InterMED-Rx

Overview and Functional Capabilities

April, 2008
# Revision Sheet

<table>
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<th>Release No.</th>
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<tr>
<td>Rev. 0</td>
<td>2008.04.10</td>
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1.0 GENERAL INFORMATION
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1.1 Purpose

The purpose of this document is to familiarize the reader with the design and functionality of the InterMED-Rx Drug Interaction Application.

1.2 References

- PubMed web site: www.pubmed.com
- InterMED-Rx User Guide
- InterMED-Rx Interface Specifications

1.3 Acronyms and Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPU</td>
<td>Central Processing Unit</td>
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</tr>
<tr>
<td>DLL</td>
<td>Dynamic Link Library</td>
<td></td>
</tr>
<tr>
<td>DBMS</td>
<td>Database Management System</td>
<td></td>
</tr>
<tr>
<td>GB</td>
<td>Gigabyte</td>
<td></td>
</tr>
<tr>
<td>Gbps</td>
<td>Gigabits per second</td>
<td></td>
</tr>
<tr>
<td>HD</td>
<td>Hard Drive</td>
<td></td>
</tr>
<tr>
<td>HTTP</td>
<td>Hypertext Transfer Protocol</td>
<td></td>
</tr>
<tr>
<td>HTTPS</td>
<td>Secure Hypertext Transfer Protocol</td>
<td></td>
</tr>
<tr>
<td>KB</td>
<td>Kilobyte</td>
<td></td>
</tr>
<tr>
<td>LAN</td>
<td>Local Area Network</td>
<td></td>
</tr>
<tr>
<td>Mbps</td>
<td>Mega bits per second</td>
<td></td>
</tr>
<tr>
<td>MSSQL</td>
<td>Microsoft SQL Server</td>
<td></td>
</tr>
<tr>
<td>SOAP</td>
<td>Simple Object Access Protocol</td>
<td></td>
</tr>
<tr>
<td>WS</td>
<td>Web service</td>
<td></td>
</tr>
<tr>
<td>WSDL</td>
<td>Web Service Definition Language</td>
<td></td>
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<tr>
<td>XML</td>
<td>Extended Markup Language</td>
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</table>
1.4 Points of Contact

1.4.1 Information

The following contacts are provided for all end-user and support inquiries:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabriel Badea</td>
<td>Technical Director</td>
<td>514.206.4008</td>
<td><a href="mailto:gabriel.badea@intermed-rx.ca">gabriel.badea@intermed-rx.ca</a></td>
</tr>
</tbody>
</table>

1.4.2 Coordination

Coordination between end-user and software supplier may be necessary prior to its installation and operation. For all coordination requirements please contact:

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<tr>
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2.0 SYSTEM SUMMARY
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This chapter describes (in non-computer-oriented language) the system functions so as to establish a context for the application.

2.1 Background

InterMED-Rx presents a drug interaction identification application that uses a licensed web service from which it requests drug interaction analysis and recommendations. It provides the ability to present drug interaction analysis, recommendations and automated “Pharmaceutical Opinions” and may be integrated partially or completely in existing patient management applications.

2.2 System Objectives and Functionality

The application was designed with the following objectives and functionalities in mind.

- Provide fast and accurate drug interaction analysis.
- Provide a means by which existing patient management systems may easily interface with the application.
- Provide a user-friendly interface for the end-user.
- Provide a mechanism for easily and automatically producing “Pharmaceutical Opinions”.
- Minimize development efforts for third parties wishing to integrate the application or the results presented by the web service.

2.3 Methods and Procedures

2.3.1 Hardware considerations

The application has been designed to use existing infrastructures, servers and workstations.

In the simplest form, installation and operating minimal requirements are as follows:

- Workstation (Microsoft Windows 2000 or later)
- Internet access for the InterMED-Rx Request Processor.

A typical installation requires:

- Several workstations connected by a LAN.
2.0 System Summary

- Database and Application server (Windows Server 2000 or later)
- Internet access for the InterMED-Rx Request Processor.

