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The concept of reduction in logistical footprint can be applied not only to fighting forces but also to mobile surgical facilities that are co-deployed. At the beginning of this contract, we had completed preliminary work in constructing a prototype robotic surgical device that can perform, on a very limited basis, the essential job functions of the surgical scrub technician in the operating room. This machine could potentially reduce the personnel needed in the surgical facility. The work done under this contract was to improve the capabilities of the machine so that it comes closer to being able to replace a human scrub technician. The two specific goals in the statement of work were 1) to improve the robot's vision capabilities so that it can correctly recognize twelve instruments with 98% accuracy and 2) to make the robot 98% reliable in retrieving the instruments that it has recognized. We were entirely successful in meeting the first goal, and came close to meeting the second goal. Combined with additional work that was done concurrently, the contract work has the result that the robot's development has progressed such that we are on track for clinical deployment in the year of 2005.

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Introduction

The concept of reduction in logistical footprint can logically be applied not only to fighting forces but also to mobile surgical facilities that might be co-deployed. Reduction in the number of personnel required to staff mobile surgical facilities would be a way of achieving this logistical reduction. At the beginning of this contract, we had recently completed preliminary work in constructing a prototype robotic surgical device that can perform, on a very limited basis, the essential job functions of the surgical scrub technician in the operating room. In essence, the robot is a computer control system connected to a digital camera and a mechanical arm with a gripper. The computer control system also has a voice recognition system to listen to verbal requests for an instrument from the surgeon. The robot uses machine-vision via the camera to locate and identify surgical instruments and also to compute their orientation. When the surgeon requests an instrument, the mechanical arm delivers that instrument to the surgeon. When the surgeon is finished with the instrument, the arm is sent to the coordinates of the instrument lying out on the surgical field, to retrieve it and return it to the robot's Mayo stand. The work done under this contract was to improve two core capabilities of the machine so that it comes closer to being able to replace a human scrub technician for the performance of a basic repertoire of surgical procedures. The two specific goals in the statement of work were 1) to improve our robot's vision capabilities so that it can correctly recognize twelve instruments with 98% accuracy and 2) to make the robot 98% reliable in physically retrieving the instruments that it has recognized. Previously, the vision routines were able to detect and distinguish four instruments with an 80% accuracy rate and the retrieval accuracy rate was rate 85%. These systems are at the core of the robot's basic function, and errors must be reasonably infrequent. We were entirely successful in meeting the first goal, and came close to meeting the second goal. Combined with additional work that was done concurrently, the contract work has the important result that the robot's development has progressed such that we expect to meet our ultimate goal of clinical deployment in the coming year of 2005.

Body

The body of this report is divided into two main sections. The first section is a complete description of the **research accomplishments to date with respect to the approved Statement of Work for DAMD17-03-C-0083.** The specific tasks and results are described in the sub-sections following this one, entitled **Vision System** and **Motion System**. The second section is a **Narrative Description of the Development of the Penelope System.** This narrative description shows the full scope of work that occurred during this time period, including the parallel threads of development and accomplishment during this time. This narrative is provided in order to give context to the specific tasks that were accomplished in fulfillment of the Statement of Work. The narrative section shows why the specific work done with TATRC support is important to the development of a successful clinical system.

Vision System

Instrument Choice

In approaching the goal of recognizing twelve instrument types, it was first necessary to choose the instruments to include in this set. If possible it was desirable to choose a set with which one could perform a simple general surgery operation that Penelope is intended for use with. We had already compiled a database of instrument requests in some basic operations, for use in

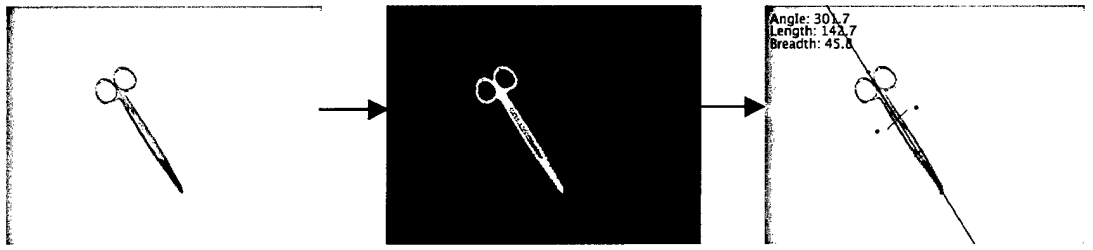
evaluating the software that allows Penelope to predict the next request. From this database we extracted the twelve most commonly requested instruments in excisions of lipomas and cysts:

Suture Scissors
Tooth Forceps
Needle Holder
Hopkins Clamp
Debakey Forceps
Brown-Adson Forceps
Richardson Retractor
Metzenbaum Scissors
Allis Clamp
Loop Retractor
Adson Clamp

The scalpel is not included in this list although it was in fact the most commonly requested instrument of all, because for safety reasons Penelope will never hand an exposed blade directly to the surgeon. If the robot delivers a scalpel, it will do so in a protective package, and since we will design such a package, we can produce it in any shape or color so as to be easily recognized.

Vision Algorithms

This section will describe all of the methods currently in use to detect and identify instruments in the robot's field of view. After the camera captures an image, the system software takes it through several stages of analysis, with the goal of separating objects from the background, then measuring and identifying the objects. The progression through the stages of analysis is shown in Fig. 1, with detailed descriptions of each stage following.



Raw Image

Screening and Blob Detection: White pixels represent those determined to be part of the object.

Fiducials: A dark line shows the object's line of maximal symmetry and dots show points from which length and width are measured.

Fig. 1. Screen captures of the most important stages of the vision processing for one image.

Raw Image Screening

When the system is first turned on, an image is captured of the surface of the transfer zone; this serves as the background against which new images are compared. As the first step in processing, the captured image is compared to the stored background image. Rather than

comparing individual pixels in each image, which would be overly sensitive, the algorithm compares each pixel in the captured image to a histogram that describes what colors occurred in the background image. Therefore, to be considered part of the foreground, a pixel in the captured image must be of a color not found anywhere in the background image. The results of this comparison are stored in a binary image array, with white pixels representing the foreground, and black pixels the background.

Blob Detection

Once we know which individual pixels may be part of an instrument, we must group adjacent and nearby ones together into what we call 'blobs.' When a set of pixels is part of one blob, it simply means they are close enough together that it is likely they are all part of the same larger shape. The algorithms turn the screened binary image array into an image with a different color for each set of pixels that represents a distinct blob. The largest of these is taken to be the instrument. Currently we assume that only one instrument is on the transfer zone at a time. At present, the software can deal with more than one instrument but only if they are not overlapping.

Fiducials

Having the blob that most likely represents the instrument, the remaining task is to measure it and determine the instrument type. The fiducials are measurements taken from the blob produced by the previous step. The system has been trained to know the measurements of each instrument, and when a new image is captured, it compares its measurements to those of all the instruments and chooses the closest match. The fiducials are the crux of the high-level vision system, and the part which we have spent the most time refining to enable identification of 12 instrument types. Currently five measurements are taken for all instrument types, and two specialized ones are only taken to help distinguish two very similar instruments. The primary five measurements are length, width, and the x-axis, y-axis, and z-axis moments of inertia. The two specialized ones are 'tip width' and 'finger loop length.' These will be discussed further below.

Acquisition of fiducials is a bootstrapping process that uses each piece of information to obtain the next one. It starts with the center of mass, or *centroid*, which is simply the pixel in the center of the blob. Next we divide the blob into four quadrants, with the centroid as the origin. We compute the centroid of the pixels in each of those quadrants, and whichever is furthest from the centroid becomes the *secondary centroid.* We found that by this method, the line connecting the centroid and the secondary centroid is the instrument's line of maximal symmetry. This line is the key to the rest of the fiducials, because it provides axes along which to measure length and width, as well as the moments of inertia (in fact the y-axis for the moment of inertia is the line of maximal symmetry itself). Fig. 2 shows a detail of the fiducials for the suture scissors: the two X's are the centroid and secondary centroid, and the dark line is the line of maximal symmetry.

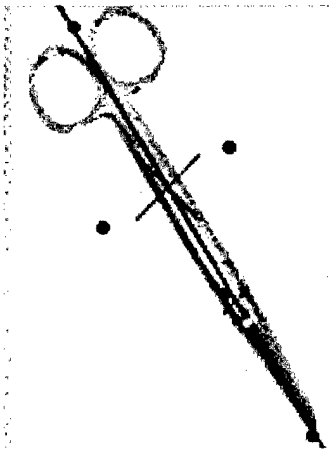


Fig. 2. Screen capture of fiducials markers placed on an instrument by the software.

Moments of Inertia

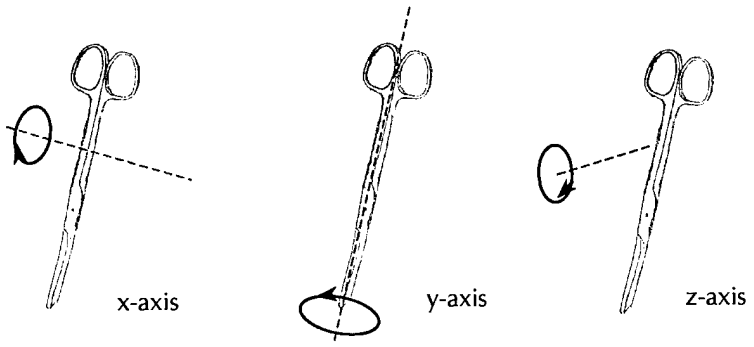


Fig. 3. The axes used for moment of inertia measurements

The moments of inertia are measures of how the weight of an object is distributed around its area. As physical properties, they describe how an object responds to rotational forces around its axes. The moments are computed as the average distance of the pixels in the object from each axis. For our purposes, they give indications about the object's shape that are subtler than the length and width alone. Shown in Fig. 3 are illustrations of the three rotational axes as we use them.

Tip Width and Finger Loop Length

After implementing the moments of inertia and performing tests to determine accuracy rates; we found we could still not distinguish between two particular instruments, the Adson clamp and the needle holder. Their profiles are simply too similar. To remedy this we looked carefully at their shapes, and thought about what could be measured once it is known that one of these two instruments is being observed. We came up with tip width, and finger loop length. The tip width is a measure of how narrow and pointed the tip of the instrument is; our own observations, and subsequent testing, showed that the Adson clamp has a sharper tip than the needle holder. Finger loop length is a measure of the size, along the clamp's length, of the loops in which the surgeon's fingers grip the clamp. It was observed and subsequently confirmed that the needle holder's loops are larger to a visually significant degree than those of the Adson clamp (Fig. 4).

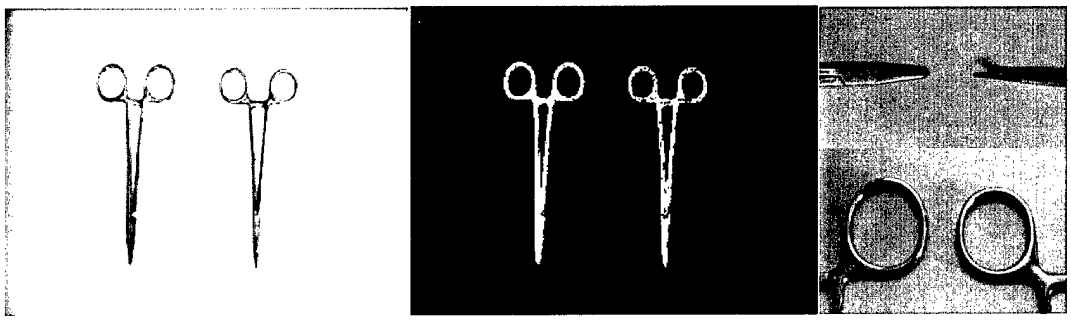


Fig. 4. In these images the needle holder is on the left, and the Adson clamp is on the right. At the left and middle are raw and screened images taken by the system's camera. At right are details of the tips and finger loops of slightly different size.

Instrument Identification Decisions

The reason multiple criteria are necessary, and that similar but not identical instruments pose problems for identification, is that the measurements are never quite the same over multiple trials. Unpredictable shadows and reflections, as well as the limited resolution of the camera, produce a range of measurements over a training set of images, that the instrument's 'actual' dimensions can be assumed to fall within. Similar instruments end up with overlapping ranges, and whenever a captured image's measurements fall within the overlap area, the system must decide between the two instruments. This is done by taking the Euclidean distance from the current measurements to the averages for each possible instrument, and choosing the shorter distance. In practice this distance is in an n-dimensional space where n is the number of criteria, up to 7 if all are being used. For an illustrative example in Fig. 5, we will use only length and width.

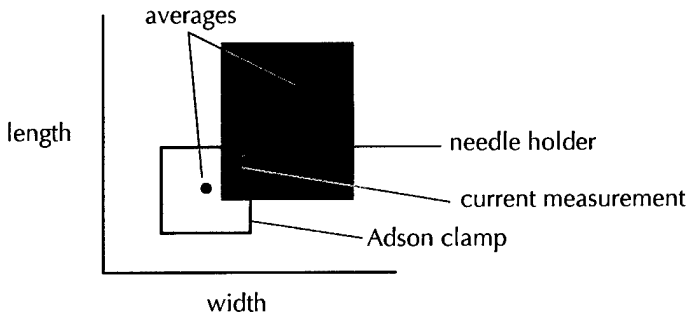


Fig. 5. A possible decision scenario. The two rectangles represent the measurement ranges for these instruments in the training set. Since the current measurement falls within the overlap area but is much closer to the average for the Adson clamp, that instrument would be chosen as the identification. Note that the average is not necessarily directly in the middle of the minima and maxima, although it is often close.

