should be present on the system.	Y
At least one person can interact with the screen display.	Y
The ability to display image and trace data using methodology currently available at the conference. In particular the replaying of image sequences at user adjustable speeds and the display in colour of doppler ultrasound images.	Y
The displayed data must be clearly identified as being associated with the selected patient.	Y
A simple, quick and easy to use user interface which does not require the user to have a good understanding of a windows-like environment.	Y
The ability to edit and amend patient notes, reports.	Y
Additional Requirements:	
The ability to interface to the range of diagnostic modalities required by the Cardiac Department.	Y
The ability to manipulate the data using methods already present on examination equipment including brightness and contrast control, magnification, edge enhancement and colour display.	Y
The facility to display data types simultaneously e.g. ECG, Angiography, Ultrasound and Nuclear Medicine.	Some - Angiography
The ability to obtain hard-copies of reports etc.	N
Desirable Requirements:	
Permit more then one person at the conference to interact with the system.	N
Record reports or observations using voice input.	N
Communicate with specialists at a remote location. This will involve the transmission of patient data to this location.	Y
Interface to the Hospital Patient Administration system for the retrieval of patient demographics or records.	N

Table 16

Discussion:
As can be determined from the above table, 100% of the baseline requirements have been achieved. The majority of the additional and 25% of the desirable requirements have also been met. The additional requirement of producing hard-copies of reports may be readily incorporated into the system by the purchase of a suitable printing device.

Using the baseline requirements as a guideline against which to assess the correctness and completeness of the completed application, the system can be considered as having achieved all its main objectives.

(IV) System Performance:

The radio network was found to operate successfully throughout the trial. Several problems were encountered with the pentium PCs and the ATM network which were attributed to an unstable mains supply in the hospital. These problems adversely affected the audio and video conferencing on several occasions.
In terms of system speed, the main disadvantage outlined by the system users was the time taken to load individual image files which was in the order of several seconds (section 11.2 A)

(V) Reliability of Data:

Throughout the course of the field trial the correct data was always found to be associated with the correct patient. There was no incidence where the patient data was found to be unreliable.

(VI) Accuracy of System Calibration:

The accuracy of the system calibration was assessed in terms of the ECG and Blood Pressure trace measurements. As can be seen from section (I) above, the accuracy of the calibration was found to be very high.

(VII) Mechanical, Electrical and Ergonomic Aspects:

These aspects were assessed via the user survey which is discussed in section 11.2 (A) below.

11.2 KAVAS Phase III - Functionality Phase:

The primary methodology used for evaluation in the functionality phase was a user survey. This survey is analysed and the results are presented in section (A) following. This phase is then briefly discussed under the headings (I-VII) detailed in section 10. The methodology used to assess parts I - VI is the user survey with the user expectations acting as the frame of reference. The methodology used to assess part VII was blind testing diagnosis (see section VII below) with the traditional methodology reports acting as the frame of reference.

(A) User Survey:

An evaluation questionnaire was circulated to all users of the system who attend the conference on a regular basis (section 4). The questionnaire, in the appendix, was closed in format, forcing users to answer questions on a five point scale. Sections were also available for free text comments. The user group polled consisted of three Cardiac Consultants, two Cardio-Thoracic Surgeons and six Cardiac Registrars. There was 91% response rate in total (10 / 11 users), with a 100% response rate from the Consultant and Registrar groups and a 50% response rate from the Cardio-Thoracic Surgeons.

Results to the main questions are tabled below with the question numbers indicated on the vertical axis and the respondent numbers and statistical analysis of results on the horizontal axis:

	1	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***	***Mean***	***Mode***	***SD***	***CV***
Q1	3	1	2	4	2	2	2	1	2	3	2.2	2	.918	41.7%
Q2	4	4	4	3	4	4	3	4	4	4	3.8	4	.421	11%
Q3	5	5	4	4	4	5	4	5	5	5	4.6	5	.516	11%
Q4	6/7	7/7	5/7	4/7	7/7	6/7	5/7	6/7	5/7	6/7	-	-	-	-
Q5	Y	Y	Y	-	Y	Y	Y	Y	Y	Y	-	Y	-	-
Q6	N	Y	N	N	N	N	Y	Y	N	Y	-	N	-	-
Q7	5	4	5	4	4	5	4	5	3	4	4.3	4	.674	15.6%
Q8	1	3	2	2	4	5	-	3	5	4	3.2	-	1.39	43%
Q9	Y	Y	Y	-	Y	Y	-	Y	Y	Y	-	Y	-	-
Q10	2	2	5	2	5	3	-	-	4	-	3.2	2	1.38	42%
Q11	4	3	1	2	2	-	5	3	3	4	3	3	1.22	33.3%
Q12	1	2	1	2	2	-	4	3	3	4	2.4	2	1.13	46.2%
Q13	5	4	3	1	4	4	2	1	4	4	3.2	4	1.39	43.7%
Q14	Y	N	N	N	N	?	?	Y	Y	Y	-	-	-	-

Table 17

Analysis of Results:
Each closed context question is given below together with the grading scale used and an analysis of the results.