A large installation requires:

- Several workstations connected by a LAN.
- Database server (Windows Server 2000 or later; MSSQL 2000/2005).
- Application Server for the InterMED-Rx Request Processor.
- Internet access for the InterMED-Rx Request Processor.

2.3.2 Input and Output

Input collection points (a.k.a. request creators) are the InterMED-Rx Viewer application by means of which the end-user may manually submit drug interaction requests and the application interface by means of which an existing patient management system can submit drug interaction requests directly from the patient file.

Output presentation points for a standard installation are the InterMED-Rx Viewer application. Drug interaction analysis and recommendations as well as any graphical representations of the interactions (a.k.a. interactions table) are also available by means of the application interface should there be a need to seamlessly integrate the application in existing systems.

Please note that in the event where the application is completely integrated into a patient management application, the input and output points are independent of the InterMED-Rx Viewer as the latter need not be used. Therefore the patient management application is responsible for all input and output points. In such case only the InterMED-Rx request processor and local database is needed for communication with the web service.

In its current license terms the web service allows for 5,000 requests per day to be processed by the web service. With an average request string length of 300 bytes (based on 4 medications per request) the total daily volume of outgoing data transferred to the web service is approximately 500 KB. The volume of incoming data cannot be accurately predicted since we cannot predict how many interactions are found and the number of PubMed article references found for each interaction. On the average however, the length of a response string has been evaluated at 20KB yielding a maximum daily incoming volume of 100MB.
2.3.3 Responsibilities

InterMED-Rx is responsible for maintaining 99.5% up-time for its web service and it does so by maintaining fail-over equipment and ISP services.

End-user installations are responsible for maintaining the application database and infrastructure as well as internet access necessary for the application to communicate with the web service.

2.3.4 Deficiencies

As with any application that relies on external factors (mainly ISP services), the InterMED-Rx WS is susceptible to service interruptions due to “unforeseeable influences” that are beyond its control.

However, due to advances in technology and equipment reliability, such service interruptions will be virtually inexistent.
3.0 DETAILED CHARACTERISTICS
3.0 DETAILED CHARACTERISTICS

This chapter provides a description (in non-computer-oriented language) of the functions to be performed and the performance requirements of the system.

3.1 Specific Performance Requirements

Design considerations had to take into account the following performance requirements:

- Accuracy and validity of the information presented.
- Response time of a request from beginning to end.
- Capacity limits

3.1.1 Accuracy and Validity

As with any application that presents information, it is imperative that this information be accurate; three areas have been identified as crucial to the operation of the application:

- **P450 Drug Interaction accuracy**: The application uses the algorithm developed by Jacques Turgeon PhD to identify drug interactions involving the P450 system. No further details are available as the algorithm is proprietary.

- **NON-P450 Drug Interaction accuracy**: Fact based information compiled from various sources by our team of pharmacists. All information is always referenced.

- **Reference accuracy**: For P450 drugs and P450 drug interactions, articles from the PubMED database have been pre-selected according to their relevance. Further information is available at [http://www.pubmed.com](http://www.pubmed.com).

3.1.2 Response Time

All components of the InterMED-Rx application rely directly or indirectly on the InterMED-Rx web service, and thus on the networking infrastructure at the clients’ site. Additionally, the clients’ ISP link speed will also have an effect on the response time of the application as a whole.

Response time for the InterMED-Rx WS: Measurements have been taken of the time needed to process a request from time of reception to time of response. In all cases response time was well under 0.5 seconds and in most cases response time was under 0.3 seconds.
Assuming that the client infrastructure and ISP service response time is adequate, the InterMED-Rx application response time from input of request to reception of response at the client site is expected to be of the order of 1~2 seconds.

### 3.1.3 Capacity Limits

Capacity limits for client installations have been considered for the following areas:

- **Storage requirements**: For workstations, the storage requirements are minimal and include mainly the space required for the initial installation. For the database server environment, weekly monitoring by the DBA is deemed sufficient and database storage requirements should be adjusted as seen fit. (Other database administration tasks are the responsibility of the DBA)

- **Concurrent users**: Concurrent use of the system at the clients’ site is assured by the database server. Keeping in mind that the system was designed for interactive use and not for batch processing, for optimal operation and acceptable response time, multiple users should not create more than 3~5 requests per second.