Confidence Interval

After the first rounds of testing, it was found that no matter how much each instrument was trained beforehand, some of the measurements taken in testing would always be slightly outside the observed range. In this situation the system would come up with no identification, even if the measurement was still quite close to one instrument and nowhere near any others. To combat this we implemented a statistics concept called the confidence interval, which is essentially a way of expanding the ranges from what has been observed so far, to try to include what will be observed in the future. Although such an expansion enlarges the overlap area for similar instruments, the distance-to-averages method for decisions prevents this from damaging accuracy rates. The confidence interval is calculated thus:

$$i = k \, x \, \frac{\sigma}{\sqrt{n}}$$

where k is a precision value indicating the percentage of future measurements that should fall within the interval, σ is the standard deviation of the training set, and n is the sample size of the training set.

Vision System Testing

In order to test our instrument identification algorithms and determine how best to improve them, we designed the following procedure. First, to isolate the algorithms as a variable, we built a light-tight box around the system's camera and installed a light inside it. We had found that with the wide window in our lab, the powerful sunlight changed the images so much that a test done during the day and taking several hours could not be reliable. Since operating rooms do not have windows for similar reasons, we assume this to be a reasonable level of control.

As a training set, each instrument is placed in a random position under the camera and the system is told that what it sees is that instrument, taking the various measurements used for identification. Each instrument is trained approximately 25 times, depending on the observed variation in the measurements. Since we did not change the way measurements were taken, we were able to use a cumulative training set for all of our tests.

In the testing phase, each instrument is placed under the camera 20 times and an attempt is made at identification. Whenever the system fails to recognize that a given instrument is there, that instrument's "true-negative" error count is incremented. If the system thinks an instrument is there which is actually not, that instrument's "false-positive" error count is added to. A case of mistaking one instrument for another counts as one error of each type. As an example, if the Metzenbaum scissors were placed under the camera, and the system reported recognition of the suture scissors instead, it would be a true-negative error for the Metzenbaum scissors, and a false-positive error for the suture scissors. At the end of the test, the accuracy rate is computed as the number of true-negative errors over the number of trials. We do not include false-positive errors in the accuracy rate, since this would be in effect counting some errors twice.

In the first round of testing, we achieved a recognition rate of 81.6%. The algorithms at this point measured length, width, and y-axis moment of inertia, and simply checked whether or not a measurement was in the range of values in each instrument's training set. We had determined that the other two moments of inertia, while reliable measurements, did not offer any additional level of distinction between similar instruments. Most of the errors in this test occurred when a measurement was just slightly outside the training set's range, causing the instrument to fall out of consideration. At this point we implemented the confidence interval. After this improvement, in the second round of testing we achieved an accuracy rate of 91.6%. The next major enhancement was to fix a problem that occurred when instruments were angled horizontally or vertically, aligned with the camera's coordinate system. This accounted for approximately 1/3 of the errors observed in the second test. To fix it, we wrote an algorithm to detect when an instrument was at such an angle, and with that knowledge use a slightly different method to take the measurements. The third test incorporated both this improvement and the ability to recognize certain instruments, such as forceps and retractors, in multiple profiles based on how they are laid down. No angle errors occurred, and the accuracy rate rose to 93.75%.

Two sources of error remained at this point, each contributing about half of the 15 errors. Errors having to do with out-of-range measurements still occurred more often than expected. This was resolved simply by increasing the precision value k in the confidence interval equation. The other source of error was confusion between the two most similar instruments, the Adson clamp and the needle holder. For these we implemented tip width and finger loop length as further distinguishing factors. After these improvements we performed a fourth round of testing, in

which we achieved our goal with a 98.3% accuracy rate.

Vision System Results

Our basic system for visually recognizing surgical instruments was improved to achieve our stated technical goal of 98% accuracy rate applied to twelve surgical instruments. This overall result came from a combination of several improvements, including initially adding additional criteria (moments of inertia), allowing for a certain amount of statistical uncertainty in the measurements (confidence interval), correcting software deficiencies that occurred at certain

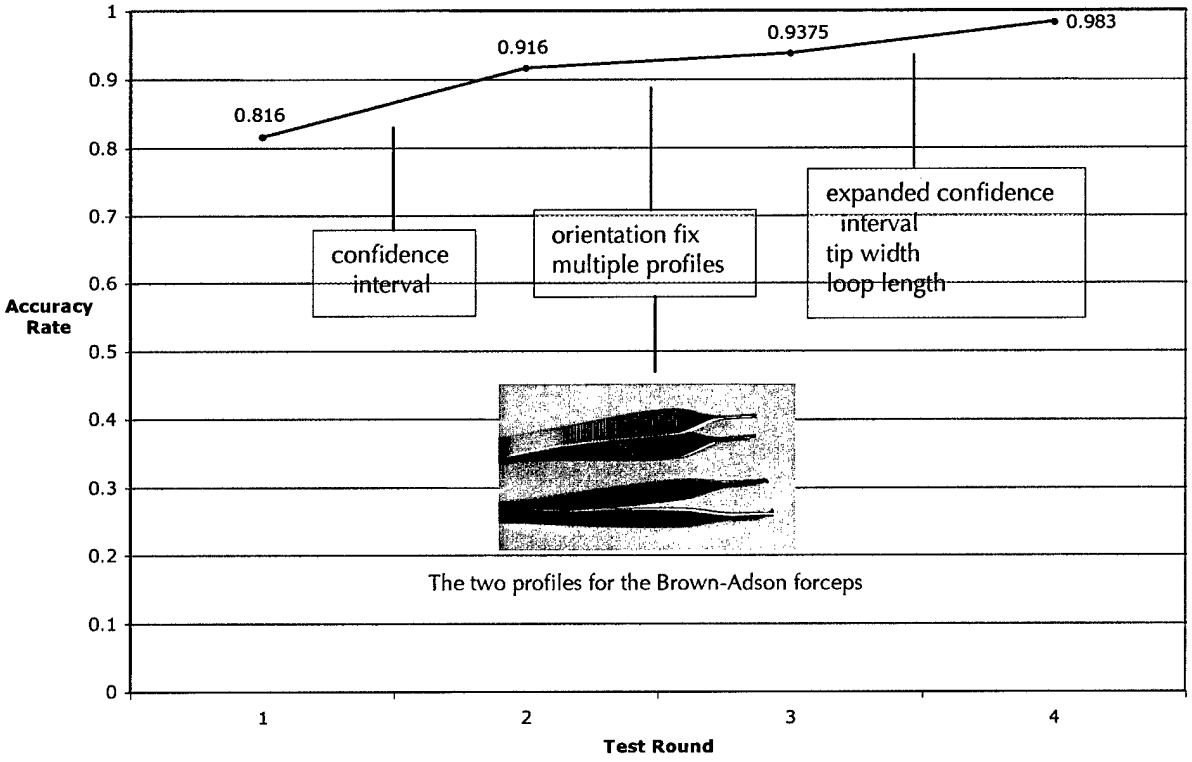


Fig. 6. Summary of the accuracy rates for each test round, and the improvements made between each.

orientations, adding capability to recognize the same instrument in different profiles, and then adding certain specific criteria that were applied by additional code when certain "look alike" instruments were encountered. These results are graphically shown in Fig. 6.

Vision System: Future Work

The vision system will undergo several changes as Penelope gets closer to a clinical version; some of these will improve performance, others will introduce new challenges. The camera will eventually be positioned higher up, able to see the Mayo stand and staging zone as well as the transfer zone. This will make all measurements smaller and closer together, creating the chance for more confusion between instruments. It can be alleviated by using a larger amount of the camera's resolution than we currently use. We will also have to deal with non-instrument

objects entering the field of view, such as sponges, syringes containing anesthetic, and gloved hands of assistants or observers. On the other hand, we will be able to use the knowledge of what instruments are in use to simplify identification decisions. If there is uncertainty over whether an instrument is an Adson clamp or a needle holder, but only a needle holder is in use, then the uncertainty is eliminated. Of course the biggest change will be the size of the instrument set, which will eventually expand to 42 types as found on the Minor Surgical Set. We are confident that the method we have used so far, adding specific identification criteria where necessary, will allow us to maintain acceptable accuracy rates as we add more instruments to Penelope's repertoire.

Motion System

Motion Algorithms

The robot's motion is controlled on the software side by a physics-based simulator, and on the hardware side by a USB-connected microcontroller and the servo motors. When the arm is told to move to a point, the simulator computes the necessary movement of each motor to bring the arm closer to its destination, and sends a command to the motors. These commands are individual time steps in the overall movement toward the destination, and are sent to the motors every 20 milliseconds. There are two motors affecting the height of the arm, at the elbow and shoulder, and another at the shoulder for the horizontal swivel.

The term "physics based" is used since the simulator's modeling of the arm is based on principles of rigid body rotation under the influence of applied forces, as calculated by applying Newton's second law of motion: Force = Mass x Acceleration. This equation is numerically integrated to solve for the acceleration, velocity and position of each rigid body, using quaternions to represent the 3D orientation of each segment of the arm. Since all of the arm's joints are effectively hinges with an angle controlled by the motor, each segment is defined as a hinged body, which is a type of rigid body. Each hinged body is defined by its constant length, width and height, mass, and center of gravity, as well as the axis on which it rotates, called the hinge-pin. The hinged body also has two vectors used in calculations, the 'pointer,' which runs from the hinge point through the center of gravity, and the 'hinge normal,' which is normal to

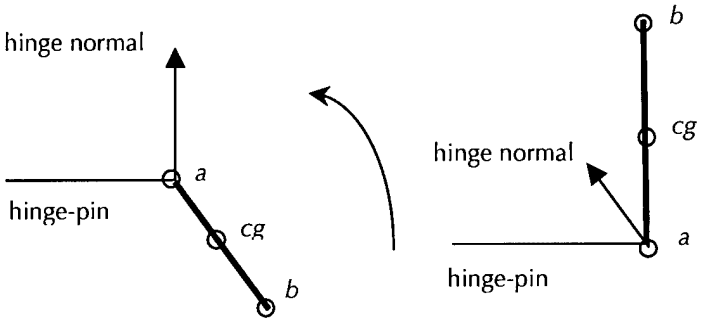
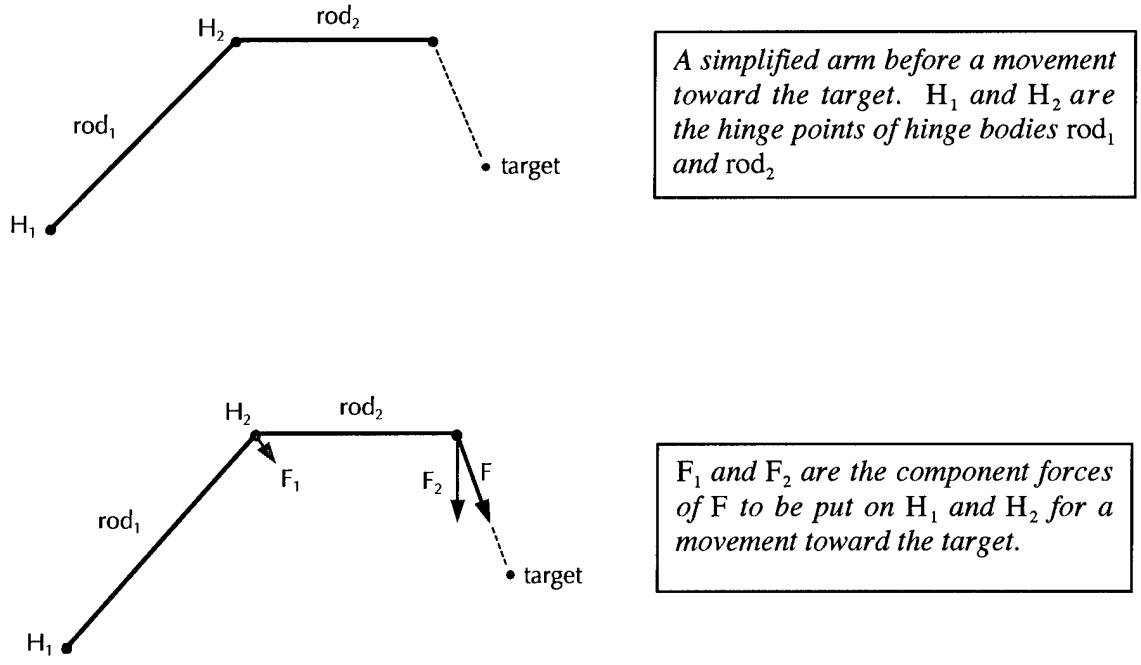


Fig. 7. A hinged body before and after a 90 degree rotation about the hinge-pin. The body is defined by the line segment ab, with center of gravity cg.

both the hinge pin and the pointer. Shown in Fig. 7 is a hinged body rotating 90 degrees about the hinge-pin axis.