- *Question 1: 'Do you have much previous experience with computer systems ?'*
  Scale: Little 1 2 3 4 5 Extensive

70% of respondents scored 2 or less on the 5 point scale with 1 indicating little previous experience and 5 indicating extensive experience. 90% of respondents scored 3 or less, revealing that the overall user familiarity with computer systems prior to the installation of the AMIE demonstrator was very low.

- *Question 2: 'What is your overall reaction to the system ?'*
  Scale: Poor 1 2 3 4 5 Extensive

80% of respondents scored their overall reaction to the system as 4 or higher and 100% scored 3 or higher, indicating the overall user reaction to the system to be very high.

- *Question 3: 'Do you feel that it is useful having all patient data together on the one system ?'*
  Scale: Not Useful 1 2 3 4 5 Very Useful

100% of respondents scored 4 or higher with 60% of users scoring 5, revealing that having all multimedia patient data present is very useful for cardiac conferencing.

- *Question 4: 'Do you feel the quality of the data is satisfactory for diagnosis ?'*

Users were asked to comment on each data type classifying it as satisfactory, unsatisfactory or unknown. Unknown was given as an answer in several cases where the users considered they had not seen enough examples to be able to comment on the diagnostic quality. Nuclear Medicine studies are the least frequently reviewed examinations and as a result several users responded with unknown when questioned about this modality. The overall breakdown itemised by modality was as follows:

1. Angiography:

80% of respondents found the AMIE angiography data to be satisfactory for primary diagnosis. 10% of respondents considered the AMIE sequence lengths to be shorter than the cine film sequences and classified them as unsatisfactory. A further 10% of respondents found the angiography sequence controls to be difficult to manipulate and thus consider the data unsatisfactory for diagnosis

2. X-ray:

80% of respondents considered the AMIE X-ray image quality to be satisfactory for primary diagnosis. 10% found there was a loss of information evident as a result of the digitisation process and classified the images as unsatisfactory. The remaining 10% of respondents were unable to comment as they had not seen sufficient examples.
Of the users that commented therefore, 89% found this data type to be of satisfactory quality.

3. Echocardiography:
80% of the respondents found the quality of the AMIE Echocardiography sequences to be satisfactory for primary diagnostic purposes. 10% of respondents found the image quality to be inferior to the traditional video recordings and 10% were unable to comment.
Therefore, of the users that commented, 89% found this data type to be of satisfactory quality.

4. Blood Pressure:
100% of the respondents found the quality of the AMIE blood pressure tracings to be satisfactory.

5. ECG:
90% of respondents considered the AMIE ECG tracings to be of a sufficient quality for primary diagnosis. 10% of respondents found the measurement grid lines difficult to distinguish and thus consider the tracings to be unsatisfactory.

6. Patient Notes:
100% of the respondents considered the AMIE patient notes to be satisfactory.

7. Nuclear Medicine:
As nuclear medicine studies are reviewed infrequently at conferences many users considered they had not reviewed sufficient cases to comment on the image quality of this data type. 40% of respondents considered the data to be satisfactory, 10% considered the quality was somewhat inferior to the original nuclear medicine system and 50% of respondents were unable to comment.
Of the users that commented on the nuclear medicine imagery, 80% found the quality to be satisfactory for primary diagnosis.

In general, of the users that commented 80-100% found each data type displayed using the AMIE demonstrator to be satisfactory for primary diagnosis.

Question 5: 'Do you feel the system can aid clinical diagnosis ? Y/N'
100% of respondents consider that the AMIE system can aid clinical diagnosis.

Question 6: 'Do you feel the system can alter clinical diagnosis ? Y/N'
60% of respondents considered that patient diagnosis is not altered by use of the AMIE demonstrator with the remaining 40% considering that use of the AMIE system leads to a more comprehensive patient diagnosis than is possible with traditional conferencing methodology.

Question 7: 'Do you find the large screen display effective ?'
Scale: Not Effective 1 2 3 4 5 Effective
90% of respondents scored 4 or higher with 100% scoring 3 or higher indicating that the large screen display device is effective for case conferencing.

Question 8: 'Do you feel the system is concurrent with the existing work practices ?'
Scale: Altered 1 2 3 4 5 Concurrent

60% of users scored 3 or higher indicating that use of AMIE is reasonably concurrent with the existing system. The main comments quoted in the free text section were that a relatively long time is required to load image sequences and that overall a longer time per patient case is required using the AMIE demonstrator as compared to the current system. Using the current methodology 3-4 minutes are required per patient case while up to 7 minutes are required per case using AMIE. This however may be offset by the fact that AMIE facilitates the review of more data than previously possible.

