

Software Requirements Specification for diagnosis-AIDs: Medical Diagnosis Prediction Tool for Acquired immunodeficiency syndrome (AIDS)

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Contents

Revision History

Date	Version	Notes
October 10 2020	1.0	Initial Draft of SRS
October 24 2020	2.0	Second Draft of SRS

1 Reference Material

This section records information for easy reference.

1.1 Table of Units

Throughout this document SI (Système International d’Unités) is employed as the unit system. In addition to the basic units, several derived units are used as described below. For each unit, the symbol is given followed by a description of the unit and the SI name.

symbol	unit	SI
m	length	metre
kg	mass	kilogram
s	time	second
°C	temperature	centigrade

Table 1: Table of Units

1.2 Table of Symbols

The table that follows summarizes the symbols used in this document along with their units. The symbols are listed in alphabetical order.

symbol	unit	description
A_1	$1 / 10^{-3}m^3$	initial amount of substance
A_2	$1 / 10^{-3}m^3$	amount of substance at second instance
$isClearing$	-	requirement of clearance rate of change
N_0	mol	initial amount of substance
N_t	mol	amount of substance at time, t
$rate_D$	$\frac{1/10^{-3}m^3}{s}$	the rate of clearance
t	s	time
t_1	s	time at instance 1
t_2	s	time at instance 2
VL	$\frac{virions}{10^{-3}m^3}$	Viral Load
VL_n	$\frac{virions}{10^{-3}m^3}$	Viral Load at instance n
VL_1	$\frac{virions}{10^{-3}m^3}$	Viral Load at instance 1
VL_2	$\frac{virions}{10^{-3}m^3}$	Viral Load at instance 2
λ	$\frac{virions/10^{-3}m^3}{s}$	the rate of clearance

Table 2: Table of Symbols

1.3 Abbreviations and Acronyms

The table that follows summarizes the symbols used in this document that allude to different sections of the Software Requirements Specification. The symbols are listed in alphabetical order.

symbol	description
A	Assumption
DD	Data Definition
GD	General Definition
GS	Goal Statement
IM	Instance Model
LC	Likely Change
PS	Physical System Description
R	Requirement
SRS	Software Requirements Specification
diagnosis-AIDS	Medical Diagnosis Prediction Tool for Acquired immunodeficiency syndrome (AIDS)
T	Theoretical Model
ULC	Unlikely Change

Table 3: Table of Abbreviations and Acronyms

2 Introduction

Human immunodeficiency virus 1 (HIV -1) is the most common type of HIV virus that attacks cells of the immune system needed to fight off diseases. After being infected with the HIV-1 virus, the patient's state worsens and the condition can be classified as Acquired immunodeficiency syndrome (AIDs), a disease which affects 38 million people worldwide (?). Although there is no cure for AIDs, antiretroviral therapy helps control a patient's condition. Having a program that assesses the efficient of a patient's immune system and predict their disease progression will be useful in creating a treatment plan. The program documented here is called diagnosis-AIDS.

The following section provides an overview of the Software Requirements Specification (SRS) for diagnosis-AIDS. This section explains the purpose of this document, the scope of the requirements, the characteristics of the intended reader, and the organization of the document.

2.1 Purpose of Document

The main purpose of this document is to outline the software requirements of the medical prediction system. Different aspects of the system including goals, assumptions, theoretical models, and definitions will be explained to ensure full understanding of the system. The following SRS document will remain abstract exploring what is being solved rather than how

it will be solved.

This initial document is the start of a series of documents that will outline the development of the software tool, diagnosis-AIDS. The SRS will describe the system context and constraints, the specific problem definition and solution characteristics, requirements and likely and unlikely changes for the development of the tool.

2.2 Scope of Requirements

The scope of the requirements includes the analysis of HIV-1 concentration over time with constant clearance rate.

2.3 Characteristics of Intended Reader

Reviewers of this documentation should have a basic understanding of virus dynamics and high school calculus. The users of diagnosis-AIDS must have a higher level of expertise, as explained in Section: User Characteristics (Section ??).

2.4 Organization of Document

The organization of the document will present the system's goals, theories, definitions, and assumptions. The template for an SRS for scientific computing will be followed. To approach diagnosis-AIDS from a higher level to a more elaborate level, readers can begin with reading the system's goal statements. Subsequently, the theoretical models will elaborate on the goal statements. Lastly, readers can finish with a more understanding of the system by reading instance models of the system.