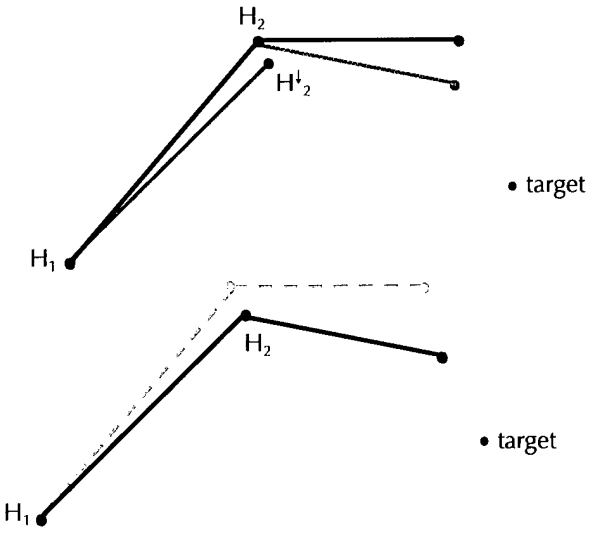
In determining how much each motor should do for the arm to execute the desired overall movement, the simulator works its way up from the elbow to the shoulder, trying to do as much as possible with the smallest part of the arm. This is analogous to how, when typing for example, we mostly move the fingers to reach the keys, rather than moving the entire arm one inch over. At each hinged body, the forces to be put on the arm as a whole are filtered to only include those along the hinge normal, so that the motor is not being asked to move in a way that it cannot. The forces that cannot be handled by one hinged body are passed up to its 'parent,' further up the arm. When a hinged body is moved, the quaternion describing its orientation is updated to reflect it. When a hinged body's parent moves, its position must be updated so that it is still 'attached' to the rest of the arm. This process of moving each hinged body and updating is performed at each simulation time step, and over many steps forms an overall arm movement. One iteration of the process with a simplified arm is shown in the following sequence.



A simplified arm before a movement toward the target. H_1 *and* H_2 *are the hinge points of hinge bodies* rod_1 *and* rod_2

F_1 *and* F_2 *are the component forces of* F *to be put on* H_1 *and* H_2 *for a movement toward the target.*

Fig. 8. (in four parts) Algorithm for motion of arm made of two rigid bodies ("rods"), which are hinged and subjected to external forces. The algorithm shows how the hinged relationship is preserved.



The forces are applied to both hinge bodies. The new hinge point H'_2 *is a result of the slew force applied to* H_1.

H_2 is moved to compensate for the slew force, and a step toward the target is completed

The calculations involved in each step of the simulator can be summarized as follows:

1: Calculate total moment of forces. Having this value enables us to evaluate changes in angular velocity.

$$Mh = \Sigma(Ri \times (Fb \cdot Nb)Nb)$$

2: Update angular velocity of the hinged body using Euler's method.

$$\omega = \omega + dtIh^{-1}(Mh - (\omega \times Ih(\omega)))$$

3: Update quaternion of hinged body for motion about hinge using Poinsot's theorem. The ability to update quaternions using this elegant equation is the reason for using them to represent orientation, instead of rotational matrices.

$$q = q + \frac{dt}{2\omega}$$

Legend

Mh	total moment of force about hinge point h
Nb	hinge normal vector
Fi	force applied to each hinged body
Ri	moment arm of application of force Fi
Fb	Fi rotated from world into body coordinates
Ih	moment of inertia about h
ω	angular velocity about h
ω'	slew angular velocity
q	hinged body quaternion
dt	change in time over one simulation time-step

4: Update quaternion for slew motion of parent. We also update the 'pointer' vector that indicates the hinged body's position, by setting it to an anchor point that is attached to the parent hinged body.

$$q = q + \frac{dt}{2\omega' q}$$

At this point, we can use the new angles of the simulated hinged bodies to send commands to the motors driving the real physical robot's joints. In the case of servos, we only can use position commands, but with stepper motors we can also send velocity and acceleration commands to the

motors as well.

Motion System Testing

We tested the current robot's reliability rate in retrieving an instrument from the transfer zone and placing it on the Mayo stand. In order to isolate the motion control system as the variable to the greatest extent possible, we set several guidelines. If we could see from the vision system's output that the instrument's blob had not been clearly identified, and this was the cause of a failure, the trial was thrown out. As long as the instrument ended up on the Mayo stand, the trial was counted as a success. The trial was a failure if the instrument was not picked up at all, or if it was dropped prematurely and did not land on the Mayo stand. We only used one instrument for these tests, the Hopkins clamp, and tested it 100 times.

Motion System Results

The result was that the robot successfully retrieved the clamp 94 times, and the other 6 it did not pick up the instrument at all. Although this does not meet our stated goal of 98%, we have for several reasons decided not to expend more effort toward improving the robot's mechanics at this time. First, we observed that all 6 errors occurred when the instrument was in a certain area of the transfer zone, furthest away from the arm, and the arm's error was the same each time. This indicates that it is likely a problem of calibration between the arm and the camera or of the magnet being so far out of the ideal perpendicular orientation (due to fixed magnet angle), and not a flaw with the motion control system. Second, the new version of the arm has been constructed and is being integrated into robot's operating system.

Motion System: Future Work

The new arm has been entirely redesigned, has been assembled and is now being integrated into the software. Its motion is produced by stepper motors which should allow positional resolution meeting or exceeding our requirements. Engineering calculations indicate that angular resolution of the joints of the arm will be 0.045 degree, exceeding our clinical requirements. The arm will also incorporate position encoders that will allow the software to detect discrepancies between commanded and achieved position. In addition, P-3 will have a feedback mechanism to tell when there is an instrument on the gripper. This way, if an instrument is missed Penelope will be aware of it before it causes any further errors. A key feature of the new arm, compared to the version of the arm on P-2.5, is that this arm has a "wrist". On the previous arms, in an effort to save weight, the wrist degree-of-freedom was not present although these arms did have the ability to rotate instruments. The angle of the magnet relative to the axis of the forearm was chosen to be the best compromise to provide (approximately) perpendicular orientation of the magnet to the instruments over the greatest area on the transfer zone. However, at the corners of the transfer zone, the magnet would be coming at a suboptimal angle and this we found was a contributing reason for the less than desired overall retrieval rate of 94%. In the new arm, the wrist produces both rotational and flexion-extension motion, but weighs about the same as the previous wrist since the motion is transmitted to a differential gear arrangement via drive belts running entirely within the carbon fiber tubes of the forearm and upper arm. The two stepper motors producing this wrist motion are mounted proximal near the shoulder joint to avoid the problems of weight carried distally on the arm. The wrist allows the magnet to be oriented perfectly perpendicularly to the instruments regardless of their location on the transfer zone or Mayo stand.

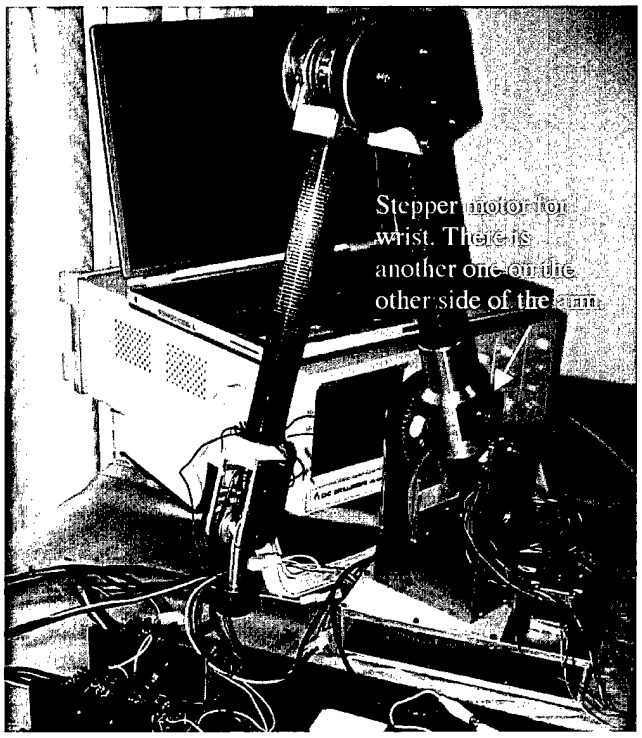


Fig. 9. New arm for Penelope 3 which uses more precise stepper motor actuators than previous arm, and also has an additional "wrist" degree-of-freedom so that the magnet will be able to always approach instruments perpendicularly.

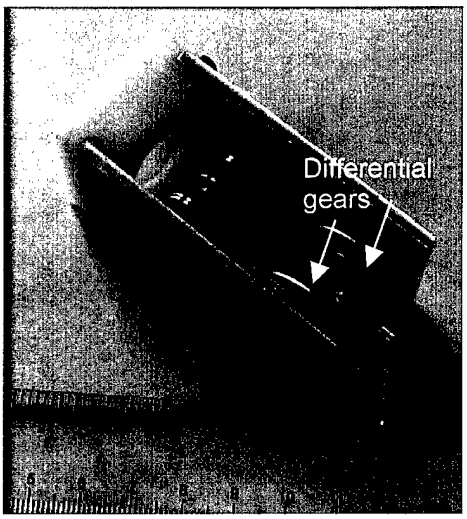


Fig. 10. Differential gear system produces combined rotation and flexion-extension of the wrist.

Narrative of the Development of the Penelope System

Penelope 1 and Penelope 2

At the time of writing in August of 2002 of our proposal entitled "Robotic Replacement for the Scrub Technician", we had finished **Penelope 1** ("P-1") and were building **Penelope 2** ("P-2"). As it was pictured in the original proposal, P-2 was incomplete, lacking a functional gripper.

P-2 was completed in time for a demonstration video, in November of 2002, which was seen by the TATRC review committee. Compared to P-1, P-2 had many physical improvements but the software was still somewhat slow and required a large dual-processor computer to run even tolerably well. Also, the camera system was not well integrated into the main body of the software, causing occasional system crashes.

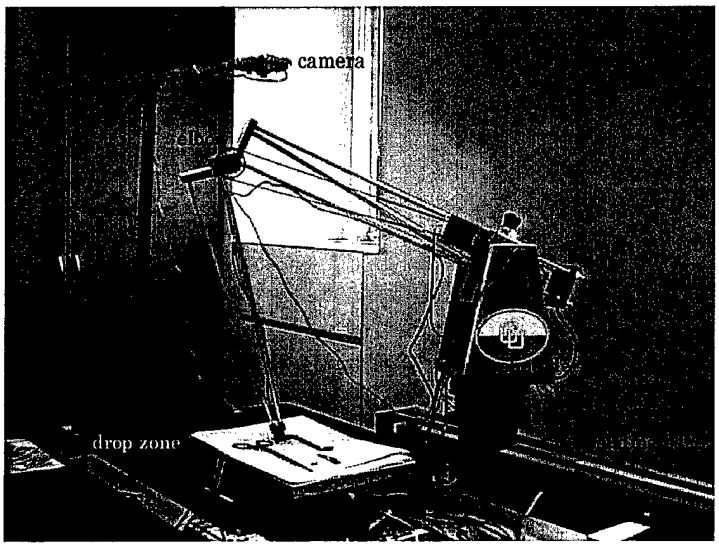


Fig. 11. ***Penelope 1*** *at time of the original proposal to TATRC, August 2002, shortly after Dr. Moses visited Columbia University.*

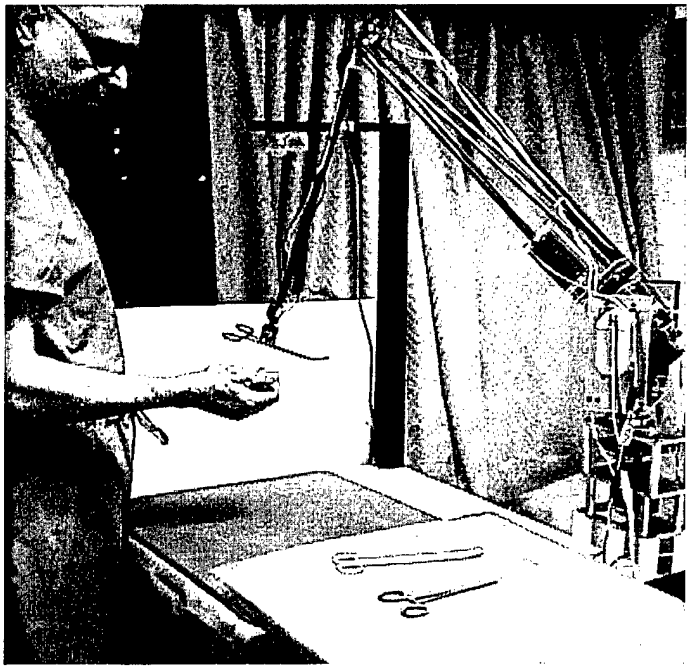


Fig. 12. ***Penelope 2****, in November 2002. This was the machine in the demo video that was viewed by the TATRC review committee for our original proposal. This machine has many physical improvements compared to P-1.*

The physical improvements for P-2 arose out of more precise construction and from servomotors which were larger and more accurate. These improvements promised to improve its physical accuracy for retrieving instruments. Additional work on P-2 was done in order to make the robot more presentable for the TATRC exhibit at the American Telemedicine Association Meeting (April, 2003). This work consisted of a major software overhaul and mechanical upgrades to the arm as well as a physical repackaging of the robot, as explained in the next sections. This work resulted in the **Penelope 2.5**, which was presented in public last April at the TATRC Exhibit at the American Telemedicine Meeting in Orlando, Florida, April 2003.