Question 9: 'Are you confident about making clinical decisions using this system ?Y/N'

80% of respondents are confident making clinical decisions using the AMIE system only, without reference to the traditional methodology with the remaining 20% reserving judgement until a larger number of patients have been reviewed.

Question 10: 'Do you find the control pen pad easy to use ?'
Scale: Hard 1 2 3 4 5 Easy

There was a large coefficient of variation (42%) in the answers to this question. 60% of respondents scored 3 or higher, 20% scored 2 or lower and 10% did not comment. The main comments raised in the free text section were that:

(a) It is difficult to co-ordinate hand and eye movements between the pen pad and the large screen
(b) The control of movement of the angiography sequences is more difficult than with the traditional cine projector
(c) As the AMIE system takes a certain time to react to adjustments (i.e. contrast enhancement, zoom, increase/reduce image sequence replay speed) there was a tendency to overcompensate and therefore not achieve the required adjustment.

In general it was found that the more previous experience the user had with computer systems, the easier they rated the usage of the control pen pad.

Question 11: 'Do you feel a remote station facilitating full audio and video conferencing is worthwhile ?'
Scale: Not Worthwhile 1 2 3 4 5 Worthwhile

60% of respondents scored 3 or higher, 20% scored 2 or lower and 10% did not comment indicating that there is usage in having a remote conferencing facility. In the free text section several users indicated that such a remote station would be beneficial for teaching purposes. Other users indicated that it would be beneficial to link to another hospital, particularly to the main Cardio-Thoracic surgical hospital.

Question 12: 'Do you feel the remote link to the CCU is useful ?'
Not Useful 1 2 3 4 5 Useful

There was a large coefficient of variation in the answers to this question (46.2%). Although the users consider the CCU to be the optimal location within St. James's Hospital to which to link; this connection is only beneficial if all the conference data is available for review at this location. During the period of the field trial 2 patients out of the list of approx. 20 - 30 patients were discussed on a weekly basis using the AMIE system. It was more beneficial for the doctors to attend the conference and participate in the review of all cases than to participate in the review of only 2 cases at the remote site.

Question 13: 'Do you find the system reliable (in terms of breakdowns) ?'

Not Reliable 1 2 3 4 5 Reliable

70% of users scored 3 or higher and 30% of users scored 2 or lower. The lower scores are as a result of overheating problems encountered.

Question 14: 'Do you prefer this system to the traditional system used in case conferencing ? Y/N'

40% of users prefer the traditional system of reporting to the AMIE system. 40% of users prefer the AMIE system and the remaining 20% would prefer the AMIE system if speed issues were addressed (i.e. if the time taken to load image files is reduced).

In terms of advantages and disadvantages of the AMIE demonstrator, the following is a summary of the questionnaire free text comments:

100% of respondents found that the main advantage of the AMIE system is having all patient data available on one source. 80% of respondents found the main disadvantage to be the time taken to load image sequences thus resulting in a longer time per patient case being required. Other disadvantages cited were the inability to control the angiography replay rate with the same eloquence as the traditional cine film projector with 40% of users finding this control difficult to manipulate.

10% of users cited the large storage required per patient case as a disadvantage of the system and 10% of users considered the time required to download all patient data onto the system as a disadvantage. These two aspects however were largely transparent to the users throughout the field trial.

When questioned as to what improvements could be made to the system in the future 80% recommended that the time taken to load images should be reduced. 50% of respondents suggested that the control of the angiography replay rates could be simplified; 30% recommended that the user interface could be made easier to use; 20% advised that the image quality of selected data types could be improved upon and 20% of users commented that co-ordination of hand and eye between the mobile pen control and the large screen was difficult to achieve. 20% of respondents recommended that a remote link to the surgical site may be useful; 20% recommended that the system would have value for teaching purposes and 10% commented that a mouse driven user input may be more simple to use than the mobile pen devices.

(I) Usefulness of the System:

As indicated in section (A) above, 100% of system users responding to the user questionnaire agreed that having all patient data in one system was very useful. 100% of respondents also agreed that the system provides a beneficial aid in clinical diagnosis. It can therefore be readily concluded that the AMIE demonstrator is a beneficial and useful tool.

(II) Does the system meet the user Requirements ?:

As documented in section 11.1 part III, the developed system has achieved all of the baseline system requirements. More than 50% of the additional and 25% of the desirable requirements have also been achieved. From the user perspective, as documented by the user survey, the presentation of data types is satisfactory to 80% or more of responding user and 80% of users are confident in making clinical decisions based on the AMIE demonstrator alone. The system can be seen as having met the majority of user requirements and future improvements that might be addressed are outlined in section (A) above.

