Demo Requirements Specification

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| Rev | Date | Author | Description |
|-----|---------|--------|-----------------------------------------------------------|
| 1 | 6/10/04 | SWD | Initial draft |
| 2 | 6/10/04 | SWD | Integrated some initial comments from Susan and Q (only a |
| | | | partial edit). |
| 3 | 6/11/04 | SWD | Finished integrating comments from Susan and Q. |

Introduction

The state of this document is pretty rough and will stay that way for a while. The content of the document will change in the following dimensions over the next few weeks:

- 1. Some of the screen presentations will change as Edie's art director makes changes and as we see how the demo fits together. It is anticipated that most of these changes will require little changes in the spec (the functionality of the screens might not change) and hopefully little changes to the coding (optimistically most of these changes will be in the stylesheets). I'm not even sure that the screenshots that I have are the latest. Please let me know where I have old screens or screens that are about to be old.
- 2. There are some inconsistencies that need to be nailed down. These have been labeled below.

- 3. There is some missing information. Anytime you see a TBD it means that I know something is to be done for the demo (or something may have been done but I don't know about it). Sometimes a ?? is used when a small addition is needed to the spec.
- 4. The requirements need to be clearly numbered so that they can be referred to in other documents and in Mantis.
- 5. The definition of the screens and the relationships between them are the main intent of this document. Other requirements are put up front because they are important. For the demo we probably don't need to add more requirements (I hope).
- 6. This document builds on top of the storyboard. The storyboard needs a bit more work (there are multiple markups of comments; it's not clear what approval state it is in) but it is close to being converged.

User Interface Requirements

General User Interface Requirements

- 1. User interfaces should be visually in the same family unless there is some compelling reason to do something different. Fonts, colors, general layout, names of actions are all covered by this requirement.
- 2. The demo user interface must provide the illusion of a finished product. This means:
- 3. All links must do something plausible or be no-ops.
- 4. The demo is a closed universe. All behavior is predictable.
- 5. On screens containing patient demographics the patient identifiers (patient name, medical record number) should always be visible on the screen. Scrolling the window must not remove the patient identifiers or there must be multiple identifiers to ensure that the patient identifiers are not offscreen.
- 6. Image viewer
 - a. Image presentation must be correct. This must be verified against an external program (DICOMScope) to ensure that window/level, bit masking, and any other DICOM image presentation logic has been correctly applied.
 - b. Demographics are displayed on each image. There are three types of demographics:
 - i. Patient demographics (name, medical record number, date of birth (or age if date of birth is not available)
 - ii. General study information: study date and time.
 - iii. Modality specific information: KVP, echo number.
 - c. A particular study must be able to be bookmarked in a browser.
 - d. Any page which launches the order form or the WADO viewer must detect the size of the window in which the order form/WADO viewer will be

- rendered and pass this as a URL parameter. This permits rendering in landscape or portrait mode.
- e. Resizing the window may cause a refresh of the entire window if the resizing transforms a window from landscape to portrait aspect ratios (or vice versa).
- 7. Speed. CT images 4 fps on a 1GHz machine with the router running over a 100Mb conection.
- 8. Usability Requirements. TBD.

Browser requirements

- 1. All screens will work in a browser with zero installation required. No JRE, no ActiveX controls.
- 2. The demo must support Internet Explorer 6.0 because this is what our customers run.
- 3. The demo should support Mozilla 1.7 because it makes life easier for developers: the debugging tools are superior to the ones in IE. In the future Mozilla support may be necessary for supporting client platforms other than Windows because Windows is the only platform where IE runs (IE on the Macintosh has been discontinued).
- 4. If a feature is not supported in Mozilla the following is required: a Mantis bug must be filed describing the problem. This does not mean it will be fixed in the product; only that it is documented.
- 5. The following screen dimensions must be supported:
 - a. Tablet (both portrait/landscape put pixel dimensions here)
 - b. 1600x1200 (typical desktop monitor)