Penelope 2.5

Software Improvements

The software improvements incorporated in Penelope 2.5 were major and resulted in code for the motion control system that runs approximately ten times faster than the code we had when we submitted the proposal. This new code allows the robot system to run very nicely on a laptop computer, whereas formerly it took a rather large and heavy dual processor system to run the code. The faster, more efficient code means it will be possible to achieve a greater number of calculations per second of the update of the motion of the arm. As was explained in the preceding section on the Motion System, the calculations of the motion of the arm proceed on time-step by time-step basis. For each time-step, a small increment of the position, velocity and acceleration of the arm is calculated from the instantaneous forces applied to the arm at the beginning of the time-step. Smaller time-steps can produce a finer grain of the motion calculations, but require more computing cycles. Faster, more efficient code means it is possible using a reasonable sized computer to break the motion down into smaller time-steps while still having enough computer resources left to manage the other tasks of the robot, particularly the vision system which is also fairly demanding.

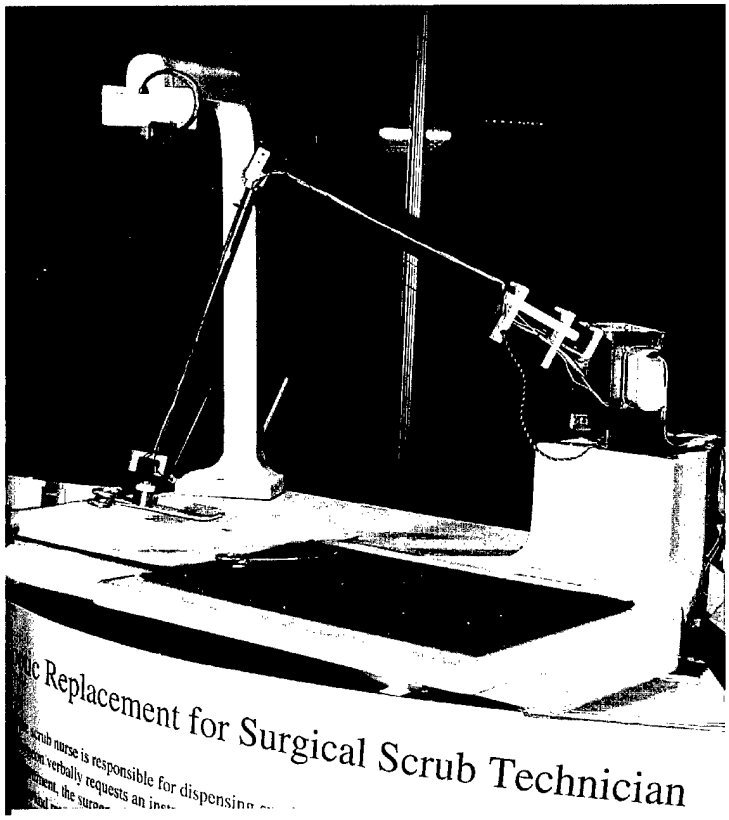


Fig. 13. ***Penelope 2.5****, delivering a Kelly clamp at the TATRC Exhibit, April 2003. This machine has revised shoulder, upper arm and elbow as well as an angled gripper. There are also extensive software improvements over Penelope 2 which allow the machine to run on a laptop computer and to be relatively impervious to variable lighting conditions.*

Another important aspect of the system was the integration of the camera system into the main body of the robot code. Prior to this, for P-2, the code for the running of the camera hardware was run as a separate application which timeshared with the main application that handled the image processing, motion control and other aspects of the robot. The image processing (i.e. object localization and identification) in the main application required as input the output of the camera hardware, which was running continuously, producing a continuous stream of image data. The output of the camera hardware was made available to the main application by means of a shared file containing the camera output data. The operating system of the computer was generally, but not always, able to handle the conflicts that sometimes arose when the camera hardware was trying to update the shared data file and the image processing software was trying

to read in the file. This problem was exacerbated at frame rates over 5 fps and would occasionally result in system crashes. A major breakthrough was development of software drivers for the camera hardware that could be called directly from the main application. This development eliminated the inter-application conflict, removed the frame speed barrier and increased the speed of the overall application. Undoubtedly, this integration was the key contributor to the successful demonstration of the robot at the TATRC Exhibit in April, 2003.

In terms of the motion control software, we completely reorganized and rebuilt the physics-based simulation which is at the heart of the motion control system. This work was done with an eye to minimizing the number of software "objects" that are created by the code. In the older code, software objects that were needed to run the simulation were re-created at each time-step of the simulation. This made the code easier to read and understand but ended up creating an enormous number of such objects, since the simulation was being run at the fairly high rate of fifty steps per second. Minimizing the number of software objects created during each time step was accomplished by re-using these objects. This made the code somewhat less intuitive to understand but the performance increase was very impressive. The impact of the performance increase was that we were able to run the robot code on a laptop with approximately half the computing power as the machine required to run P-2's code. As explained above in the Motion System section, the robot is represented by a "model" which is put together out of specified components when the program is started up. These components are the "rigid bodies" which correspond to the segments of the arm. The software revision was also done with an eye to making the robot models independent of the part of the software that runs the simulation. This makes it easier to change the model in order to mirror the robot's physical structure.

Other changes incorporated in the P-2.5 code were useful for the successful demonstration that we had at the TATRC Exhibit. These were changes to the user interface that allowed much easier and accurate calibration of the camera system and the servomotors, and to register the camera system coordinates with the coordinate system in which the arm moves. The camera system user interface now included calibrating out the effects of background illumination and shadows. This ability to calibrate the camera system "on-the-fly" was crucial to the vision system's effective performance at the TATRC Exhibit. At various times, during the exhibit, a moving speckled pattern of light played across the transfer zone. We are able to calibrate out the color of that light such that the vision system could ignore it and successfully recognize the instruments.

In general, the TATRC Exhibit was good test for the robot's ability to perform under something approximating real-world conditions.

Mechanical Improvements

As mentioned, the shoulder, upper arm, and elbow were rebuilt to eliminate structural weaknesses of the P-2 design. At the shoulder level, we eliminated the "twist " degree of freedom servo, since this capability was of no use in picking up instruments. The upper arm was revised to be stiffer, lighter and simpler to align. Instead of the box-truss construction of the P-2 arm, a single large bore carbon fiber tubing was used for the forearm. This permitted a simplification of the elbow joint, resulting in a joint that was less prone to distortion under stress and also lighter. Another mechanical change was to position the electromagnetic gripper at a

20% angle offset from the long axis of the forearm. The change in gripper placement was subtle, but it allowed the robot to pick up instruments more reliably over a larger area of the transfer zone. We also designed and built a fiberglass mounting platform, which integrates the arm, the camera post, the Mayo Stand and the transfer zone. This fiberglass platform gave the robot a more polished look and suggested how an actual clinical system would be configured. We designated this system, with the software improvements described above, as **Penelope 2.5**.

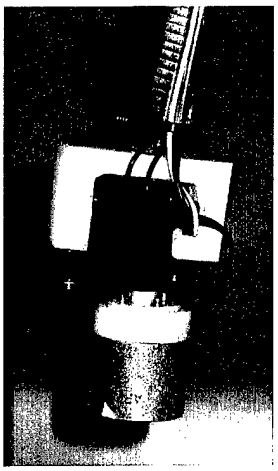


Fig. 14. Slightly offset gripper improved pick-up capability over the transfer zone, but also suggested need for an actual "wrist".

Performance Results of P-2.5

This section describes the performance of the system after the above hardware and software improvements were made and incorporated. It does not take into account the results of the improvements to the Visual System, as this work is being integrated at the present time into P-3.

The P-2.5 system performed very well at the TATRC exhibit with an instrument assortment of Kelly clamp, Hopkins clamp, Metzenbaum scissors and Adson-Brown forceps. It successfully completed several hundred instrument retrievals with an overall success rate of nearly 90%. This success rate was not rigorously determined at the meeting, but was subsequently in fact shown to be correct by formal testing in the lab. This success rate is the combined overall success rate for the entire system, working on four instruments. Individual components of the system worked well. The vision routines worked very well, in the setting of variable lighting conditions. Mechanical accuracy was quite good, but the pick-up success rate was definitely better for instruments dropped near the center of the transfer zone. The voice recognition worked reasonably well with the use of a headset microphone but remains an area which needs improvement.

Penelope 3

When we returned from the April TATRC Exhibit, we realized as the result of demonstrating that machine to many people that it would have to be much faster. It was clear that we were up against the mechanical limits of the servos that we were using, both from the speed and accuracy standpoint. It is clear also that overall physical layout of P 2.5 would not support the 42 types of instruments found in the Minor Tray. We decided at that time that the path to take to achieve a clinically useable machine was not to work on the software solution via visual servoing in improve the performance of the servomotors, but to completely re-design the arm from the ground up, using a better type of actuator- steppers motors. The new actuators would solve not only the accuracy problem, but the speed problem, which could never be overcome with the servos of P-2. We also undertook the large task of designing a full clinical machine. This was a complex process that was undertaken with an eye to producing the documentation that would be necessary to apply for FDA approval. To this end, we instituted a Quality System with Design Controls for the clinical robot development program.

In the past six months, we have produced a completely redesigned arm, which is based on a

completely redesigned physical layout of the entire system. The design goal of the new system is to minimize instrument transfer time while providing the physical structure to be able to accommodate the 42 instrument types found on the conventional Minor Tray. The new system is designated **Penelope 3** and is being completed at this time. It incorporates the results of the work done under our TATRC contract and builds on these results to approach our ultimate goal of clinical usability.

Engineering Requirements

The engineering requirements of our clinical grade robot, Penelope 3, have been codified in our Requirements Specification Document (RSD). The working draft of the RSD contains over 100 requirements covering all aspects of the robot's functionality. In developing the RSD, we gathered user inputs from clinical staff at the Allen Pavilion of the New York Presbyterian Hospital. The top-level requirement is that the robot in no way impede the safe and expeditious completion of the operation. There are many other specific requirements that support this overall requirement. The key items are summarized as follows:

> Instrument Handling: The robot has the physical architecture to handle all the instrument types on the Minor Surgical Tray. The physical architecture includes the following instrument holding surfaces: Mayo stand, transfer zone, staging zone and back tray.
> Sterile Draping: The robot can be prepared for sterile use by the circulating nurse who applies specially designed sterile drapes. We have designed proprietary draping fixtures and tools that cover the various working surfaces such as the Mayo stand and the transfer zone.
>
> Vision System Performance: The requirement is to be able to recognize all the instruments on the minor surgical set, about 42 types. As a result of the TATRC work, the computer vision system has been extended to be able to recognize and distinguish twelve instruments with over 98% accuracy. Just as importantly, the general methods for extending the vision routines to handle more instruments have been developed.
>
> Speed and Accuracy of Performance: Our engineering analysis of the completely redesigned arm indicates that the arm will be able to meet or exceed requirements for speed and accuracy.
>
> Safety: Basic patient safety has been designed into the physical architecture of the robot. The robot is physically not able to impact its arm on the patient or to even drop an instrument onto the patient. The robot will not directly handle sharps (scalpels and loaded sutures). As recommended by OSHA for human scrub technicians, these items will be made available to the surgeon in specially designed (proprietary and disposable) scalpel and suture holders that can be picked up by the robot's electromagnetic gripper.

Penelope 3, albeit with the arm of Penelope 2.5, was presented at TATRC DAY during the Medicine Meets Virtual Reality Meeting in Newport Beach, CA, January 2004. The robot was recognizing twelve instruments very well in real world conditions, and was moving them fairly well, given the limitations of the older 2.5 arm. As a demonstration of the versatility of the vision and motion system, the robot was programmed to visually recognize a piece of paper upon which a Tic-Tac-Toe playing grid was drawn, and then to inquire "How about a game of Tic-Tac-Toe?" For the game, the robot visually recognizes the positions of color coded "X" markers placed by the human player and then places "O" markers (steel washers) onto the board for its

own moves.

As part of our exhibit, the new arm was on display, but was not at that time functional.