(III) Concurrency of the System with existing work practices:

As outlined in section (A) above, 60% of users scored 3 or higher indicating that use of AMIE is reasonably concurrent with the existing system. The main positive difference highlighted was the advantage of having a large variety of patient data available. The main negative difference highlighted was the time required to load each image sequence into system memory and the resulting longer time per patient case required by use of the AMIE demonstrator. Using the current methodology the angiography cine film or the ultrasound video is loaded once only. Due to the large amount of data to be digitised, the AMIE image sequences are divided into several individual runs (section 9) which each require loading. Using the traditional system 3-4 minutes are required per patient case while up to 7 minutes are required per case using AMIE. This however may be offset by the fact that AMIE facilitates the review of more data than previously possible.

(IV) Appropriateness of the System hardware in the clinical environment:

As documented in section (A) above the majority of system users found the large screen display device and associated hardware very effective. Questions were posed to the system users regarding the other hardware devices. The radio network was considered to be very appropriate to the conferencing toolkit by all users. 50% of users considered the mobile pen computers to be appropriate for the user interface, 10% of users recommended that a mouse driven user interface would be preferable to the pen computers and further 40% of users suggested that some form of control device resembling the speed control knob on the cine film projector would be more suitable for the manipulation of image sequences.

The multimedia devices (microphones, speakers and cameras) were considered by all to be suitable for conferencing.

(V) Presentation of Data and User Interface:

The overall user reaction to the system was very high as documented in section (A) above. 80% or more of all users questioned considered the display and presentation of all data types to be satisfactory. The majority of users considered the user interface to be appropriate however there were some reports of difficulties in using the interface which are also documented in section (A).

(VI) System functionality:

The users were asked to grade the system functionality on a 5 point scale, where 1 indicates a low envisaged usage and 5 indicates a high usage. The results are summarised in table 18 below with the system functions on the vertical axis and the user numbers and statistical analysis of results on the horizontal axis.

Function	***1***	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***	***Mean***	***Mode***	***SD***	***CV %***
Zoom	5	3	5	2	2	3	5	3	4	5	3.7	5	1.25	33.8%
Contrast / Brightness	4	4	5	3	4	-	5	2	4	5	4	4	1	25%
Pointer	5	4	5	1	3	-	5	5	4	5	4.1	5	1.36	33.1%
Play (normal speed)	5	4	3	4	3	-	5	5	5	5	4.3	5	.866	19.9%
Play (reduced speed)	4	4	3	3	4	-	5	1	5	5	3.7	4-5	1.3	34.4%
Play (increased speed)	2	3	3	2	1	-	5	1	4	5	2.8	1-5	1.53	53.1%
Freeze	5	4	3	4	4	-	5	5	5	5	4.44	5	.726	16.3%
Go to last image	5	4	5	2	2	-	1	3	4	5	3.44	5	1.50	43.8%
Go to first image	5	4	5	4	2	-	5	3	4	5	4.11	5	1.054	25.6%
Step forw. Through frames	4	4	1	4	1	-	5	3	5	5	3.55	4-5	1.589	44.7%
Step back through frames	5	4	1	4	1	-	5	3	5	5	3.66	5	1.65	45.2%
Fit to screen	5	2	3	4	2	-	3	1	3	5	3.77	3	1.09	28.9%
Edge sharpening	5	2	3	3	4	-	5	3	4	5	3.77	3-5	1.09	28.9%
Image / trace move/scroll	4	2	3	3	2	-	1	1	4	2	2.44	2	1.13	46.2%

Table 18

Discussion:

All system functions were considered to have high usage with the exception of ‘fit to screen’ and ‘image move/scroll’. The reason for this is that the default display for the main imagery (angiography, echocardiography and patient notes) was fitted to the size of the screen and thus these options were not frequently required. There was a considerable variation as to whether ‘image sequence play at increased speed’ is a useful function. Some users found this function useful however other users found that image frames were dropped at the faster replay rates and considered this to be unsatisfactory.

On observing the users at work, the most frequently used functions, in order of usage were as follows:

1. Play at normal speed,
2. Freeze,
3. Pointer,
4. Zoom,
5. Play at reduced speed,
6. Step forward through frames.

These observations correlate well with user questionnaire results.

(VII) Clinical Accuracy of Digitised Data:

As documented in AD2.2. Field trial scenario, system users were requested to partake in blind testing of the various data types to assess the clinical accuracy of the digitised data. Blind testing involves the reporting of patient data by independent observers using a standard methodology without any information on or knowledge of the patient case. The cases are reported from both the test system (the AMIE system) and the traditional system and a comparison of the results made.

Large numbers of patient cases are required to ensure accurate blind testing results and ROC (Receiver Operator Characteristics) analysis is usually performed to assess the findings. ROC analysis involves graphing the true positive (TP), false positive (FP), true negative (TN) and false negative (FN) results. Typically several months are required between blind testing reporting sessions as medical staff can frequently remember specific patient cases.