### 3.2 System Functions

- **Request Processor**: The request processor is responsible for communicating with the InterMED-Rx web service for the purpose of sending client requests and receiving responses.

- **Interface Requests**: Drug interaction requests may automatically be sent to the request processor from the patient management system operating at the clients’ site by means of the provided application interface.

- **Request/Response Viewer**: InterMED-Rx provides a user interface that renders requests and their responses to the user. The user interface, when used concurrently with the patient management application has the capability of synchronizing with the last request presented to the request processor by means of the provided application interface.

- **Manual Requests**: By means of the InterMED-Rx user interface, users can build their own requests, send them and receive a response. Pharmaceutical Opinions however cannot be generated for manual requests.

- **Pharmaceutical Opinions**: Pharmaceutical opinions for interface requests only, can be generated by the InterMED-Rx viewer at the user’s request.
3.3 Input and Output

- Reports and queries to be generated by the system will be constructed as needed in accordance with the clients' needs.

- InterMED-Rx does not need interface to any other systems for the moment. Other systems may interface with the application at the client site by means of the supplied DLL.

- Input collection points are the InterMED-Rx Viewer application by means of which the end-user may manually submit drug interaction requests and the application interface by means of which an existing patient management system can submit drug interaction requests directly from the patient file.

- Output presentation points for a standard installation are the InterMED-Rx Viewer application. Drug interaction analysis and recommendations as well as any graphical representations of the interactions are also available by means of the application interface should there be a need to seamlessly integrate the application in existing systems.
3.4 Failure Contingencies

Five areas have been considered:

- **Database failure**: In the case of a database failure, the database needs to be brought back to an operational state by restoring the last full backup and re-applying the logs. This is the responsibility of the DBA. Maintenance plans for the database server should be set up by the DBA to perform full database backups regularly (preferred configuration would be a daily backup) and regular log backups (preferred configuration would be an hourly backup). This issue has been identified as the only failure that will render the system completely inoperable.

- **Request Processor failure**: Although this is unlikely, the failure must be investigated and resolved by InterMED-Rx.

- **User interface failure**: The user interface application must be restarted. If the problem persists, the failure must be investigated and resolved by InterMED-Rx.

- **Application interface failure**: the failure must be investigated by the application owner. If it is determined that the application (intermed.dll) interface is at fault, the failure must be investigated and resolved by InterMED-Rx.

- **Web service failure**: InterMED-Rx is solely responsible for the operation of the web service and is committed to 99.5% up time.

Note: Only a database failure will render the system completely inoperable. Failure in any other module or failure of the web service will see system capability crippled but the system as a whole remains operational.
4.0 ENVIRONMENT
4.0 ENVIRONMENT

In this section the hardware and software environment is described.

4.1 Equipment Environment

As described earlier, InterMED-Rx requires no special equipment or capabilities. Of course the infrastructure at the clients’ establishment should be able to support the needs of the system. As such Pentium class workstations and servers with internet access are sufficient. Please note that the application server and the database server may be the same, however sufficient resources are needed for both the application and the database are necessary.

4.1.1 Workstation Environment:

- Processor class: Pentium or equivalent
- Memory: 512 MB
- Internet Browser: Microsoft Internet Explorer 6.0 minimum
- LAN access: 10 Mbps (100 Mbps preferred)
- Access to a LAN or attached printer

4.1.2 Application Server Environment:

- Processor class: Pentium or equivalent
- Memory: 1GB
- LAN access: 100 Mbps (1 Gbps preferred)

4.1.3 Database Server Environment:

- Processor class: Dual Core Pentium or equivalent
- Memory: 2GB
- LAN access: 100 Mbps (1Gbps preferred)
- Storage: 100MB minimum

4.2 Software Environment

Operating systems:

- Workstation: MS Windows 2000 professional or later (Windows XP professional preferred)
- Application Server: Windows Server 2000 or later (Windows Server 2003 preferred)
- Database Server: Windows Server 2000 or later (Windows Server 2003 preferred)
4.0 Environment

DBMS:
- MS SQL Server 2000 or later

NOTE: MSXML4 must be installed on the application server.