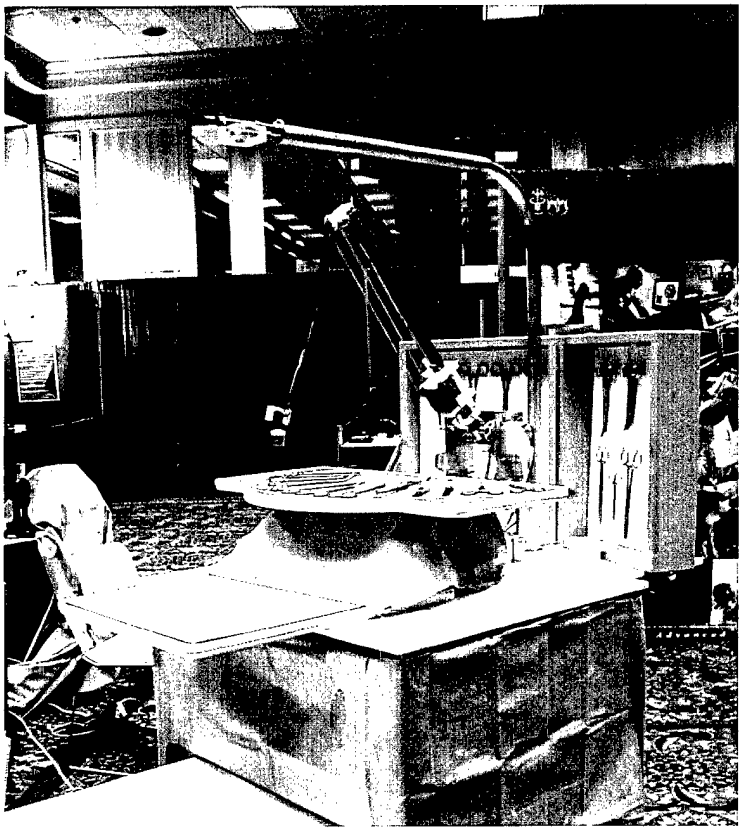


Fig. 15. ***Penelope 3*** *at TATRC DAY, January, 2004 in Long Beach, CA as part of the Medicine Meets Virtual Reality meeting. This robot has the physical architecture to support many more instruments than previous versions.*

Related Work Contributing to Clinical Goal

NSF SBIR Phase I Work

During the past six months, we also successfully completed our Phase I Technical Project for the National Science Foundation SBIR award that we received. The Phase I research objective was to determine the feasibility of using artificial intelligence and statistical techniques to predict the surgeon's instrument requests. This will allow the robot to keep one step ahead of the surgeon, much like an experienced human scrub technician. With this predictive capability the robot can decide how to organize its limited storage space to keep those instruments likely to be needed soon closer to the surgical field. This will greatly improve the responsiveness of the device, a critical factor in achieving clinical acceptance and ultimately commercial viability.

These results will provide a crucial framework for the broader task of creating a *cognitive architecture* for the robot. This architecture will control the robot's behavior and enable it to adapt to the ever-changing environment in the OR. A reliable instrument prediction capability will allow the robot to exhibit *proactive* behavior, as opposed to merely *reacting* to explicit commands. This is a fundamental distinction, separating traditional devices from truly autonomous robots. We believe that this autonomy is an essential advance for robotics in the OR.

In the Phase I work, we recorded from actual surgeries a database of over 50 surgical procedures, cataloging over 2000 individual instrument requests. We then used this time series data to train and evaluate a prediction algorithm. Our best algorithm was a *modified N-gram sequence matcher*. At each point in the surgical procedure, the algorithm produces a *prediction score* for every instrument type. The *score* for an instrument is the likelihood of its being the next instrument selected, given a particular prior sequence of instruments. The instrument with the highest score would be the one which has the greatest chance of being selected next. In doing our Phase I work, we had to consider carefully how these scores were going to be used to deliver on our objective of improving the robot's overall performance. Due to the variable nature of surgery, relying on a prediction of *one* instrument could commit the robot to an inappropriate action, i.e. presenting the surgeon with the wrong instrument. However, we found that by taking into account the *set of most likely instruments*, we could significantly improve overall performance. In order to use the information provided by predicting the set of likeliest instruments, we developed the concept of the robot as an *instrument server*, analogous to a computer file server. In the instrument server concept, the robot's job is to keep frequently requested instruments on the "fast" caches (the ones closer to the surgeon) and less frequently used instruments on the slower caches (the ones further away from the surgeon). The robot uses the prediction scores to decide which instruments to keep on the various caches. This concept elegantly integrates the results of the prediction algorithm with a physical architecture for the robot that is optimized for responsive instrument delivery. It is also very reminiscent of the situational awareness of the experienced scrub person, who proactively manages the instruments to stay in step with what the surgeon is doing.

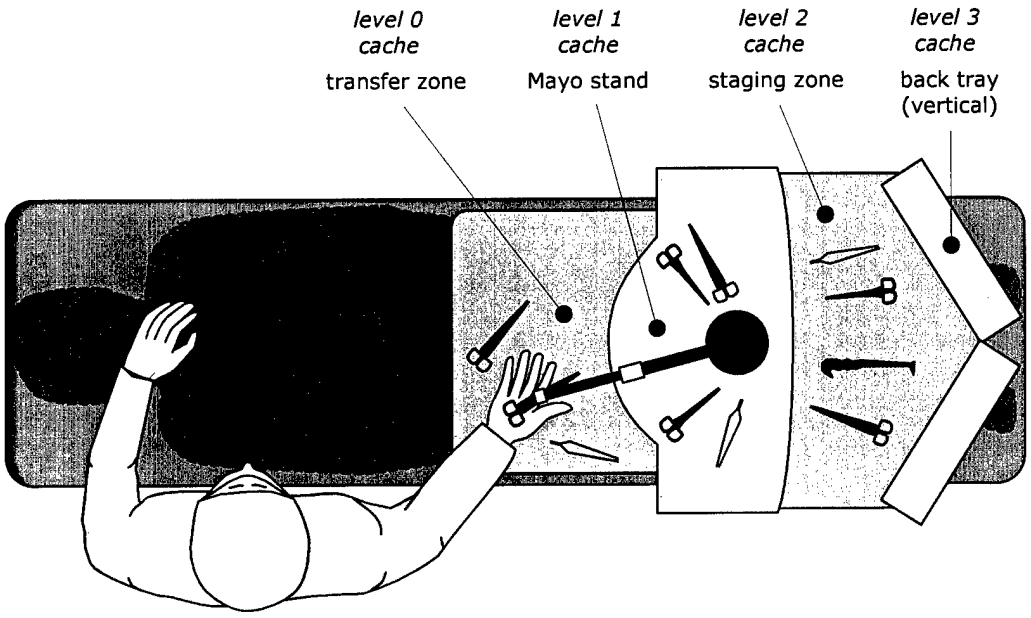


Fig. 16. An overhead view of the robotic scrub technician (shown without sterile draping for clarity). Note the various surfaces on which the robot stores instruments. Some are close to the surgeon for quick delivery, while others require the robot to spin around taking more time.

We proved this performance increase by means of a simulation in which the prediction algorithm, after being trained, was run against a test case that was not part of the training set. The basis for comparison was a baseline strategy of keeping the twelve overall most commonly used instruments on the Mayo stand, which is a "fast" cache close to the surgeon. In the simulation, the prediction scores are used to decide which instruments to move forward to fast caches including the transfer zone and which to move back to "slower" caches. The right moves will keep the requisite instruments close to the surgeon, minimizing our primary metric, average instrument delivery time. We found that our algorithm could recommend favorable moves **88%** of the time. This resulted in a **51%** decrease in the average instrument delivery time as compared to our baseline strategy. Moreover, when trained on each surgical procedure from the data set in chronological order, the algorithm's performance improved over time (fig. 17).

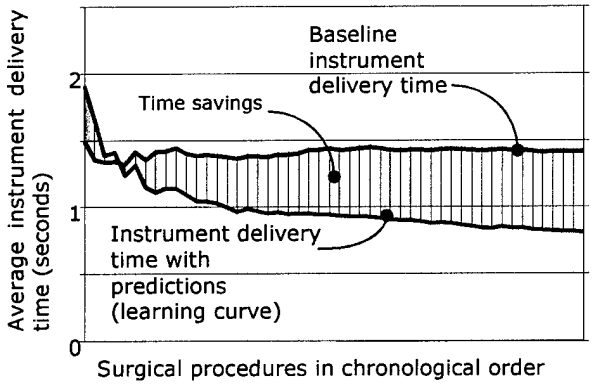


Fig. 17. The chronological learning curve showing the decrease over time in instrument delivery time as the prediction algorithm is trained on more and more data.

In Phase I, we showed how the output of the prediction engine could be used by a simple rule-based system to improve instrument delivery time. This is a first and critical step towards a *rule-based cognitive architecture*. The purpose of the cognitive architecture is to give the robot situational awareness. In our work,

'situational awareness' means a multifaceted knowledge of the status of the procedure so that it can take the appropriate actions that facilitate its completion. Anticipating instrument requests provides a certain amount of situational awareness. A more complete situational awareness enables the robot to deal with routine as well as off-nominal conditions such as errors and emergencies. In addition to the Prediction Engine, we will use the outputs of other systems, such as the vision system, as inputs for rules of behavior. This richer set of rules will bring us closer to our overall goal of a **robotic scrub technician which can match the overall functionality of a human scrub technician in the operating room.**

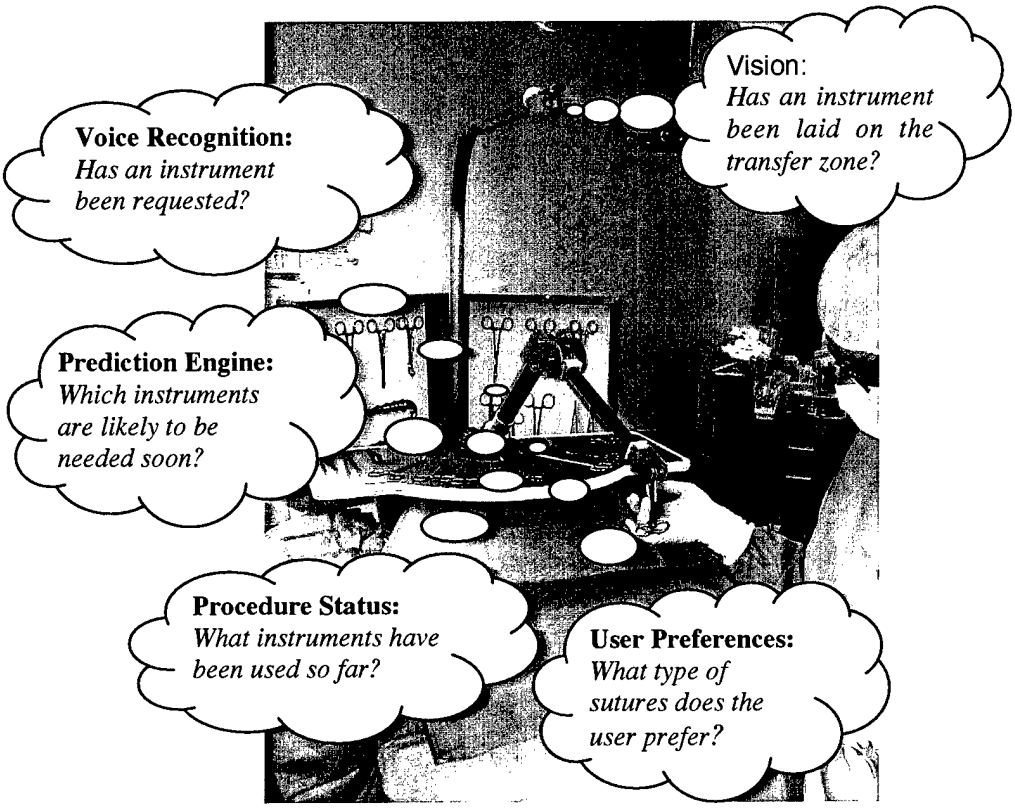


Fig. 18. Functional overview of what a cognitive architecture does for Penelope.

A cognitive architecture (CA) is a description of a mind, uniting the sensory and reasoning subsystems and processes that together provide for cognition. The design of a CA dictates how these subsystems are functionally interrelated. Many CA's of widely varying design have been created during the past 23 years, primarily for the benefit of two fields: cognitive psychology and artificial intelligence. Most of the established CA's have a set of top-level elements in common. Multiple sensory subsystems provide inputs that are considered together before the system produces behavior through one or more physical output subsystems. There is a knowledge base, a set of things it knows to be true without having to reestablish them every time a decision must be made. This corresponds roughly to our human memory, and many CA's divide it into long-term and working memory. Reasoning ability is provided by the *production system*, a set of if-

then rules or 'productions' that together determine the mapping from inputs to output behaviors. Each rule has several conditions and one or more output actions. Every time a new piece of information comes in from an input, the rules are reevaluated to update the system's understanding of the situation, and new actions may be taken. The advantage afforded by a CA is the ability to balance and consider the multiple inputs in producing an overall perception and to reconcile discrepancies in the information from the inputs. These abilities are vital in a system that must understand and participate in the complex OR environment without impeding the operation. The design of our cognitive architecture will draw on that of previously developed systems, particularly one called "Soar". Soar is a very capable system developed for artificial intelligence and has been fielded in applications ranging from intelligent game opponents to fighter plane navigation.

Validating the Cognitive Architecture

To make a distinction between verification and validation, it is often said that "verification is building the system right; validation is building the right system." The 'right system' can be a difficult concept to pin down but we feel that the process outlined will over time result in the clinically desired behavior. To validate the utility of the cognitive architecture, we must devise a suitable means of evaluating its performance as a whole. Testing the entire system requires a realistic setting where the robot will experience the full range of interactions with the OR environment. The main activity will be a repetitive process of validation and modification, until acceptable clinical behavior has been achieved.

Key Research Accomplishments

The vision routines are handling twelve instruments with an accuracy rate of over 98%.
The motion system is currently performing at a 94% accuracy rate.
The completely re-engineered stepper motor arm has been built and is nearing operational status. It was made available for inspection TATRC Day, January 14, 2004. This new arm will take care of accuracy and speed issues.