Due to the short field trial period it was not possible to do a complete blind test using independent observers on each modality, however two large studies are currently being conducted. One study involves the reporting of 50 digitised X-rays by 5 independent observers using the AMIE system and the traditional methodology. A comparison of the results may then be made. The other study involves the reporting of 20 angiography patient cases by 5 independent observers using the American Heart Association (AHA) protocol. This protocol is described in section 1 following.

Both of theses studies have been accepted for presentation at the European Congress of Radiology (ECR '97) conference in Vienna on March 1997. This is the largest annual European Medical Radiology conference.

In addition to the two large studies which are currently being conducted, several smaller blind testing studies were carried out to obtain a clinical assessment of each data type. These are summarised below:

The results for each imaging modality are documented below:

- *Angiography:*

frame of Reference:
The frame of reference against which to assess the AMIE angiography sequences was the traditional cine film sequences.

Methodology:
A standard format for reporting cardiac angiograms has been devised, documented and widely accepted by the American Heart Association (AHA). This method involves the division of the coronary artery tree into 15 distinct segments. The percentage narrowing of each segment is graded into one of the following categories:

0-10%, 10-20%, 20-30%, 30-40%, 40-50%, 50-60%,
60-70%, 70-80%, 80-90%, 90-99%, 100%.

An evaluation form was compiled to the specifications of the AHA for reporting on cardiac angiograms. This form is included in the appendix. Other parameters on the evaluation form included Left ventricular function evaluation, regurgitant jet assessment, presence or absence of collateral vessels, assessment of Left ventricular ejection fraction and assessment of image quality. (see below)

Intra- and inter-observer variability in reporting of angiogram segments is always evident using this rigid method of reporting and as a result the reporting was conducted by two independent cardiology registrars. Twenty angiogram patient cases were identified for inclusion into the blind testing evaluation. These twenty cases were reported blindly on the AMIE system and again several weeks later using the cine projector.

In total 300 segments were graded (15 segments from 20 patients) by two independent clinicians on both the traditional system and on the AMIE system.

Intra-observer cine evaluation:
Tables 20 overleaf outlines the intra observer agreement of the cine film readings. The patient identification numbers are indicated on the vertical axis. The agreement between observers is indicated along the horizontal axis. The number of coronary artery segment gradings (max. 15) which agree are listed in the column labelled 'Agree'. The number of segments which differ by one step (i.e. one clinician reports 10-20% stenosis and the other reports 20-30%) are listed in the column entitled D1. The number of segments which differ by two steps (i.e. 10-20% Vs 30-40%) are listed in column D2 etc.

Cardiac patients may develop collateral blood vessels which improve the blood supply to the cardiac muscle. The clinicians were requested to indicate the presence of absence of these vessels. In the column labelled 'Coll', agreement between the observers is indicated by 'Y' and disagreement represented by 'N'.

Left ventricular (LV) function in cardiac patients may be damaged. The clinicians were asked to indicate whether the function was Normal, Hypokinetic, Hyperkinetic, Dyskinetic, Akinetic, Aneurysmal or unknown. In the column labelled 'LVFN', intra-observer agreement is indicated by 'Y', a one step difference in replies is represented by D1 etc.

An aortic or mitral valve regurgitant jet may be evident on the image sequences. If present, this jet was classified as mild, moderate or severe. In the column entitled 'Jet', agreement in responses is represented by 'Y', a one step deviation by D1 etc.

The term Left Ventricular Ejection Fraction (LVEF) represents the percentage of the left ventricular volume that is ejected during one heart beat (systole). The clinicians were requested to estimate this fraction to the nearest 10%. The results are represented in the 'LVEF' column where 'Y' represents agreement between users, D1 represents a one step difference (i.e. 40% Vs 50%) etc.

Pt	*Agree*	*D1*	*D2*	*D3*	*D4*	*D5*	*D6*	*D7*	*D8*	*D9*	*D10*	*Coll*	*LV FN*	*Jet*	*LV EF*
2	12	3										Y	Y	Y	D3
3	11	2						1			1	N	D3	Y	Y
5	10		2	1	1		1					Y	D1	Y	D1
7	11	4										Y	-	D2	-
8	11	2	1				1					Y	Y	Y	Y
9	12		2					1				Y	D2	Y	Y
20	15											Y	Y	D1	Y
22	11		1			1		2				Y	Y	Y	D1
24	15											Y	Y	Y	D1
27	8	2			1	1			1	1	1	Y	Y	Y	D1
28	15											Y	Y	Y	Y
30	9	2	2								2	Y	Y	Y	D2
31	13		1	1								Y	Y	Y	Y
32	13	1	1									Y	Y	Y	Y
40	15											Y	Y	Y	Y
41	13		1	1								Y	Y	Y	Y
42	12	1		1							1	Y	-	Y	-
43	10		2	1		1				1		Y	Y	D2	Y

Table 20: Intra-observer cine film agreement.