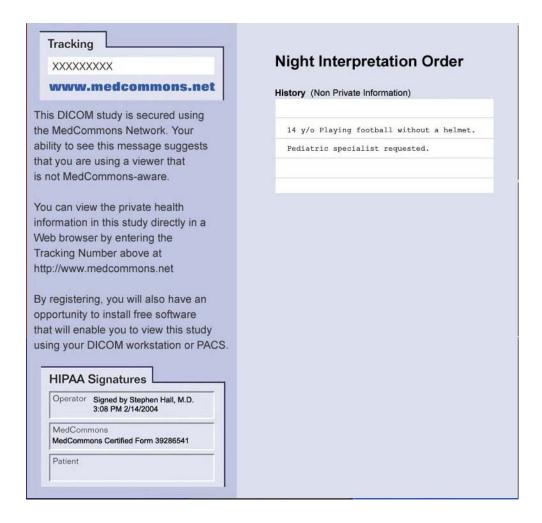


Central System Requirements

- 1. The central system must always be available.
- 2. The central system accepts HIPAA logging information. For the demo there are two types of loggable events:
 - a. Order Submitted.
 - b. Order Viewed.
- 3. The central system provides GUIDs to clients which ask for them. These GUIDs are used to identify studies and orders.

Screen Definitions

DICOM Invitation



Why it exists: The DICOM invitation is an invitation to a potential customer from a current MedCommons customer. It's a word-of-mouth advertising mechanism – one user thinks that another will want to be notified of a certain order. When they receive this as an email they can immediately go to the order to view its contents.

What data is presented:

| Field | Use |
|-----------------|-----------------------------------------------|
| Tracking Number | Assigned by Central when the order was |
| | created. Used by Central as the identifier of |
| | the order. |

| Invitation text | Describes to the recipient what |
|--------------------------------------|-----------------------------------------------|
| _ | MedCommons is. |
| HIPAA Signatures: Operator | Name of person who sent the order. |
| HIPAA Signatures: Form Number | Static text. In the future this is the number |
| | of the form; MedCommons only permits |
| | registered forms to be used here. |
| HIPAA Signatures: Patient | TBD ?? Patient name? How could this be |
| 7 | here and have this be a non-HIPAA |
| | loggable event? |
| History: non-private patient history | Contains patient medical history relevant to |
| | the order. Must not contain any patient |
| | identifying information (otherwise – |
| | reading the invitation would itself be a |
| | HIPAA loggable event) |

Actions:

TBD:

There is a conflict here about what makes sense for the demo. The text of the invitation says to enter the tracking number on the MedCommons site. We we don't have a screen for this in the demo. Also – some implementation suggestions have included making this a JPEG which means that the tracking number can't be cut&pasted.

Alternatively – we could just make this clickable (a better UI choice in my opinion). But we should then change the text to match the action.

Further details:

- The text currently claims that the doctor's viewer isn't 'MedCommons-aware'. This needs to be defined a bit more perhaps just for verbal descriptions. Something like: 'we can make any DICOM workstation MedCommons-aware by adding a router to your local environment. This permits secure transmission of studies to your local network." or (post-demo) "we can use the IHE workflow queries and notifications to be part of the workflow of a remote PACS system on a case-by-case basis".
- The 'non-private patient history' is entered in the Order Form. The intent of this field is to provide medical detail in anonymous form. In the manual for this system we may want to describe in some detail what this means (don't put in the patient's name, don't put in other identifying information that others could use to guess the name).
- It seems to me that in the product we might want to add a 'non-private comment' field. If this invitation goes through email to a physician why would they open it? Is the intent "look at this interesting case you might want to add it to your teaching collection" or "this patient is coming to my office at noon can you tell me what you think of X?".
- The text on this screen is not editable in any way. It might be useful to have the tracking number be selectable text but it can not be edited.

Terms/Disclaimers

TBD

Why this page exists:



What data is presented: Actions:

This was listed in one email – I'm not sure what is meant here. Is it the indications for use from our 510(k) filing?

In any event this is a static web page. If required for the demo we need two things:

- 1. The required text, appropriately formatted.
- 2. Assuming it's a static web page what other pages link to it?



Registration



Why this page exists:

- 1. The FDA requires that products receiving a 510(k) clearance be able to be recalled. By requiring that the user register before a download of the router we can send notification messages if a recall or update is available.
- 2. MedCommons wishes to have a list of customers.
- 3. ? Registering permits the users to be authenticated so that they can send orders. This information is used to populate the HIPAA Signatures field.