Oppositely, readers can read from the instance models to the goal statements for a more specific to general understanding.

3 General System Description

This section provides general information about the system. It identifies the interfaces between the system and its environment, describes the user characteristics, and lists the system constraints.

3.1 System Context

The flow chart in (Figure ??) shows the system context. The circles represent a user that interacts with the software. The rectangle represents the software system (diagnosis-AIDS). The arrows display the input data from the user and the output data that is useful for the user. The interaction presented will be facilitated using an application programming interface (API).

- User Responsibilities:

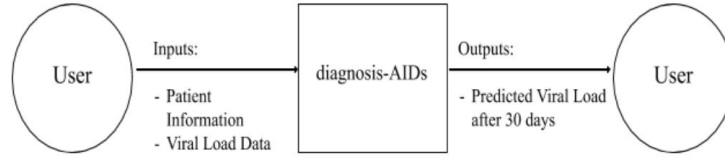


Figure 1: System Context

- Provide viral load data for two consecutive days.
- Ensure required software assumptions (Section ??) are appropriate for any particular problem the software addresses.
- Program (diagnosis-AIDs) Responsibilities:
 - Assess the input data and determine if the required physical and software constraints (Section ??) are met.
 - Calculate predictions of 30 day viral load concentration.

3.2 User Characteristics

The users of diagnosis-AIDS should be HIV healthcare providers including doctors of medicine (MD) or doctors of osteopathic medicine (DO), nurse practitioners (NP), or a physician assistant (PA). (?)

3.3 System Constraints

The system, diagnosis-AIDs, is limited to only instances where viral load is clearing. If the viral load is increasing, the immune system has not recognized the intruders and a estimation of immune efficiency cannot be found. More specifically, the initial viral load must be greater than the viral load on the consecutive day.

4 Specific System Description

This section presents the problem description, which gives a high-level view of the problem to be solved. This is followed by the solution characteristics specification, which presents the assumptions, theories, definitions and finally the instance models.

4.1 Problem Description

AIDs is one of the most serious health challenges in our global community. Many individuals infected with HIV visit healthcare facilities with hopes to find solutions to manage their conditions. A system ensuring accurate and quick characterization of a patient's condition

can prove useful in predicting the progression of viruses like HIV, and the diagnosis of diseases like AIDs. Using this system, important decisions reached by healthcare professionals will be more data-driven and quick.

This system could be used to assess risk before substantial immune destruction has occurred. The system is intended to predict the viral load at 30 days, and predict the patient's progression to AIDs.

4.1.1 Terminology and Definitions

This subsection provides a list of terms that are used in the subsequent sections and their meaning, with the purpose of reducing ambiguity and making it easier to correctly understand the requirements:

- Virus: Submicroscopic parasites that infect cells.
- Virion: A single entire virus particle.
- Infected cells: Once a virus comes into contact with a host cell, the infected cell will begin to undergo viral replication.
- Viral Replication: Process where infected cells rapidly reproduce the genetic material of the virus rather than it's own products(?).
- Helper T cells: The cells of the immune system that help activate T cells.
- T cells: The cells of the immune system that kill infected target cells. A common type of T-cell are CD4+ cells. (?)
- HIV Virus: HIV infects cells in the immune system.
- Immune Response: The defensive reaction of the human body against the harmful substances like HIV.
- Viral load: The amount of virus in your blood.
- Clearing: Physical quantity undergoing a constant decline.
- Clearance Rate: Rate of decline of a physical quantity undergoing a constant decline.
- AIDs: Acquired Immunodeficiency Syndrome is where the Viral Load increases to an extent where the CD4+ cell count decreases to below $200 \text{ cells}/10^{-3}m^3$.(?)
- Diagnosis: The medical decision determining a patient's condition reached by a healthcare professional.
- Progression: The development towards a more advanced stage.
- Progression Speed: The rate of developing to a more advanced stage. For example, slow, moderate and fast progression.

4.1.2 Physical System Description

The physical system of diagnosis-AIDs, as seen in (Figure ??), occurs within the human body and includes the following elements:

PS1: The HIV Virion.