Reportable Outcomes

A complete design of a full featured, realistic clinical grade system, **Penelope 3**, with supporting documentation needed for FDA application, is well underway.
A physical implementation of Penelope 3 was available for demonstration at TATRC Day, January 14, 2004. This is not the final implementation, since the new arm is not integrated yet, but it convincingly shows the key design features needed for clinical use.
As a result of all of this work, we are in a strong position to apply for our Phase II SBIR funding. Our Phase II SBIR work is about developing a **cognitive architecture** for P-3. The cognitive architecture will extend the instrument prediction software that we developed under the SBIR Phase I work. The **TATRC** sponsored research is entirely supportive of this Phase II application, since this work demonstrates the software and hardware infrastructure needed to make the cognitive system and the entire robot reality.
As a result of this work, we have also won matching funds from the **New York State**

Office of Science, Technology and Academic Research (NYSTAR).
The work has also led to a commitment from Dr. Herbert Pardes, President and CEO of the New York-Presbyterian Hospital to be the first clinical site.
Progress with the development has attracted the attention of local and national media, including the New York Times. The innovation and societal value of the robot are apparent and are well received by health care professionals, hospital administrators, and the public.
Technical success has strengthened our position to reach out to investors. A **business plan** for Robotic Surgical Tech, Inc. has attracted the support of the Columbia Business School faculty and has been accepted into the **Greenhouse Competition.** The Greenhouse competition means that the plan will be vetted by Business School faculty and if successful, will be awarded seed money from the **Lang Fund**, an in-house fund to encourage entrepreneurial activity.

Conclusions

The TATRC research contract has made possible significant improvements in the technology base of the robotic scrub technician. The TATRC support has also been very useful in helping us to gain other types of support, including National Science Foundation support and matching funds from New York State. We believe that *all* of the benefits of *all* this work, technological and other, are contributing to the overall goal of a clinically successful robotic scrub technician. We are very thankful to TATRC for giving us this opportunity. We will do whatever possible to bring credit to TATRC by producing a product that will advance the art of surgical care in both civilian and military settings.

Report respectfully submitted by:

Michael R. Treat MS, MD

February 2004

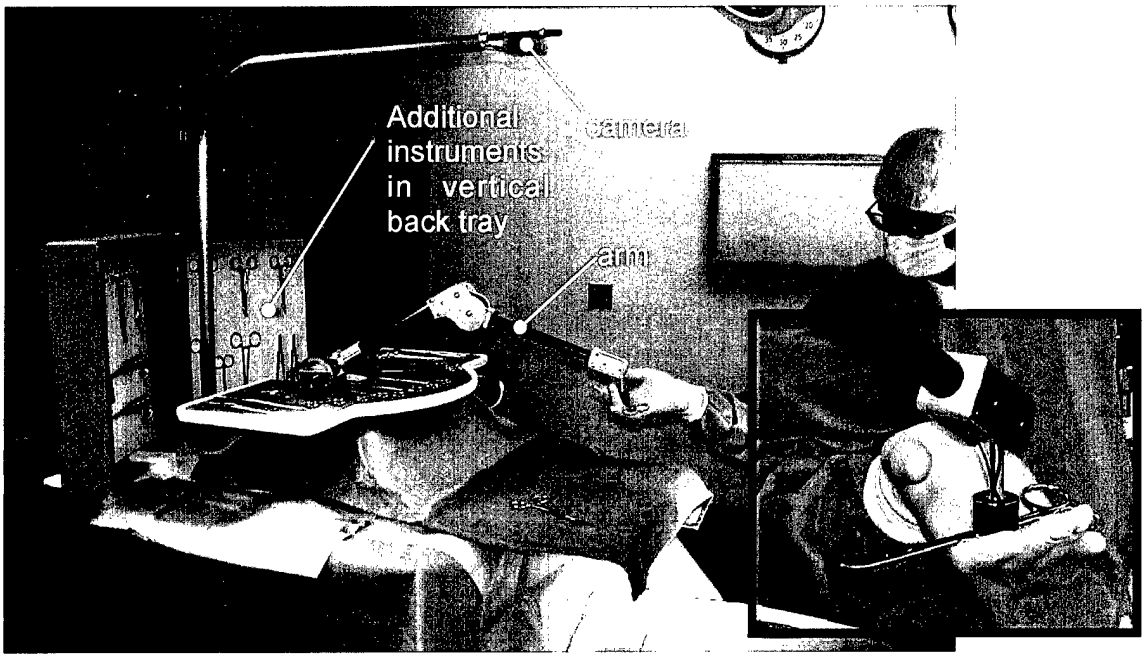


Fig. 19. The ***Penelope 3*** *prototype will be able to handle clinical cases. This robot will be the test-bed for the proposed cognitive architecture to validate overall clinical utility of the entire system, hardware and software, including advances made under the TATRC contract. This version is shown with the new stepper motor arm.*

Fig. 20. Penelope Development Team: from left to right, Michael R. Treat, Russell L. Baker, D. Michael Brady and Jay A. Klein.

References

Surgical Robotics and Surgical Technology

Treat MR. New Technologies and Future Developments for Endoscopic Surgery *in* Endoscopic Surgery (eds. Greene and Ponsky). Philadelphia, W.B. Saunders Co, 1994

Treat MR. Surgical Robotics *in* Principles of Laparoscopic Surgery (eds. Arregui et al.) New York, Springer-Verlag, 1994

Machine Vision

Whelan PF, Molloy D (2001) *Machine Vision Algorithms in Java*, Springer-Verlag

Statistical prediction

Jurafsky D, Martin JH. "N-Grams," *Speech and Language Processing*. Prentice Hall, 2000

Situational Awareness

Nofi AA. Defining and Measuring Shared Situational Awareness. Center for Naval Analyses 4825 Mark Center Drive • Alexandria, Virginia 22311-1850 For copies of this document call: CNA Document Control and Distribution Section at 703-824-2943, November 2000

Sukthankar, R., *Situational Awareness for Tactical Driving*. Ph.D. Thesis, Robotics Institute, Carnegie Mellon University, 1997.

Cognitive Architectures

Isla D, Blumberg B. "Blackboard Architectures," *AI Game Programming Wisdom*. Steve Rabin Ed., Charles River Media, Hingham, Massachusetts, 2002

Isla D, Burke R, Downie M, Blumberg B. A Layered Brain Architecture for Synthetic Creatures The Media Laboratory, Massachusetts Institute of Technology

Newell A, Simon HA. *Human Problem Solving*. Prentice Hall, Englewood Cliffs, NJ, 1972

Newell A. *Unified Theories of Cognition*. Harvard Press: Cambridge, MA, 1990

Laird JE, Newell A, Rosenbloom PS. Soar: An architecture for general intelligence. *Artificial Intelligence, 33*(1): 1-64, 1987

Jones RM, Laird JE, Nielsen PE, Coulter KJ, Kenny P, Koss FV. Automated Intelligent Pilots for Combat Flight Simulation. *AI Magazine*. Spring, 1999.

Anderson J, Lebiere C. *Atomic Components of Thought*. Lawrence Erlbaum, 1998.

Howes A, Young RM. The Role of Cognitive Architecture in Modelling the User: Soar's Learning Mechanism. Human Computer Interaction, Vol.12 No. 4, pp. 311-343, 1997

Verification and Validation

Preece A. Building the Right System Right. *AAAI-98 Workshop on Verification and Validation of Knowledge-Based Systems*, Technical Report WS-98-11, AAAI Press, 1998.

Appendices

Health & Fitness
The New York Times
N F5
TUESDAY, JANUARY 6, 2004

Nursing Shortage Forces Hospitals to Cope Creatively

By LAURIE TARKAN

Banter in the hospital operating room may be less lively if the surgeon's assistant is a robot rather than a nurse, but that is of no concern to the inventor of Penelope. With a six-year-old nursing shortage showing no signs of easing, Dr. Michael R. Treat of the Columbia-Presbyterian Center in Manhattan is hoping that his one-armed robot will replace the nurse who hands the surgeon the instruments, freeing the nurse to give postoperative care.

Other robots already ferry medications and supplies around hospitals.

With mechanical help, flexible shifts and online auctions of shifts, hospitals are surpassing the creative in dealing with the nursing shortage that experts predict will worsen in a decade or two.

The pressure on hospitals to attract and retain nurses continues to grow, largely because of a mounting body of evidence that being short staffed compounds the rate of medical errors and deaths.

On Jan. 1, California became the first state to mandate specific nurse-to-patient ratios. Hospitals there have been scrambling to meet the deadline.

Around the country, using various strategies, some are beginning to see their efforts succeed, leading to lower vacancy rates in nursing jobs, lower turnover and lower mortality rates for patients. In addition, hospitals are seeing higher ratings of satisfaction among nurses and greater satisfaction among patients.

In efforts to keep health care costs down in the 1980's and early 90's, hospitals eliminated nursing positions and tried to increase efficiency, but often at the expense of nurses' working conditions, experts contend, decreasing their flexibility, increasing their workload and reducing their roles in decision making.

About 13 percent of nursing positions nationwide are vacant, the American Hospital Association reports. Experts predict that the rate will increase to 20 percent by 2015.

"Every hospital wants to hire more nurses and improve the working conditions," said Amy Lee, spokeswoman for the American Hospital Association, "but hospitals are in fragile financial states, and some don't have financial capital to do it."

The nursing shortage may have helped Charles Cullen, the nurse who the police say has admitted killing 30 to 40 patients, to move from one hos
Jersey and Pennsy
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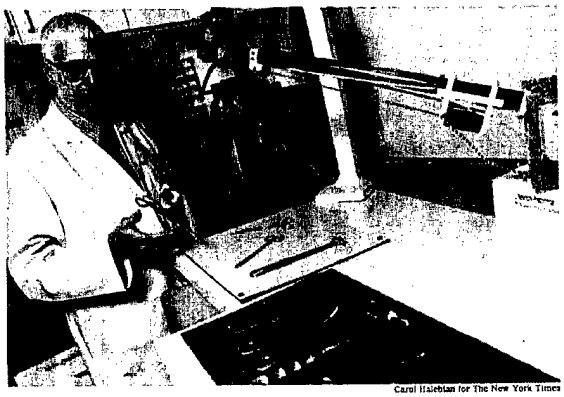
hospitals less cons
to be less particular about their prospective employees, said Dr. Linda Aiken, a professor at the University of Pennsylvania School of Nursing, who is a leading researcher on the shortage.

"High turnover rate," Dr. Aiken said, "is a very big problem and potentially leads hospitals to be desperate to try to get in sufficient numbers of nurses to keep their services open."

Many hospitals have dealt with the shortage by requiring overtime in understaffed



Carol Halebian for The New York Times

Dr. Michael R. Treat hopes his one-armed robot will someday replace the nurse who hands the surgeon the instruments, freeing the nurse to give postoperative care.

That relationship is not the only problem that has to be noticed. A report just released by the Institute of Medicine of the National Academies found that nurses' working conditions were contributing significantly to medical errors.

High patient-to-nurse ratios, fatigue on long shifts and mandatory overtime, a lack of experienced staff, and inadequate time to monitor patients have been associated with poor medical results and higher death rates for patients, the report said.

"Nurses can commit errors, and they also play a crucial role in protecting patients from errors," said Dr. Donald M. Steinwachs, who led the panel that issued the report.

According to a paper by the Joint Commission on the Accreditation of Healthcare Organizations, low numbers for nursing staffs was a factor in 19 percent of medical errors resulting in deaths or serious injuries in hospitals. Nurses' inadequate orientation and training were cited as factors in 58 percent of serious errors.

A study by Dr. Aiken found that patients scheduled for routine surgery were 31 percent more likely to die in a hospital with a patient-to-nurse ratio of eight to one than in a hospital with a ratio of four to one. The study was published last year in The Journal of the American Medical Association.

A majority of nurses say they believe that they cannot do their jobs as well under their current working conditions, a 2001 survey by the American Nurses Association shows.

The survey found that 75 percent of nurses said the quality of nursing care at their medical centers had declined in the prior two years. More than 40 percent said they would not feel comfortable having a family member cared for in their hospitals.

January 6, 2004 article from the *New York Times* featuring Penelope. For the full text of the article visit our website at http://www.roboticsurgicaltech.com/NYTimesArticle.pdf

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June 17, 2003

Michael R. Treat, M.D.
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Dear Michael,

Thanks very much for the information on the Robotics Scrub Tech project. I believe you said a clinical debut was possible in 2004. I gather that you are working closely with David Liss. It may well be that you cannot be anymore specific about the date for a rollout, but I am excited about the possibility of rolling it out first at NewYork-Presbyterian and am very pleased with the work you are doing.

Let me know what you think and keep me posted.

All the best.

Sincerely,

Herbert Pardes, M.D.

HP/ys

cc: Jonathan David Liss

Letter of support from Dr. Herbert Pardes, President and CEO of New York-Presbyterian Hospital, stating his interest in being the first customer for the robotic scrub technician.

Penelope System

PS-RSD-090803, Draft 1

Requirements Specification Document

ROBOTIC SURGICAL TECH, Inc.

September 8, 2003

Penelope System

Requirements Specification Document

(PS-RSD-090803, Draft 1)

SEPTEMBER 8, 2003

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ABSTRACT

The Penelope System Requirements Specification Document, PS-RSD-090803, is provided in accordance with the Penelope System Project Plan, PS-PP-<TBD>. This document is prepared by Robotic Surgical Tech, Inc. It contains the requirements for development of the Penelope System Robotic Scrub Technician.