What data is presented:

| T' 11 | TT |
|-----------------------------------------|---------------------------------------------|
| Field | Use |
| Email | The customer's email address. This is used |
| | for communication to the customer, |
| | including the generation of an email |
| | containing their initial password for |
| | accessing MedCommons. |
| Name | The user's name. |
| Age | The user's age. |
| Gender ¹ | Male or female. |
| Phone number | The phone number where the customer can |
| | be reached. |
| Are you a healthcare professional (y/n) | TBD: The indications for use say that our |
| | software is meant for use by healthcare |
| | professionals. What are we doing with this |
| | information? Are we going to send |
| | different notifications to healthcare |
| | professionals vs. others? |
| Are you licensed? | TBD. |
| If so, in what state? | TBD. |
| Company | Company that the customer works for. |
| | ? Why 'company' rather than 'hospital' or |
| | 'institution'? |
| Comments | Free comments that are associated with this |
| | user. |
| | |





Actions:

Clicking the "Register" button registers the user in the MedCommons universe. An email is generated of the following form:

Thank you for your interest in the medcommons router demo.

Please click on the link below and enter the username and password provided.

You may use the email address this message was sent to as your username. Your password is : medcommons.

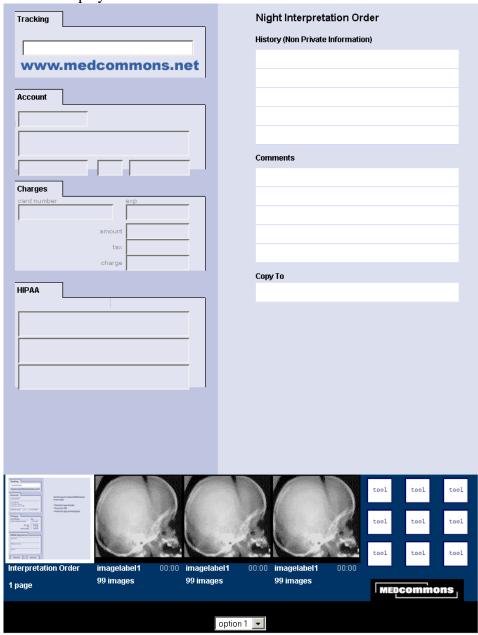
http://www.autocyt.com/mc/download.php3

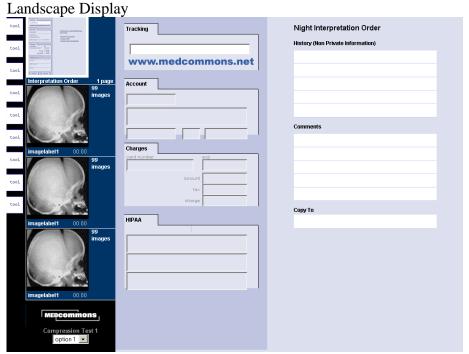
Regards,
MEDCOMMONS
the world of medical imaging on your desktop
medcommons <alex@beuscher.net>
http://www.autocyt.com/mc/

¹ I would vote for renaming this field 'Sex'. I've gotten earfuls from grammar/word pendants about sex is the biological designation and gender is the socially constructed notion of what is feminine and what is masculine. Gender is more of a continuum while sex is usually binary. The main reason for changing is that I don't want this explained to me again ⑤.

Order Form

Portrait Display:





Why this page exists:

The order is the basic clinical and business object in the MedCommons universe. Orders have data (series of DICOM data, patient history), requests for actions (image transfer, transformations of images, requests for second opinion), billing information, and routing information (who the results should go to). The order is the glue that ties all of these elements together and is the object that is tracked by a customer (they want to know if an order is completed and what the results are).