PS2: An infected cell with the virus.

PS3: The helper T cells.

PS4: The human body.

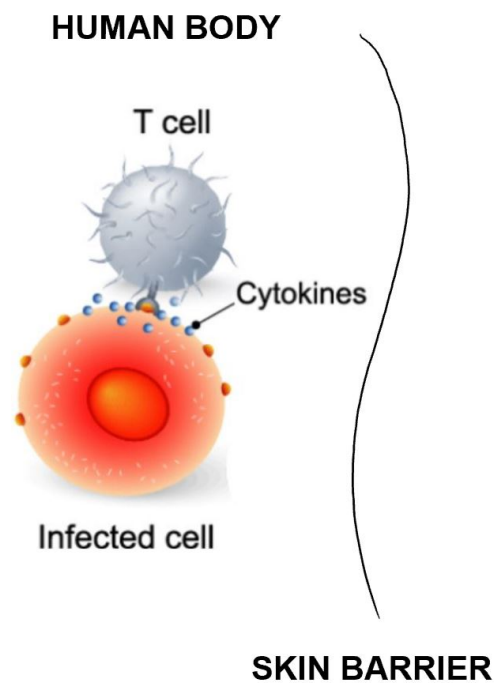


Figure 2: The Physical System
(?)

4.1.3 Goal Statements

Given two HIV-1 viral load datum taken on consecutive days, the goal statements are:

GS1: determine-clearing-rate: Determine the rate of clearance of the HIV virus due to immune response.

GS2: predict-VL-30: Predict Viral Load at 30 days.

4.2 Solution Characteristics Specification

The instance models that govern diagnosis-AIDs are presented in Subsection ???. The information to understand the meaning of the instance models and their derivation is also presented in Assumptions, Theoretical Models, General Definitions and Data Definitions, so that the instance models can be verified.

4.2.1 Assumptions

This section describes the theoretical assumptions that the system will be based on. The theoretical models will be easier to understand by explaining these assumptions. The numbers given in the square brackets refer to the theoretical model [T], general definition [GD], data definition [DD], instance model [IM], or likely change [LC], in which the respective assumption is used.

- A1: initial-inf: Initial infection of a HIV patient.
- A2: const-growth: The virions will invade uninfected cells at a constant rate (Ref By: LC??).
- A3: const-volume: The dimensions of the location associated with the infection remain constant.(Ref By: UC??)
- A4: const-conditions: Temperature in the infection location remains constant. Higher temperatures boost replication. (Ref By: A??, UC??)(?)
- A5: all-productive: All infected cells are productively infected cells meaning there are no infected cells that do not affect other cells. (Ref By: UC??)
- A6: always-clear: Although slight fluctuations in viral load do occur even after the peak, it is assumed that there are no significant upwards trends.
- A7: neglect-drugs: The clearance rate will not be affected by drugs or other therapy that may cause faster clearance. (Ref By: LC??)
- A8: neglect-sick: The clearance rate will not be affected by other viruses that may cause that may cause slower clearance.
- A9: clear-proportional-amt: At any point in time, the clearing is assumed to be proportional to the amount of viruses present. (Ref By: LC??)

4.2.2 Theoretical Models

This section focuses on the general equations that diagnosis-AIDs is based on.

Number	T1:IsClearing
Label	Determination of Clearing
Equation	$isClearing = VL_1 > VL_2$
Description	$isClearing$ is the requirement that needs to be satisfied to provide a proper estimate. VL_1 is the initial viral load. VL_2 is the viral load after 24 hours.
Source	HIV-1 Dynamics in Vivo: Virion Clearance Rate, Infected Life Span and Viral Generation Time (?)
Ref. By	A?? , Subsection ??, R??

Number	T2: ExpClearing
Label	Function of Exponential Clearing
Equation	$N_t = N_0 e^{-\lambda t}$
Description	<p>The above equation gives the exponential decrease in quantity for a certain time t and clearing rate λ.</p> <p>N_0 is the initial amount that will undergo an exponential decrease. N_0 is equivalent to $N(t = 0)$.</p> <p>e^x is the exponential function.</p> <p>λ is the clearing constant.</p> <p>t is the time elapsed from the initial time.</p> <p>N_t is the amount after time, t, has elapsed.</p>
Source	(?)
Ref. By	rate-c

4.2.3 General Definitions

This section collects the laws and equations that will be used to build the instance models.