As can be seen from the above table there was a 78.8% (213/270 segments) intra-observer agreement between coronary artery segment gradings. 6.6% of the gradings deviated by 1 step, 4.8% by 2 steps, 1.8% by 3 steps, 0.7% by 4 steps, 1.1% by 5 steps, 0.7% by 6 steps, 1.48% by 7 steps, 0.37% by 8 steps, 1.48% by 9 steps and 1.8% by 10 steps. There was thus a very high correlation of segment gradings.

The intra-observer correlations of collateral assessment, left ventricular function evaluation and regurgitant jet assessment were 94%, 81.25% and 82.35% respectively. There was a 62.5% intra-observer agreement of left ventricular ejection fraction and 25% of assessments deviated by 1 step (10%) and 6.25% of assessments deviated by 2 steps (20%).

Inter-observer AMIE Vs cine evaluation

The correlations between AMIE and cine angiography readings for one individual observer are given in table 21 below (same format as table 20).

Pt	*Agree*	*D1*	*D2*	*D3*	*D4*	*D5*	*D6*	*D7*	*D8*	*D9*	*D10*	*Coll*	*LV FN*	*Jet*	*LV EF*
2	13			1		1						Y	D1	D1	D2
3	9	1	1			2		1			1	N	Y	D1	Y
5	10	2		2							1	N	Y	Y	D1
7	14		1									Y	-	D1	-
8	12	1				2						Y	D2	Y	D1
9	15											Y	Y	Y	D1
20	15											Y	Y	Y	D2
22	10	1	1			1		1	1			Y	D1	Y	D2
24	15											Y	D3	Y	D1
27	9	3	1	1					1			Y	Y	Y	Y
28	15											Y	Y	D1	Y
30	11	2	1								1	Y	D2	Y	D1
31	13	1	1									N	Y	Y	D1
32	14		1									Y	Y	Y	Y
40	15											Y	Y	Y	D1
41	12		2			1						Y	Y	Y	Y
42	13		2									Y	-	Y	-

Table 21: Observer 1 - AMIE Vs cine.

As can be seen from table 21, there is a segment grading agreement of 84.31% (215/255 segments) between the cine and AMIE readings for this observer. The percentage agreements for collateral assessment, LV function assessment, regurgitant jet evaluation and LV ejection fraction are 82%, 66.65%, 76% and 33% respectively. 45% of the AMIE ejection fraction assessments differ from the cine assessments by one step (10%).

The correlations between AMIE and cine angiography readings for the second individual observer are given in table 22 below (same format as table 20).

Pt	*Agree*	*D1*	*D2*	*D3*	*D4*	*D5*	*D6*	*D7*	*D8*	*D9*	*D10*	*Coll*	*LV FN*	*Jet*	*LV EF*
2	12	1		2								Y	D1	Y	Y
3	8	4	1	1							1	Y	D4	D2	D2
5	10	3	1				1					N	D1	Y	Y
7	9	6										Y	-	D1	-
8	10	2	1	1			1					Y	Y	Y	D1
9	13	1						1				Y	Y	Y	Y
20	15											Y	Y	Y	D1
22	12	2	1									Y	D1	Y	Y
24	15											Y	D4	Y	D1
27	6	4	1	1				1	1	1		Y	Y	Y	D1
28	15											Y	Y	Y	Y
30	11	1	1							2		Y	-	Y	-
31	13	1	1									N	Y	Y	D1
32	14	1										Y	Y	Y	Y
40	15											Y	Y	Y	Y
41	14	1										N	Y	Y	Y
42	12	2									1	N	-	Y	-
43	8	3	1			1	1				1	N	Y	Y	Y

Table 22: Observer 2 - AMIE Vs cine.

As can be seen from table 22, there is a segment grading agreement of 78.5% (212/270 segments) between the cine and AMIE readings for this observer. The percentage agreements for collateral assessment, LV function assessment, regurgitant jet evaluation and LV ejection fraction are 72.2%, 66.6%, 88.8% and 60% respectively.

AMIE evaluation Vs cine evaluation:
In order to assess the actual clinical correctness of the AMIE readings, the intra-observer cine film readings which were in agreement were taken as definitive correct values (from table 20). These correct values were taken as the standard against which to assess each observers AMIE readings. The results for each observer are summarised in tables 23-24 below where the column 'cine agree' identifies the number of intra-observer segment gradings which were in agreement in table 20 (i.e. the standard).

Pt	*Cine Agree*	*Agree*	*D1*	*D2*	*D3*	*D4*	*D5*	*D6*	*D7*	*D8*	*D9*	*D10*	*Coll*	*LV FN*	*Jet*	*LV EF*
2	12	11			1								Y	N	D1	-
3	11	9		1			1						-	-	D1	Y
5	10	8	1				1						N	Y	Y	-
7	11	11											Y	-	-	-
8	11	10					1						Y	D1	Y	D1
9	12	12											Y	-	Y	D1
20	15	15											Y	Y	-	D2
22	11	9	1	1									Y	D1	Y	-
24	15	15											Y	D1	Y	-
27	8	7	1										Y	Y	Y	-
28	15	15											Y	Y	Y	Y
30	9	8	1										Y	D2	D1	-
31	13	12	1										N	Y	Y	D1
32	13	13											Y	Y	Y	Y
40	15	15											Y	Y	Y	D1
41	13	11		2									Y	Y	Y	Y
42	12	11	1										-	-	Y	-

Table 23: Observer 1 - AMIE readings Vs standard.