What data is presented:

| Field | Use | |
|----------|------------------------------|--|
| Tracking | A number generated by | |
| | Central which uniquely | |
| | identifies an order. This | |
| | number is generated when | |
| | this web page is generated - | |
| | it predates the order being | |
| | submitted. | |
| Account | Patient identification | |
| | information. In the demo | |
| | this is both the person | |
| | paying for the order and the | |
| | patient. | |

| Charges | In the demo we assume that the patient pays via his credit card. In the future other billing models are possible. |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------|
| HIPAA | ?? TBD. |
| HISTORY (non-private | Patient history which does |
| information) = | not contain any identifying |
| | information. This means |
| | that the history can be |
| | displayed in an Invitation |
| | without having to make an |
| | entry in the HIPAA log. |
| Comments | Comments about the study. |
| | Typically this will be |
| | similar to the DICOM Study |
| | Description field (e.g., |
| | "HEAD CT", "STONE |
| | PROTOCOL") but any |
| | information could be added |
| G. T. | that makes the order clearer |
| СоруТо | Email addresses to send |
| | Invitations to. |
| Toolbar: Interpretation Order | |
| Series Thumbnail(s) | Contain a thumbnail image |
| Series Thumbhan(s) | of a series. Only three series |
| | at a time can be displayed. |
| Selection menu. | Contains a list of all series |
| Selection menu. | which can be selected; also |
| | contains any other |
| | information that the user |
| | might want to navigate to |
| | (for example: the order). |
| | (=== 0.1001p10. 0.1001). |

Actions:

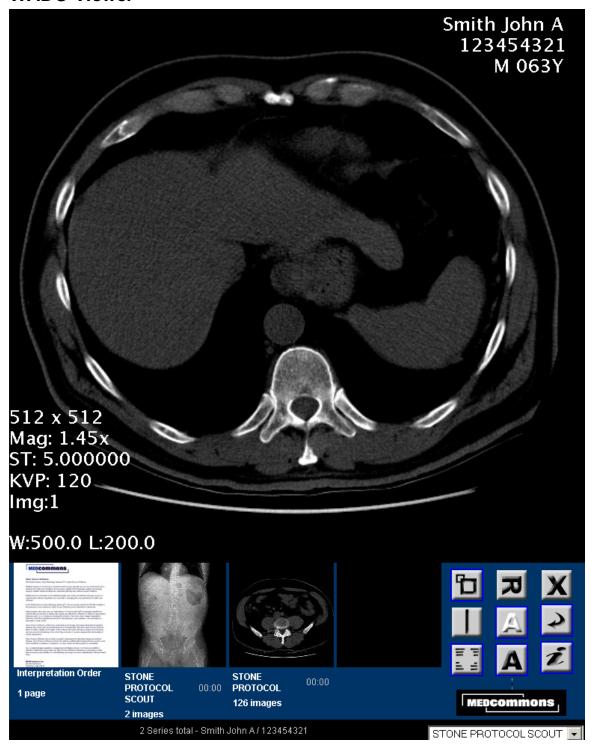
Clicking on any of the images brings up the WADO viewer with the focus on the selected series.

Selecting any of the series on the selection menu brings up the WADO viewer with the focus on the selected series.

All of the tools are inactive when the order is being viewed with the following exception: the 'i' key always links to the HIPAA log.

TBD: The HIPAA log has an entry created when the order is entered – but shouldn't there also be an entry when the order form is initially displayed? Otherwise a person could view confidential patient information without being added to the HIPAA audit trail.

WADO Viewer



Why this page exists:

The WADO viewer permits the viewing of medical images within a customer's browser. All images in the study are viewable with a small set of tools.

What data is presented:

See the user's manual for a description of fields.



Actions:

See user's manual for description of buttons and actions.

Clicking on the order form thumbnail displays the order form screen.

Submission page

The Submission page appears when the order has been placed. It appears in a web window which appears to be like a modal dialog box.

Thank you for your order, John A Smith.

Your tracking number is: 662DB

See your HIPAA entries.

Why this page exists:

This page shows the customer that the order has been successfully received by Central. The user can print the contents of the page as a receipt of the transaction.

What data is presented:

| Field | Use | |
|-----------------|----------------------------------------------|--|
| Customer's name | Useful for the receipt. | |
| Tracking number | This is the same tracking number that | |
| | appears on the order form. This is the key | |
| | used by the customer for tracking the order. | |
| HIPAA Entries | Link to all HIPAA entries for this | |
| | customer. | |

Actions:

HIPAA entries link leads to customer's HIPAA logs.

Print. The customer can print the page using CTRL-P.

TBD:

There is a real danger of confusion in the demo at this page. Here's what is unclear:

- The customer who entered the order (in this case "John Smith") isn't the patient. The customer is probably a radiology technologist or administrator.
- What is "your HIPAA entries" mean here? It isn't the patient's.