KEY WORDS

Robotics	Hospital Automation	Scrub Technician
Surgery	Requirements	Specification

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ABBREVIATIONS AND ACRONYMS

OR	Operating Room
PS	Penelope System
RST	Robotic Surgical Tech, Inc.
SIU	Scrubbed Instrument User
TBD	To Be Determined

SECTION 1, INTRODUCTION

1.1 SYSTEM OVERVIEW

The Penelope System Robotic Scrub Technician is designed to perform the functions of the scrub nurse or technician in the Operating Room (OR). The robot uses voice recognition to respond to a surgeon's request for an instrument. A manipulator arm with an electromagnetic gripper delivers the instrument from the Mayo stand to the surgeon. When the surgeon is finished with the instrument he/she places it on the transfer zone. The vision system equipped with a digital camera locates and identifies the instrument and provides coordinates to the motion control system to direct the robot's arm to retrieve the instrument.

In general terms, the objectives of the Penelope System are to:

A. Listen for instrument requests from the surgeon or, more generally, any scrubbed instrument user (SIU).

B. Deliver requested instruments from either the Mayo stand or the back tray to either the SIU or the transfer zone.

C. Scan the transfer zone for relinquished instruments.

D. Move relinquished instruments from the transfer zone to the Mayo stand.

E. Give a verbal instrument count when requested.

1.2 DOCUMENT OVERVIEW

This document defines the design requirements for the Penelope System Robotic Scrub Technician. All requirements for the system are defined herein. All requirements defined in this document will be mapped to one or more system components documented in the System Design Document (PS-SDD-TBD). Furthermore, during system validation testing, each requirement defined herein will be tested for compliance as per the Verification And Validation Plan (PS-VV-TBD). Successful completion of the Penelope System Robotic Scrub Technician will be defined as the successful validation of all of the requirements defined in this document.

These design requirements will be broken down into three categories: functional, performance, and interface. Functional requirements define the operational capabilities of the system. They describe the high-level tasks the system shall perform. Performance requirements define the set of quantitative, measurable parameters within which the system must operate to be effective and safe. They include parameters describing the performance of the robot and the environmental conditions under which the robot must

be operated. Interface requirements define all interdependencies between the Penelope System and external systems. This includes any interactions with human operators.

1.3 USAGE LIMITATIONS

The term *scrubbed instrument user*, or SIU, is used to refer to any OR team member who is sterile and can manipulate instruments. Any requirement relating to the transfer of instruments to or from a human is restricted to SIUs in accordance with the Proper Use Procedures (<document number TBD>) for the system. The Penelope System is specifically *not* required to distinguish between SIUs and nonsterile personnel in any way. Any attempt by nonsterile personnel to access the instrument transfer capabilities of the Penelope System is considered improper use of the system.

All surgical instruments introduced into the Penelope System's instrument set must be sterile in accordance with the Proper Use Procedures (<document number TBD>) for the system. The Penelope System is specifically *not* required to distinguish between sterile and nonsterile instruments. Any attempt to introduce nonsterile instruments into the Penelope System is considered improper use of the system.

Any command input to the system, such as a voice command, is restricted to authorized OR team members in accordance with the Proper Use Procedures (<document number TBD>) for the system. The Penelope System is specifically *not* required to distinguish between command inputs from authorized OR team members and unauthorized personnel. Any attempt by unauthorized personnel to issue commands to the Penelope System is considered improper use of the system.

All requirements relating to the manipulation or processing of surgical instruments in any way is restricted to only those instruments of a type listed in requirement 3.1.3.1, "Supported Instrument Types."

<TBD: more about what we do not *have the ability to know. This is the garbage-in garbage-out section.>*

SECTION 2, APPLICABLE DOCUMENTS LIST

2.1 APPLICABLE DOCUMENTS

The following documents form a part of these requirements to the extent specified herein.

RST:

PS-SG-090803	Penelope System Glossary
PS-PP-<TBD>	Penelope System Project Plan
PS-SDD-<TBD>	Penelope System Design Document

FDA:

<TBD>

UL:

<TBD>

SECTION 3, ENGINEERING REQUIREMENTS

3.1 FUNCTIONAL REQUIREMENTS

3.1.1 Start Up And Shut Down Requirements

The following subparagraphs list all functional requirements related to the processes of starting up and shutting down the Penelope System.

3.1.1.1 Power_Up_Command

Upon receipt of a Power_Up_Command, the Penelope System shall perform the following operations in order.

1. Issue a System_Start_Up_Command.
2. Determine whether the robotic arm is properly positioned in its designated initial position.
3. If the arm is not properly positioned, announce "*<TBD: warning>*" and then issue a System_Shut_Down_Command.
4. Otherwise, move the robotic arm to its home position and begin command processing.

3.1.1.2 System_Start_Up_Command

Upon receipt of a System_Start_Up_Command, the Penelope System shall perform the following operations in order.

1. Supply power to all system components, including the microcontroller, the robotic arm, and System Control Processor.
2. Wait for the System Control Software to issue a System_Started_Command, indicating that the System Control Software has been successfully initialized.
3. If, after *<TBD: number>* seconds, no System_Started_Command is issued, remove power to all system components, including the microcontroller executing this procedure.
4. Otherwise, continue.

3.1.1.3 Power_Down_Command

Upon receipt of a Power_Down_Command, the Penelope System shall perform the following operations in order.

1. Move the end effector and any instrument it may be holding to a resting position on the instrument platform, such that the robotic arm will not fall when power is removed.

2. Issue a System_Shut_Down_Command.

3.1.1.4 System_Shut_Down_Command

Upon receipt of a System_Shut_Down_Command, the Penelope System shall perform the following operations in order.

1. Remove power to the robotic arm.

2. Issue a System_Halt_Command to the System Control Software instructing it to cease execution and halt the System Control Processor.

3. Wait for the System Control Processor to shut down.

4. If, after *<TBD: number>* seconds, the System Control Processor has not shut down, continue to the next step.

5. Remove power to all remaining system components, including the System Control Processor and the microcontroller executing this procedure.

3.1.1.5 Halt_Command

Upon receipt of a Halt_Command, the Penelope System shall stop any movement of the robotic arm, terminate the processing of any other commands in progress, and disable any command input other than the Power_Down_Command or the Resume_Command. If upon receipt of a Halt_Command the end effector is currently holding an instrument, the Penelope System shall continue to hold that instrument.

3.1.1.6 Resume_Command

Upon receipt of a Resume_Command, the Penelope System shall enable movement of the robotic arm, issue a Cancel_Command, and enable command input for all commands.

3.1.2 Instrument Request Requirements

The following subparagraphs list all functional requirements related to the handling of requests for instruments by SIUs.

3.1.2.1 Gestural Instrument Requests

The Penelope System shall detect and identify gestural instrument requests from SIUs. Upon identification of a gestural instrument request, the Penelope System shall issue an Instrument_Request_Command. *<TBD: more detail here about what kinds of gestures and so on.>*

3.1.2.2 Multiple Instrument Requests

The Penelope System shall be capable of handling more than one Instrument_Request_Command at a time. If during the processing of one such command another is issued, the Penelope System shall store the pending requests for later processing. These pending instrument requests are not required to be processed in any particular order.

3.1.2.3 Instrument_Request_Command: Instrument Is Not Available

Upon receipt of an Instrument_Request_Command, if all instruments of the requested type are in use, the Penelope System shall announce "*<TBD: warning>*". This requirement defines a special condition for the Instrument_Request_Command.

3.1.2.4 Instrument_Request_Command: Holding An Instrument

Upon receipt of an Instrument_Request_Command, if the end effector is currently holding an instrument, the Penelope System shall check to see if the instrument being held is of the type requested. If so the instrument being held shall be delivered to the SIU. Otherwise, the Penelope System shall issue a Free_End_Effector_Command and then continue processing the Instrument_Request_Command. This requirement defines a special condition for the Instrument_Request_Command.

3.1.2.5 Instrument_Request_Command

Upon receipt of an Instrument_Request_Command, if there are no special conditions for this command, the Penelope System shall deliver the requested instrument from the instrument cache or transfer zone to the SIU.

3.1.2.6 Instrument Request Voice Feedback

If so configured, the Penelope System shall, after identifying an instrument request, if there is an instrument of the requested type that is not in use, announce the instrument type as feedback for the SIU.

3.1.2.7 Configurable Instrument Delivery Mode

The Penelope System shall be configurable so as to allow the surgeon to specify a preference for either handoff instrument delivery or transfer zone instrument delivery. The preferred delivery method shall be attempted first.

3.1.2.8 Ignored Instrument Requests

If an SIU requests an instrument but does not take it after delivery, the Penelope System shall, after no less than *<TBD: number>* seconds, return the instrument to the instrument cache.

3.1.3 Instrument Set Requirements

The following subparagraphs list all functional requirements related to the supported instrument types and the maintenance of a list of instruments used in a surgical procedure.

3.1.3.1 Supported Instrument Types

The Penelope System shall support the following surgical instrument types.

Large Ricardson Retractors	Skin Hooks
Medium Ricardson Retractors	Yankauer Suction
Small Ricardson Retractors	Poole Suction Tip
Baby Ricardson Retractors	Frazier Suction
Large Loop Retractors	Needle Holder
Small Loop Retractors	Plastic Needle Holder
Bull Retractors	Short Sponge Stick
Bent Weitlander Retractors	Curved Adsons
Plastic Raker Retractors	Babcocks
Plastic Vein Retractors	Kochers
#3 Knife Handle	Kellys
#2 Knife Handle	Allis
Groove	Curved Mosquitos
Probe	Criles (Straight)
Debakey Forceps 5 1/2	Curved Criles (Hopkins)
Plain Forceps	Straight Mayo Scissors
Mouth Tooth Forceps	Curved Mayo Scissors

Brown Adson Forceps	Metzenbaum Scissors 7in.
Plastic Mouth Tooth Forceps	Plastic Straight Scissors
Appendix Forceps	Plastic Curved Scissors

3.1.3.2 Retain_Back_Tray_Instrument_Command

Upon receipt of a Retain_Back_Tray_Instrument_Command, the Penelope System shall remove an instrument of the specified type from the back tray and add it to the instrument set.

3.1.3.3 Retain_Added_Instrument_Command

Upon receipt of a Retain_Added_Instrument_Command, the Penelope System shall ascertain the instrument's type, move it from the receiving zone to the transfer zone or instrument cache, and add it to the instrument set.

3.1.3.4 Instrument Set Size Warning

Upon receipt of either a Retain_Back_Tray_Instrument_Command or a Retain_Added_Instrument_Command, if the size of the instrument set after the instrument is retained is within *<TBD: number>* instruments from the maximum size specified in requirement 3.2.1.3, "Instrument Sets," the Penelope System shall announce "*<TBD: warning>*".

3.1.3.5 Discard Stack

Upon receipt of either a Retain_Back_Tray_Instrument_Command or a Retain_Added_Instrument_Command, if the size of the instrument set before the instrument is retained is equal to the maximum size specified in requirement 3.2.1.3, "Instrument Sets," the Penelope System shall move one instrument from either the Mayo stand or staging zone to the discard stack and then proceed with the given command.

3.1.3.6 Withdraw_Instrument_Command: Instrument Is In Use

Upon receipt of a Withdraw_Instrument_Command, if an instrument of the specified type is currently in use, the Penelope System shall remove one in use instance of that type from the instrument set.

3.1.3.7 Withdraw_Instrument_Command: Instrument Is Not In Use

Upon receipt of a Withdraw_Instrument_Command, if no instrument of the specified type is currently in use, the Penelope System shall announce "*<TBD: warning>*".

3.1.3.8 Instrument_Count_Command

Upon receipt of an Instrument_Count_Command, the Penelope System shall give a verbal instrument count listing, for every instrument type in the instrument set, the quantity in use, the quantity in the ready state, and the quantity withdrawn.

3.1.3.9 Specific_Instrument_Count_Command

Upon receipt of an Specific_Instrument_Count_Command, the Penelope System shall give a verbal instrument count listing, for the specified instrument type, the quantity in use, the quantity in the ready state, and the quantity withdrawn.

3.1.3.10 Shared_Instrument_Count_Command

Upon receipt of a Shared_Instrument_Count_Command, the Penelope System shall <TBD: determine exactly how this procedure between Penelope and the circulating nurse will be carried out.>

3.1.4 Instrument Movement Requirements

The following subparagraphs list all functional requirements related to the movement of and handling of surgical instruments by the robotic arm.

3.1.4.1 Relinquished Instrument Scanning

The Penelope System shall detect, locate, and identify the type of any relinquished instrument on the transfer zone. This shall be accomplished regardless of the orientation of the instrument or whether it is open or closed.

3.1.4.2 Relinquished Instrument Return

The Penelope System shall be capable of moving a relinquished instrument from any point on the transfer zone to either the Mayo stand or the staging zone. This shall be accomplished regardless of the orientation of the instrument or whether it is open or closed.

3.1.4.3 Instrument Closing

The Penelope System shall be capable of determining if a scissor-action instrument is open and, if so, closing it before putting it on the Mayo stand or staging zone.

3.1.4.4 Instrument Storage Orientation

The Penelope System shall be capable of determining the orientation of an instrument on the transfer zone and rotating it so that it can be stored efficiently on the Mayo stand or staging zone. This shall be accomplished regardless of the orientation of the instrument.

3.1.4.5 Instrument Delivery Orientation

When executing either a handoff instrument delivery or a transfer zone instrument delivery, the Penelope System shall orient the instrument in a predefined delivery orientation that shall be specified for each instrument type.