From the above table it can be seen that there is a 92.7% correlation between the angio. segment gradings evaluated by observer 1 using the AMIE system and the standard values. In terms of collateral identification, LV function assessment, regurgitant jet evaluation and LV ejection fraction determination, the correlations between this observer and the standard values were 87.5%, 58.3%, 80% and 44.4% respectively.

Pt	*Cine Agree*	*Agree*	*D1*	*D2*	*D3*	*D4*	*D5*	*D6*	*D7*	*D8*	*D9*	*D10*	*Coll*	*LV FN*	*Jet*	*LV EF*
2	12	10	1		1								Y	N	Y	-
3	11	8	3										-	-	D1	D2
5	10	8	2										N	Y	Y	-
7	11	9	2										Y	-	-	-
8	11	9		1	1								Y	Y	Y	D1
9	12	12											Y	-	Y	Y
20	15	15											Y	Y	-	D1
22	11	11											Y	D1	Y	-
24	15	15											Y	D2	Y	-
27	8	6		1						1			Y	Y	Y	-
28	15	15											Y	Y	Y	Y
30	9	9											Y	Y	Y	-
31	13	12	1										N	Y	Y	D1
32	13	13											Y	Y	Y	Y
40	15	15											Y	Y	Y	Y
41	13	12	1										N	Y	Y	Y
42	12	11	1										-	-	Y	-

Table 24: Observer 2 - AMIE readings Vs standard.

From the above table it can be seen that there is a 92.2% correlation between the angio segment gradings evaluated by observer 2 using the AMIE system and the standard gradings. In terms of collateral identification, LV function assessment, regurgitant jet evaluation and LV ejection fraction determination, the correlations between this observer and the standard values were 75%, 75%, 93.3% and 55.5% respectively.

Discussion:

Two independent cardiac registrars were requested to evaluate several parameters on 20 angiography sequences using the AMIE system and the traditional cine film system. The cine film readings were taken to be definitively correct (the standard) in cases where the two users scored the same value. Each users AMIE readings were then compared to the standard. The percentage of the AMIE readings which agreed with the standard values are documented in the table below for each observer. The average score is compared with the cine intra-observer agreement values.

	Angiography Segment grading	Collateral Identification	LV function assessment	Regurgitant Jet assessment	LV ejection fraction determination
Observer 1	93.2%	87.5%	58.3%	80%	44.4%
Observer 2	92.2%	75%	75%	93.3%	55.5%
Average	92.7%	81.25%	66.6%	86.65%	49.95%
Intra-Observer	78.88%	94%	81.25%	82.35%	62.5%

Table 25

As can be determined from table 25, the results for the AMIE angiography segment gradings demonstrate a very high correlation with the standard values. The correlation for left ventricular function assessment and left ventricular ejection fraction are somewhat less, however these parameters suffer from more intra-observer variability.

- *X-ray:*

Frame of Reference:
The frame of reference against which to assess the clinical accuracy of the AMIE X-rays was the traditional film based system.

Methodology:
A small sample of 10 plain X-ray films were reported using the AMIE system and the associated image processing functionality. Several weeks later the same X-rays were reported using the traditional methodology. There was a correlation of 85% between the two reportings. The larger scale study currently being conducted will reflect this figure more accurately.

- *Nuclear Medicine:*

Frame of Reference:
Nuclear medicine studies are currently diagnosed from paper format images printed by the Link Medical Maps 1000 system. This system was used as a baseline against which to assess the AMIE nuclear medicine imagery.

Methodology:
A small sample of 10 plain nuclear medicine studies were reported using the AMIE system and the associated image processing functionality. These studies were re-reported by the same radiologist several weeks later using the traditional methodology. There was a correlation of 60% between the two reportings. This was discussed with the radiologist responsible who considered the AMIE system to be superior to the traditional system as diagnosing from paper imagery does not facilitate the adjustment of image brightness and contrast. A further study is being considered to investigate the differences in reporting from static imagery Vs. On-line imagery.
When questioned on the image quality of the AMIE nuclear medicine images, the Radiologist considered the AMIE studies to be of satisfactory diagnostic quality.

- *ECG:*

Frame of Reference:
The frame of reference against which to assess the clinical accuracy of the AMIE ECGs is the traditional paper based system.

Methodology:
25 ECG traces were reported from the AMIE system and again several weeks later using the traditional paper format. There was a 93.5% between the two readings indicating very high clinical accuracy of ECG tracing.