I don't know that any code changes are needed here but this is a big pothole in the narrative of the demo.

TBD. If this appears to be 'like' a modal dialog box – what appears when the dialog is dismissed? We don't want to leave the order form there- the user might click on it again to submit it a second time.

TBD: In some emails it has been suggested that this window will also display progress of the order (such as transmission progress to central). If so – perhaps some static graphic could be put there for the demo.

Selection Screen



Selection Screen - MedCommons Central

| Patient | ID | Date/Time | Description | Status |
|--------------|-----------|------------------------|---------------------|--------|
| Doe Joseph B | 543212345 | 6/5/4/2004 11:33:01 PM | CT Scan, 131 Images | New |
| Doe Joseph B | 543212345 | 6/5/4/2004 11:33:01 PM | CT Scan, 131 Images | New |
| Doe Joseph B | 543212345 | 6/5/4/2004 11:33:01 PM | CT Scan, 131 Images | New |

Select studies that you would like to see and then click the Order button to view and/or order these studies.





Why this page exists:

There may be several studies on a MedCommons routers spage permits the study of interest to be selected by the customer.

What data is presented:

The basic information required to identify a study is presented.

| 1 | J J 1 |
|-------------|-----------------------------------------------|
| Field | Use |
| Patient | Patient Name (derived from the Patient |
| | Name field in the DICOM header) |
| ID | Patient's medical record number (derived |
| | from the Patient ID field in the DICOM |
| | header of the study) |
| Date/Time | The StudyDate and StudyTime fields from |
| | the DICOM header. |
| Description | ?? This appears to be the number of series |
| - | and images in the study and not the |
| | DICOM Study Description field. Why? |
| Status | New. |
| | TBD: Other status fields should be |
| | identified if they are relevant for the demo. |

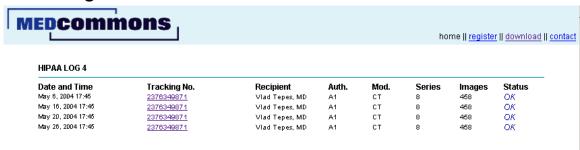
Actions:

Order launches the order form for this study. Central generates a tracking number for the order form before it is displayed in the browser.

The selection screen also detects the size of the window that it is being launched in and passes to this to the order form as a URL parameter. This permits the rendering of the order form in either portrait or landscape mode.

TBD: Log out logs the user out. This implies that there is a login screen somewhere. There currently is a login screen on central but the selection screen is on the router. For the demo is this simply a no-op?

HIPAA log



Why this page exists:

This page contains the audit trail for a specific customer's HIPAA log.

What data is presented:

Actions:

| Field | Use | |
|-----------------|----------------------------------------------|--|
| Date and Time | Date and time of the HIPAA loggable | |
| | action. | |
| Tracking Number | This is the same tracking number as in the | |
| | order form. | |
| Recipient | | |
| Auth | ?? | |
| | Need a table or some link to a definition of | |
| | what A1 and other entries mean. | |
| Modality | Matches whatever is in the DICOM header. | |
| | CT or MR are typical values. | |
| Series | Number of series in the order. | |
| Images | Number of images in the order. | |
| Status | TBD. No idea what it means. | |

TBD:

- [1] Is a distinction going to be made between 'order' and 'view'. If so what field does it belong in? Perhaps replacing status (status of what?) with 'action' and having the action be 'order' or 'view' would work.
- [2] Whose HIPAA log is this? The customer's name should be displayed.
- [3] Whose HIPAA log is this? I'm confused by who gets to look at the log and how it is filtered. This isn't an implementation question I don't think anything is needed for the demo but it is a clarity one. What are we telling people is displayed here; how is it filtered (is it "who looked at the my study"? Then the log shouldn't be accessible from

the WADO viewer where a clinician can click on the 'i' tool. The story needs to be clear; perhaps some static text can be added to the screen to make the demo intent clear.

[4] Why is the number of images and series here rather than (say) the study description and the study date/time?