Number	GD1: $rate_c$
Label	Concentration Rate law
SI Units	$\frac{1/10^{-3}m^3}{s}$
Equation	$rate_c = -\frac{\Delta A}{\Delta t} = -\frac{A_2 - A_1}{t_2 - t_1}$
Description	<p>The Concentration Rate law describes a clearing rate of a substance that is directly proportional to it's concentration.</p> <p>$rate_c$ is the time-dependent concentration gradient. ($\frac{1/10^{-3}m^3}{s}$).</p> <p>$\Delta A = A_2 - A_1$ is the change in amount of substance ($\frac{1}{10^{-3}m^3}$).</p> <p>$\Delta T = t_2 - t_1$ is the time elapsed between A_2 and A_1 (s).</p>
Source	(?)
Ref. By	A??, T??, T??

4.2.4 Data Definitions

This section collects and defines all the data needed to build the instance models.

Number	DD1: conc-virus
Label	Viral Load within the body at a given time
Symbol	VL
SI Units	$\frac{virions}{10^{-3}m^3}$
Equation	$VL = \frac{num_{virions}}{volume}$
Description	<p>Viral load describes the concentration of the virus within the body at certain time t.</p> <p>VL is the viral load at a given time ($\frac{virions}{10^{-3}m^3}$).</p> <p>$num_{virions}$ is the number of virions in the body ($volume$).</p> <p>$volume$ is the amount of three-dimensional space associated with the body ($10^{-3}m^3$).</p>
Sources	(?)
Ref. By	IM?? , IM??

4.2.5 Instance Models

This section transforms the problem defined in Section ?? into one which is expressed in mathematical terms. It uses concrete symbols defined in Section ?? to replace the abstract symbols in the models identified in Sections ?? and ??.

The goals GS ??: determine-clear-rate and GS ??: predict-VL-30 are met by IM: VLclear and IM:VLat30.

Number	IM1: VLclear
Label	Using clearance rate λ to find VL_{30}
Input	VL_1, VL_2, t The input is constrained so that $VL_1 \geq 0, VL_2 \geq 0, t \geq 0$ (A??) and $VL_1 \geq VL_2$ (A??)
Output	$\lambda \leq 0$, such that $\frac{dVL}{dt} = -\lambda VL$, $\lambda = -VL \frac{dt}{dV}$
Description	λ is the clearance rate of the viral load. $\frac{dVL}{dt} = \frac{VL_2 - VL_1}{t_2 - t_1}$ is the change in viral load over time. VL_n is the viral load at a certain point.
Sources	(?)
Ref. By	GD??

Number	IM2: VLat30
Label	Exponential Clearance function relating the viral load and time
Input	VL_1, λ, t The input is constrained so that $t \geq 0$ and $\lambda \leq 0$
Output	$VL_t, VL_t \leq VL_1$, such that $VL_t = VL_1(1 - \lambda)^t$
Description	VL_1 is the initial viral load. λ is the clearance rate of the viral load. t is the time elapsed between VL_t and VL_1 .
Sources	(?)
Ref. By	T??

4.2.6 Input Data Constraints

Table ?? shows the data constraints on the input variables. The column for physical constraints gives the physical limitations on the range of values that can be taken by the variable. The column for software constraints restricts the range of inputs to reasonable values. The software constraints will be helpful in the design stage for picking suitable algorithms. The constraints are conservative, to give the user of the model the flexibility to experiment with unusual situations. The column of typical values is intended to provide a feel for a common scenario. The uncertainty column provides an estimate of the confidence with which the physical quantities can be measured. This information would be part of the input if one were performing an uncertainty quantification exercise.

Table 4: Input Variables

Var	Physical Constraints	Software Constraints	Typical Value	Uncertainty
VL_1	$VL_1 > 0$	$VL_1 > VL_2$	$10^6 \frac{\text{virions}}{10^{-3}m^3}$	10%
VL_2	$VL_2 > 0$	$VL_1 < VL_2$	$10^6 \frac{\text{virions}}{10^{-3}m^3}$	10%

4.2.7 Properties of a Correct Solution

A correct solution must exhibit a viral load less than the initial viral load (VL_1). Table ?? shows the data constraints for the output variables.