3.1.5 Command Cancellation Requirements

The following subparagraphs list all functional requirements related to the cancellation of command inputs into the system.

3.1.5.1 Cancel_Command: Holding An Instrument

Upon receipt of a Cancel_Command, if the end effector is currently holding an instrument, the Penelope System shall issue a Free_End_Effector_Command and then continue processing the Cancel_Command. This requirement defines a special condition for the Cancel_Command.

3.1.5.2 Cancel_Command

Upon receipt of a Cancel_Command, if there are no special conditions for this command, the Penelope System shall return the robotic arm to its home position and disregard any pending commands being processed.

3.1.5.3 Free_End_Effector_Command

Upon receipt of a Free_End_Effector_Command, if the end effector is currently holding an instrument, the Penelope System shall return that instrument to either the transfer zone or the instrument cache.

3.2 PERFORMANCE REQUIREMENTS

3.2.1 Safety Requirements

The following subparagraphs list all performance requirements related to the overall safety of the Penelope System.

3.2.1.1 Human Safety

The Penelope System shall not be capable of harming the patient or any OR staff member. This includes the following.

Harm due to physical contact with the robotic arm.

Harm due to physical contact with a surgical instrument being held by the arm.

Harm due to physical contact with a surgical instrument that has been dropped by the robotic arm.

Harm due to any form of electromagnetic contact.

3.2.1.2 Surgical Procedure Preclusion

The Penelope System shall not, under any operating condition either nominal or aberrant, be capable of precluding the completion of the surgical procedure. The complete failure of the Penelope System to operate at all shall not preclude the completion of the surgical procedure.

3.2.1.3 Electromechanical Device Safety Standards

The Penelope System shall be designed in accordance with and tested for compliance with the following standards as they apply to electromechanical medical devices in general and the Penelope System in particular.

UL 2601-1

IEC 60601-1

IEC 60601-1-4 Software Collateral Standard *<TBD: Is this applicable?>*

<TBD: Others?>

3.2.1.4 Robotic Arm Operational Envelop

The Penelope System shall not, under any operating condition either nominal or aberrant, be capable of moving the robotic arm so that any portion of it extends beyond the

maximum operational envelop. The perimeter of this operational envelop shall be defined by the perimeter of the instrument platform and it shall extend upward, perpendicular the surface of the Mayo stand, to a height of *<TBD: number>* centimeters above the Mayo stand.

3.2.2 Sterility Requirements

The following subparagraphs list all performance requirements related to the maintenance of proper sterile technique for all sterile surfaces and interactions with the robotic arm.

3.2.2.1 Sterile Drape Set

The Penelope System shall include a set of sterile drapes covering all sterile surfaces of the system. These surfaces are defined as follows.

robotic arm

back tray

receiving zone

Mayo stand

staging zone

transfer zone

upper system stand assembly

Once draped the Penelope System shall meet all sterility requirements listed in *<TBD: OR sterility guidelines/requirements document>*.

3.2.2.2 Sterile Draping Procedure

The Penelope System shall define a sterile draping procedure specifying step-by-step instructions to be followed by a nonsterile OR team member to apply the sterile drape set to all sterile surfaces. This procedure shall adhere to all sterility requirements listed in *<TBD: OR sterility guidelines/requirements document>*.

3.2.2.3 Repairing Breaks In Sterile Technique

The Penelope System shall define a procedure for repairing breaks in sterile technique caused by unintentional contact between some part of the system and nonsterile personnel or equipment. Repair procedures shall be defined for each the following.

robotic arm

back tray

receiving zone

Mayo stand

staging zone

transfer zone

upper system stand assembly

3.2.2.4 Sterility Level

All sterile draping and sterile materials included in the Penelope System shall meet all sterility requirements specified in <*TBD: some standard. FYI: Aesop out sourced their sterile draping to Hydro-Med Products, Inc. and boasts a 1996 sterility validation to ANSI/AAMI/ISO Standard 11135-1994. They also claim a sterility level of* 10^{-6}>.

3.2.3 Instrument Safety Requirements

The following subparagraphs list all performance requirements related to the safe handling of surgical instruments.

3.2.3.1 Instrument Release Height

The Penelope System shall not, under any operating condition either nominal or aberrant, release a surgical instrument from the end effector from a height of more than *<TBD: number>* centimeters from either the instrument platform or an SIU's hand.

3.2.3.2 Instrument Surface Safety Rims

The Penelope System shall include, on all sterile surfaces on which instruments will be placed, a safety rim around the surface's perimeter raising no less than *<TBD: number>* centimeters.

3.2.3.3 Residual Magnetism

The Penelope System shall not, through the handling of any surgical instrument, induce a residual magnetism in that instrument of sufficient strength to allow the instrument to lift a ferromagnetic object weighing *<TBD>* grams or more.

3.2.4 Anomaly Detection Requirements

The following subparagraphs list all performance requirements related to the detection and handling of anomalous operating conditions.

3.2.4.1 Power Interruption

The Penelope System shall be capable of detecting the loss of electrical power. At such time a Power_Down_Command shall be issued and executed.

3.2.4.2 Impeded Motion Detection

The Penelope System shall be capable of detecting any impediment to the motion of the robotic arm. At such time the Penelope System shall announce "*<TBD: warning>*".

3.2.5 Instrument Handling Performance Requirements

The following subparagraphs list all performance requirements related to the Penelope System's speed and accuracy in handling surgical instruments.

3.2.5.1 Instrument Delivery Speed: Handoff Delivery

The time required for the Penelope System to deliver an instrument from the Mayo stand to an SIU, when no instrument is currently being held by the end effector, shall not exceed <*TBD: perhaps 3*> seconds. This delivery time shall be measured from the completion of the instrument request to the arrival of the instrument within the nominal instrument handoff zone as defined in section "<*TBD*>" in the System Design Document (PS-SDD-<*TBD*>).

3.2.5.2 Instrument Delivery Speed: Transfer Zone Delivery

The time required for the Penelope System to deliver an instrument from the Mayo stand to the transfer zone, when the end effector is currently holding no instrument, shall not exceed <*TBD*> seconds. This delivery time shall be measured from the completion of the instrument request to the release of the instrument.

3.2.5.3 Instrument Sets

The Penelope System shall support instrument sets comprised of instruments of any type defined in requirement <*TBD: Paragraph Number*>, "Supported Instrument Types." Instrument sets up to and including a maximum of <*TBD*> instruments shall be supported.

3.2.5.4 Instrument Weight

The Penelope System's robotic arm shall support instruments up to and including a maximum weight of <*TBD*> kilograms.

3.2.5.5 Instrument Request Replicability

The Penelope System shall be capable of repeating the process of identifying an instrument request, delivering the instrument to the SIU, identifying that instrument when it is relinquished, and returning it to the Mayo stand through no less than <*TBD: number*> iterations without any cumulative degradation of accuracy.

3.2.5.6 False-Positive Relinquished Instrument Identification

The Penelope System shall achieve a false-positive error rate for relinquished instrument identification of no more the <*TBD*>%. A false-positive relinquished instrument identification error is defined as the perception by the system that a relinquished instrument is on the transfer zone when that instrument is not in fact present. This also

includes the case where a valid instrument is on the transfer zone, but not the one the system identifies.

3.2.5.7 True-Negative Relinquished Instrument Identification

The Penelope System shall achieve a true-negative error rate for relinquished instrument identification of no more the *<TBD>*%. A true-negative relinquished instrument identification error is defined as the failure of the system to correctly identify a relinquished instrument on the transfer zone that is known to be in use.

3.2.6 Verbal Command Recognition Performance Requirements

The following subparagraphs list all performance requirements related to the accuracy of the Penelope System's speech recognition system.

3.2.6.1 False-Positive Verbal Command Recognition

The Penelope System shall achieve a false-positive error rate for verbal command recognition of no more the *<TBD>*%. A false-positive verbal command recognition error is defined as the recognition by the system of a verbal command when that command was not given. This also includes the case where a valid verbal command was given but was incorrectly identified by the system.

3.2.6.2 True-Negative Verbal Command Recognition

The Penelope System shall achieve a true-negative rate for verbal command recognition of no more the *<TBD>*%. A true-negative verbal command recognition is defined as the failure of the system to recognize a verbal command.

3.2.7 Environmental Requirements

The following subparagraphs list all performance requirements related to the operational conditions under which the Penelope System must function.

3.2.7.1 Electrical Power

The Penelope System shall operate on AC power at any voltage from *<TBD: maybe 108>* volts to *<TBD: maybe 132>* volts.

3.2.7.2 Noise Level

The Penelope System shall be capable of meeting all verbal command recognition requirements in an environment with an ambient noise level up to *<TBD: number>* decibels.

3.2.7.3 Lighting Level

The Penelope System shall be capable of meeting all instrument identification and handling requirements in an environment with an ambient light level as low as *<TBD: number>* lumens per square meter.

3.2.7.4 Splash Resistance

The Penelope System shall be capable of withstanding splash exposure to as much as *<TBD: number>* liters of blood, bodily fluids, or disinfectant solution without sustaining any performance reducing damage.

3.2.8 Structural Requirements

The following subparagraphs list all performance requirements related to the structural integrity of the Penelope System.

3.2.8.1 System Stand Strength and Stability

The system stand of the Penelope System, with all functional components attached, shall capable of supporting, without tipping over or sustaining any structural damage, a weight of no less than *<TBD: number>* kilograms placed at any point on the instrument platform.

3.2.8.2 Total Weight

The total weight of the Penelope System, with all functional components attached, shall not exceed *<TBD: number>* kilograms.

3.2.8.3 Impact Resistance

The Penelope System shall be capable of withstanding, without sustaining any performance reducing damage, an impact from a mass of up to *<TBD: number>* kilograms traveling at a velocity of up to *<TBD: number>* meters per second. This impact shall be withstood when applied to any exposed surface of the Penelope System. *<TBD: Need a more precise way of expressing this, possibly in terms of momentum.>*

3.3 INTERFACE REQUIREMENTS

3.3.1 System Control Input Requirements

The following subparagraphs list all interface requirements related to the input of commands into the Penelope System.

3.3.1.1 Voice Commands

The Penelope System shall be capable of detecting and the activating of the following commands through voice input.

Instrument_Request_Command

Cancel_Command

Instrument_Count_Command

Specific_Instrument_Count_Command

Shared_Instrument_Count_Command

Retain_Added_Instrument_Command

Withdraw_Instrument_Command

3.3.1.2 Master Power Switch

The Penelope System shall include a power switch, which either engages or interrupts power to all system components.

3.3.1.3 Halt/Resume Button

The Penelope System shall include on the control panel a toggle button or switch via which an OR team member can alternatively issue either a Halt_Command or a Resume_Command.

3.3.1.4 Power Down Button

The Penelope System shall include on the control panel a button via which an OR team member can issue a Power_Down_Command.

3.3.2 System Mode Feedback Requirements

The following subparagraphs list all interface requirements related to the output of system mode information from the Penelope System.

3.3.2.1 Power Indicator

The Penelope System shall include an visible indicator signifying that the system is powered.

3.3.2.2 Verbal Command Input Indicator

The Penelope System shall include an visible indicator signifying that the system is listening for voice commands.

3.3.3 Mobility And Positioning Requirements

The following subparagraphs list all interface requirements related to moving the Penelope System around and positioning it prior to a surgical procedure.

3.3.3.1 In-Hospital System Stand Transportability

It shall be possible for one person to accomplish in-hospital transportation all functional components of the Penelope System across a level, flat surface.

3.3.3.2 Robotic Arm In-Transit Tie-down

The Penelope System shall include a mechanism for securing the robotic arm during transportation.

3.3.3.3 Cabling In-Transit Tie-down

The Penelope System shall include a mechanism for securing all required cabling during transportation.

3.3.3.4 System Stand In-Transit Envelop

During in-hospital transportation, all functional components of the Penelope System shall be no more than <*TBD: number*> centimeters wide and <*TBD: number*>centimeters tall.

3.3.3.5 System Stand Positioning Lock-down

The Penelope System shall include a mechanism for locking the system stand down so that it cannot move. The Penelope System shall also include a mechanism for unlocking the system stand.

3.3.3.6 System Stand Positioning Over OR Table

The Penelope System shall include a mechanism for positioning the system stand at any point over the operating table.

3.3.3.7 System Stand Height Adjustment

The Penelope System shall include a mechanism for adjusting the height of the system stand from <*TBD: number*>centimeters to <*TBD: number*>centimeters above the floor.

3.3.4 Field Maintenance Requirements

The following subparagraphs list all interface requirements related to maintenance of the Penelope System after it has been deployed.

3.3.4.1 Field Repairable Components

The following system components shall be repairable by qualified service personnel at the installation site.

robotic arm

instrument deck

camera mount assembly

<TBD: Identify these components. This is essentially the list of replacement parts a technician would carry around.>

3.3.4.2 System Diagnostics

The Penelope System shall include a set of diagnostic tests that can be run by a qualified service representative. These tests shall confirm that all essential components of the system are functioning in accordance with their specifications. *<TBD: list which components must be tested.>*

3.3.4.3 System Software Upgrades

The Penelope System shall include a mechanism allowing qualified service personnel to upgrade portions of the system software as required. Any such update shall not invalidate or corrupt any site-specific data stored for the installation. *<TBD: list types of software upgrades.>*