Central Site Welcome Screen

| MEDCOMMONS | home <u>register</u> <u>download</u> <u>contact</u> |
|----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| WELCOME Welcome to Medcommons, providing the world of medical imaging on your desktop | |
| NEW USERS New users <u>register here</u> for our viewer download | |
| CONTACT For more information, please send email to agropper@medcommons.org . | |
| REGISTERED USERS Registered users enter username and password below to download the viewer: | |
| email: sdoyle@medcommons password: | |
| | |

TBD: Viewer download needs to be replaced with 'router download'

TBD: Email text box should be larger so that reasonable email addresses fit.

Why this page exists:

So the customer can log into the MedCommons system. Logging is required to look at the HIPAA log, download the router, or view at your set of studies on central.

What data is presented:

No information is presented to the customer. Information is required of the customer to log in.

Actions:

Registration. Takes the user to the registration page; the registration page's action provides the password required by this screen.

Contact: sends an email to Adrian.

Login: Entering the username/password combination logs the user into MedCommons central.

Central Site Successful Login

After the user has successfully logged into the Central Site Welcome Screen the user's page is displayed. For the demo all of these pages are the same – there are no user configurations.

| MEDCOMMONS | | <u>home</u> <u>register</u> download <u>contact</u> |
|--------------------------------------------------------------------|----------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| Welcome back to MEDCOMMONS. You are logged in as Sean Doyle | | |
| | The HIPAA log lists out currently available studies in your personal list. | |
| | You can download a Router / Gateway tool. Clearly, this tool has a specific function. | |
| | Bring up a list of all studies available for viewing at YOUR COMPANY NAME. CENTRAL FACILITY | |
| | | |
| | | |

TBD: "Clearly this tool has a function" should be removed.

Why this page exists:

To present the universe of actions permitted on central to the customer.

What data is presented:

The user's name. The user's company name. All other information is static.



Actions:

HIPAA log. Displays the HIPAA log for the customer.

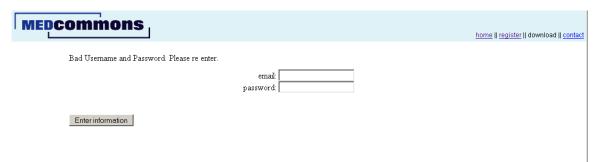
Download Router. Downloads the router.



Central Facility. Displays a list of studies available for viewing at Central.

TBD: Suggest that the "Central Facility" and "Download Router" lead to static pages.

Central Site Unsuccessful Login



Why this page exists:

To tell the user that they failed to successfully log into MedCommons.

What data is presented:

None.

Actions:

Enter Information provides them with a mechanism to attempt logging in again.

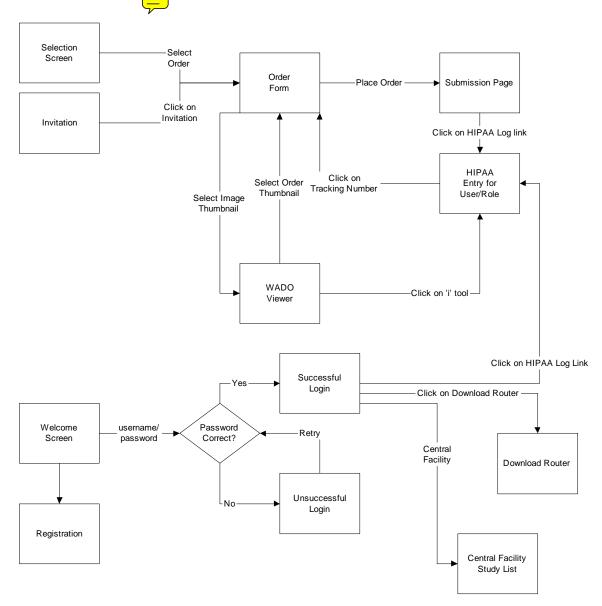


Installer

Why this page exists: What data is presented: Actions:

Connections between Screens

The following diagram shows all screens that are defined for the demo and the direction of the relationships between them. Some relationships are unidirectional, others bidirectional.



Appendix: Stories outside the storyboard.

The Invitation to Referring Physician demonstrates no security unless it clearly forces Registration or assumes a previously Registered physician. We need to be clear about which one we're demoing.

We do not discuss any interactions where images get into the system. Those use cases would be Radiologist or Technologist. This is potentially not a Demo problem but we need to have our stories clarified.