4.3 Interface

The interface to the application is supplied in the form of a DLL. The use of this DLL is mandatory if the application is to be interfaced by a patient management system. Please refer to the interface documentation for further details.

4.4 Constraints

The product map must be defined and implemented prior to operation if patient management system proprietary medication codes are to be used.
5.0 SECURITY
5.0 SECURITY

This chapter provides a description of the system security measures in place and the physical security measures necessary to control the dissemination of sensitive information.

5.1 Background Information

The information used by the application may expose the identity of the patient. Therefore InterMED-Rx requires only minimal information as it pertains to the functions that need to be performed by the application (i.e. if it is deemed unnecessary to produce pharmaceutical opinions, then patient or physician personal data need not be sent to the InterMED-Rx system).

5.2 Vulnerabilities and Safeguards

InterMED-Rx has been specifically designed to minimize security risks and vulnerabilities as they pertain to sensitive information. As such only the absolute minimal information is exchanged by the application and this information remains within the physical confines of the clients’ technological environment.

Effectively, the information that is exchanged with the InterMED-Rx WS is stripped of all patient data and only the data that is needed to for drug interaction analysis is sent to the web service. Therefore, since no sensitive data is sent, none can be stored or transmitted back by the web service.

5.2.1 Input/Output Points

Input and output points of the application have been identified as the vulnerabilities of the system...

5.2.1.1 Input Points

- **Origin**: Two points are used for data entry. The application interface and the InterMED-Rx viewer.
- **Data Entry**: Only the application interface uses sensitive information, as there is no way to enter this type of information by means of the InterMED-Rx viewer application.
- **Error detection**: It is possible for the application interface to send erroneous information. However this is of no consequence for the system as whole since the requestor processor will verify that the information received is
correct. If it is not then an error is flagged for the request and the next request is then processed.

5.2.1.2 Output Control Points

Production of output: InterMED-Rx request/response output is available at two types of control points if the patient management system chooses to make this output available via its own interface. Needless to say, in this case the application is solely responsible for the security of sensitive data. Otherwise the only output control point is the InterMED-Rx viewer application. As this application has no means of transmitting sensitive information, physical security measures in effect are considered sufficient.

5.2.2 Safeguards

InterMED-Rx does not provide any safeguards as the physical ones in place at the clients’ establishment are deemed sufficient.

5.2.2.2 Physical Safeguards

Physical access to the application, database and application server have been identified as vulnerabilities. As such, the clients’ physical security measures in effect are deemed sufficient.

5.2.2.3 Technical Safeguards

Technical safeguards are provided by the software environment present at the clients’ establishment.

Effectively, access to the InterMED-Rx application interface is protected by the authentication measures of the operating system on the user’s workstation.

Database security relies on the permissions setup by the DBA for each user or user group.

5.3 System Monitoring and Auditing

System monitoring and auditing are achieved by examining the log files of the system components.

5.3.1 Journalizing

A journal of all requests, responses, emitted pharmaceutical opinions and errors is kept at the database level as well as system component log files.
5.3.1.1 Identification Information

All identification information available is kept by the database journals. Such information includes only date and time as well as the name of the workstation used. If further identification information is needed it can be obtained from the operating system audits if they are available.

5.3.1.2 Journal Use

Review of the journal is available in the form of reports. As stated previously, reports are developed in conjunction with the client and according to specified needs.

5.3.2 Audit Trail

All required information for audit trail is available from the database journals and component log files. Audit trail gathering procedures are to be made available after such needs are identified by the client.

5.3.2.1 Record Disposition Procedures and Retention Periods

Data retention periods and record disposition are the responsibility of the client. The client should rely on a schedule to perform database and log archiving as well as database purges. InterMED-Rx provides all needed software support (i.e. database archiving and purging procedures).

Please note that audit trail and journal reports rely on available data. Therefore all journal reports and audit trail must be finalized before database purges are performed.