Table 5: Output Variables

Var	Physical Constraints
λ	$\lambda \leq 0$
$_{30}$	$0 < VL_{30} < VL_2$

5 Requirements

This section provides the functional requirements, the business tasks that the software is expected to complete, and the non-functional requirements, the qualities that the software is expected to exhibit.

5.1 Functional Requirements

- R1: R-Inputs: The viral load concentrations taken on two consecutive days is input. (Subsection ??)
- R2: R-Assumptions: The system should set the known numbers within values.
- R3: R-Constraints: AIDSDiagnosis will ensure the input values are not out of bounds and are in accordance to the data constraints. Otherwise, an error message will identify the inability of AIDSDiagnosis to run.(Ref by: (Subsection ??))
- R4: R-AIDSDiagnosis: If all constraints are met, the AIDSDiagnosis will output: 30 day viral load estimation. (Ref by: IM??, IM??)
- R5: R-VerifyOutput: The output values will be cross referenced with the output constraints table to ensure the input values are not out of bounds and are in accordance to the results constraints.
- R6: R-Output: Output related requirements.

5.2 Nonfunctional Requirements

- NR1: Correctness: The output values have to adhere to the output properties in (Subsection ??).
- NR2: Verifiable: The code is tested with a complete verification and validation plan.
- NR3: Usability: The code will consist of several modules to ensure usability.
- NR4: Understandability: The code will be completed with a module guide and an easy to understand interface.
- NR5: The traceability between requirements, assumptions, theoretical models, general definitions, data definitions, instance models, likely changes, unlikely changes, and modules is completely recorded in traceability matrices in the SRS and module guide.

6 Likely Changes

This section lists the likely changes to be made to software

- LC1: Time Frame: The program may be expanded to cover a wide range of time frames, greater than 30 days.
- LC2: Better Progression Accuracy: The program may become more exact in terms of determining the time to AIDs.
- LC3: Addition of Therapy: The program may be extended to assess the progression due to the patient's immune response as well as the retroviral therapy. (Ref by: A??)

7 Unlikely Changes

This section lists the unlikely changes to be made to the software.

- UC1: determine-decay-rate: The goal to simulate the interactions between the virions and the immune System cells will remain unchanged. (Ref By: ??)
- UC2: external-input: There will always be a source of input data external to the software. (Ref By: R: ??)
- UC3: constant-conditions: Constant temperature and body conditions are met. (Ref by: A??, A??)

8 Traceability Matrices and Graphs

The purpose of the traceability matrices is to provide easy references on what has to be additionally modified if a certain component is changed. Every time a component is changed, the items in the column of that component that are marked with an “X” may have to be modified as well. Table ?? shows the dependencies of theoretical models, general definitions, data definitions, and instance models with each other. Table ?? shows the dependencies of instance models, requirements, and data constraints on each other. Table ?? shows the dependencies of theoretical models, general definitions, data definitions, instance models, and likely changes on the assumptions.

The purpose of the traceability graphs is also to provide easy references on what has to be additionally modified if a certain component is changed. The arrows in the graphs represent dependencies. The component at the tail of an arrow is depended on by the component at the head of that arrow. Therefore, if a component is changed, the components that it points to should also be changed.

	T??	T??	GD??	DD??	IM??	IM??
T??			X			
T??			X			
GD??	X	X				
DD??					X	X
IM??			X	X		X
IM??		X	X	X	X	

Table 6: Traceability Matrix Showing the Connections Between Items of Different Sections

	??	R??	R??	R??	R??	R??	R??
IM??	X	X	X	X			
IM??	X		X		X	X	X

Table 7: Traceability Matrix Showing the Connections Between Requirements and Instance Models

	A??	A??	A??	A??	A??	A??	A??	A??	A??
T??	X					X			
T??		X	X	X	X		X	X	X
GD??		X	X	X					X
DD??		X	X	X	X				X
IM??		X	X	X	X				X
IM??		X	X	X	X	X			X
LC??	X								
LC??					X	X			X
LC??							X	X	X

Table 8: Traceability Matrix Showing the Connections Between Assumptions and Other Items

9 References