12. User Interview:

An Interview was conducted with a system user for presentation on the AMIE Internet web page. The user was:

Dr. Peter Crean,
Consultant Cardiologist,
Department of Cardiology,
Crest Directorate,
St. James's Hospital,
Dublin 8.

The text of the interview follows:

- *Have you much experience with computer systems ?*

"I have no extensive training in the use of computer systems although I have always used these for preparation of documents and reports and obviously in the use of the every day running of the inpatient care in tracing patient notes, results etc. I have not been involved with designing specific computer programs except for using data base analysis for statistics of studies which we carry out in our Department."

- What is your overall reaction to the system ?

"I think that this is an excellent system which combines a number of different investigation techniques and allows them to be reviewed at the same time without resorting to looking at each different test, i.e. an exercise test, an echocardiogram and an angiogram or a nuclear scan, usually using different modalities. This is easy to use, provides excellent images and an outstanding amount of detail."

- *What do you think are the main advantages of this system ?*

"The main advantages appear to be:

1. The high quality of the image resolution.
2. The ability to provide a number of different imaging techniques and details recording patient information in the one format, i.e. on a large computer screen. To date the system allows the use of patient notes, ECG, exercise testing, pressure tracings, nuclear scans, echocardiograms and angiograms to provide a complete profile of patient results. This is an excellent advantage in that it doesn't require to turn to looking at a video, to taking out part of the patient notes, to look at their ECG or exercise test or pressure tracings and then to look at a video format of an echocardiogram, as these are all on the one computer. They can be reviewed rapidly in succession and all of the information then used to decide on the best treatment for the patients."

- *Do you feel this system can aid clinical diagnosis ?*

"Yes, by integrating all of the information on one format on a computer system. It means that all of the data can be reviewed at the same time. It means that there is less likelihood that a particular and important piece of information i.e. chest X-ray may be missing at an appropriate decision making conference. To date we have tried this in use for evaluating patients who have coronary artery disease and we are reviewing all of the relevant clinical information and the results of their tests at the one time. It allows for rapid decision making based on all the current available data for that patient."

- *How does this system compare with the current system?*

"This system incorporates all of the usual methods which we currently use to evaluate the patients. However it offers the main advantage, that these are provided in a single format, are all available at the time of the conference and therefore speed up the appropriate diagnosis and treatment for the patient. The image quality provided from the echo, the angiograms, the ECG etc. is excellent."

13. Discussion and Conclusions:

Using the baseline requirements as a guideline against which to assess the correctness and completeness of the completed application, the AMIE system can be considered as having achieved all its main objectives.

All data types were assessed in terms of technical and clinical accuracy. Through the use of image processing functionality the nuclear medicine and echocardiographic data produced on the AMIE system are equivalent to the traditional technologies in terms of grey scale linearity, contrast and spatial resolution. Angiographic data produced on the AMIE system is equivalent to that produced on the system monitors in the cardiac angiography suite which are used for primary diagnosis. There is a loss of spatial resolution in the digitisation process of plain film X-rays and a large scale clinical study is currently being conducted to assess this effect. AMIE ECG and blood pressure tracings replicate the traditional systems with greater than 90% accuracy.

Large scale blind testing studies are required to assess the clinical accuracy of a system such as AMIE. Several small scale studies were conducted on individual data modalities to determine the clinical performance of the system and correlations of greater than 85% between the AMIE report and the traditional report were noted for most modalities. The hand writing recogniser was evaluated and word success rates of up to 90% were found in cases where the users were well trained on the use of the system.

User opinion was assessed by means of an evaluation questionnaire which was circulated to all system users with an overall response rate was 91%. Results of the user survey reveal that having all data types integrated on the one diagnostic workstation is a significant advantage in patient diagnosis. 100% of users scored 4 or higher on a 5 point scale with 5 indicating that multimodality presentation of data is very useful. 40% of respondents indicated that the demonstrator may provide a more comprehensive patient diagnosis that possible with traditional methodology. All users had little previous experience with computer systems and scored their overall reaction to the system in terms of data presentation and clarity of information as 4 or higher on a 5 point scale with 5 denoting excellent.

The disadvantage the users found with the system is that a comparatively longer time per patient case is required. This may be offset by the fact that a larger range of data is reviewed.

Other benefits highlighted by the users included efficiency, ease of data management and ease of data manipulation during conferencing and the ability to present complete data sets effectively to a moderate sized audience. In terms of video and audio conferencing, 60% of respondents scored 3 or higher on a 5 point scale with 5 denoting that a remote audio and video conferencing facility is worthwhile.

80% of respondents are confident in making clinical decisions based on the AMIE demonstrator alone without reference to traditional display systems, with the other 20% reserving judgement until a larger patient group has been reviewed.

14. References:

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8. The testing of X-ray image intensifier television systems. STB/7/82, 2ND ED., January 1985.

15. Appendix: