

Software Requirements Specification for Diagnose

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Reference Material

This section records information for easy reference.

Table of Units

The unit system used throughout is SI (Système International d'Unités). In addition to the basic units, several derived units are also used. For each unit, [Tab: ToU](#) lists the symbol, a description and the SI name.

Symbol	Description	SI Name
d	time	day
mL	volume	millilitre
mol	amount of substance	mole

Table of Units

Table of Symbols

The symbols used in this document are summarized in [Tab: ToS](#) along with their units. Throughout the document, symbols in bold will represent vectors, and scalars otherwise. The symbols are listed in alphabetical order. For vector quantities, the units shown are for each component of the vector.

Symbol	Description	Units
k	Elimination constant	d^{-1}
N	Viral load	$\frac{mol}{mL}$
N_o	Initial viral load	$\frac{mol}{mL}$
N_p	Predicted viral load at time t	$\frac{mol}{mL}$
N_t	Viral load at user-defined time t	$\frac{mol}{mL}$
n	Number of virions	mol
r	Rate of change of the viral load	$\frac{mol}{mLd}$
t	Time	d
t_p	Time duration of chosen prediction period	d
t_t	Time duration between initial and secondary viral load test	d
V	Volume	mL

Table of Symbols

Abbreviations and Acronyms

Abbreviation	Full Form
A	Assumption
DD	Data Definition
GD	General Definition
GS	Goal Statement
IM	Instance Model

PS	Physical System Description
R	Requirement
SRS	Software Requirements Specification
TM	Theoretical Model
Uncert.	Typical Uncertainty

Abbreviations and Acronyms

Introduction

HIV-1 is a virus that attacks cells of the immune system needed to fight off diseases. The virus leads to an incurable disease called AIDs. Therefore, it is useful to have a program to model these types of problems. The program documented here is called Diagnose.

The following section provides an overview of the Software Requirements Specification (SRS) for Diagnose. 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.

Scope of Requirements

The scope of the requirements includes the analysis of HIV-1 viral load concentration over time after the viremia peak of the initial infection without the influence of external factors that can affect the efficiency of the immune system.

Specific System Description

This section first 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, and definitions that are used.

Problem Description

A system is needed to assess the risk of progression to AIDs before substantial immune destruction has occurred. Diagnose will model the viral load over time for the HIV-1 virus responsible for AIDs. The system will determine the initial elimination rate of the virus and predict viral load at a user-defined time.

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.
- Viral load: The concentration of HIV virus at a point in time.
- Replication: The process where infected cells rapidly reproduce genetic material of the virus rather than its normal process of reproducing itself.
- Productivity: Cells can be productive and non-productive. Productive means that infection occurs. The HIV-1 virus needs to interact with a cell to be productive and replicate.
- Infected cells: Cells that interact with the virus replicate into cells altered by the virus.
- Helper T cell: Cells of the immune system that neutralize infected cells.
- Immune Response: The defensive reaction of the human body against harmful substances like the HIV-1 virus.
- Elimination: Physical quantity undergoing a decline in amount.
- Viremia Peak: The peak of viral load after the virus has entered the blood stream. There is a trend of elimination for viral load due to the body's immune response.
- AIDs: Acquired Immunodeficiency Syndrome develops from an increase in HIV viral load to the extent where T cell count decreases to under 200 mol/L.
- Diagnosis: The determination of a patient's condition reached by a healthcare professional.
- Progression: The development towards a more advanced stage.

Physical System Description

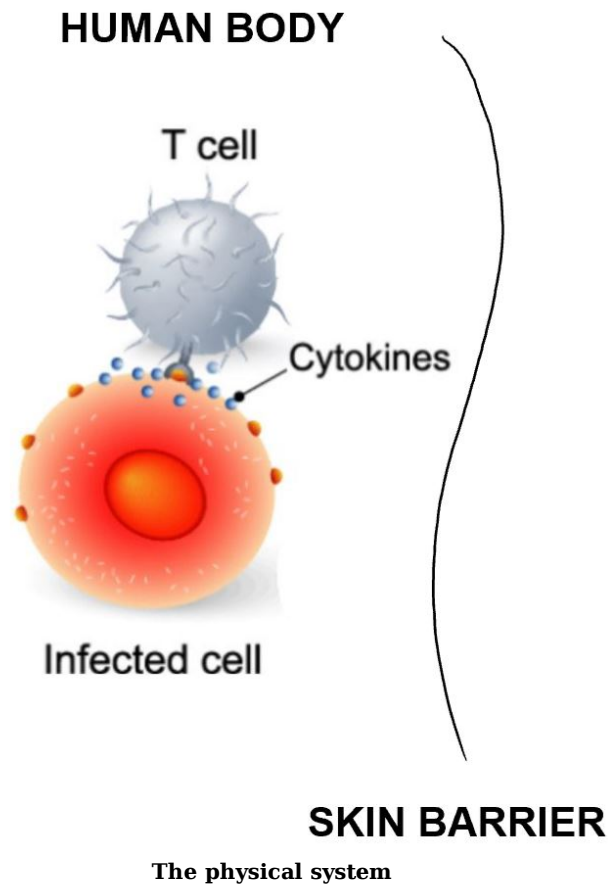
The physical system of Diagnose, as shown in [Fig.Virus](#), includes the following elements:

PS1: The HIV Virion.

PS2: The virus-infected cells.

PS3: The Helper T cell.

PS4: The human body.



Goal Statements

Given two HIV-1 viral load test datum, time duration between the tests and the chosen prediction period, the goal statements are:

detElimrate: Determine the elimination rate of the HIV virus due to immune response.

predictVL30: Predict viral load after chosen prediction period.

Solution Characteristics Specification

The instance models that govern Diagnose are presented in [Section: Instance Models](#). The information to understand the meaning of the instance models and their derivation is also presented, so that the instance models can be verified.

Assumptions

This section simplifies the original problem and helps in developing the theoretical models by filling in the missing information for the physical system. The assumptions refine the scope by providing more detail.

initialInf: Initial infection of HIV for patient is assumed (RefBy: [FR: Verify-Output](#), [FR: Verify-Input-Values](#), [IM: calofPredictedVL](#), and [A: alwaysElim](#).)

constGrowth: The virions will invade uninfected cells at a constant rate.

constVolume: The dimensions of the location associated with the infection remains constant (RefBy: [DD: viralLoad](#).)

constConditions: Temperature of the location associated with the infection remains constant (RefBy: [A: neglectSick](#).)

allProductive: All viruses within the volume infect cells productively (RefBy: [LC: More-Inputs](#).)

alwaysElim: In accordance with [A: initialInf](#), after viremia peak, no significant upward trends occur. (RefBy: [FR: Verify-Output](#), [FR: Verify-Input-Values](#), [IM: calofPredictedVL](#), and [IM: calofElimConst](#).)

neglectDrugs: The effect of antibiotic drugs or therapy on the elimination rate will be not be considered. (RefBy: [LC: More-Inputs](#).)

neglectSick: With reference to [A: constConditions](#), the effect of other infections on the elimination rate will be not be considered. (RefBy: [LC: More-Inputs](#).)

proportional: The elimination of the virus is assumed to be proportional to the amount of viruses present (RefBy: [IM: calofElimConst](#).)

Theoretical Models

This section focuses on the general equations and laws that Diagnose is based on.

Refname	TM:expElim
Label	VLoadt
Equation	$r = \frac{dN_t}{dt} = -kN_o$
Description	<p>r is the rate of change of the viral load ($\frac{\text{mol}}{\text{mLd}}$)</p> <p>$t$ is the time (d)</p> <p>N_t is the viral load at user-defined time t ($\frac{\text{mol}}{\text{mL}}$)</p> <p>$k$ is the elimination constant (d^{-1})</p> <p>N_o is the initial viral load ($\frac{\text{mol}}{\text{mL}}$)</p>
Source	libretexts2020
RefBy	GD: vLoadt

General Definitions

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

Refname	GD:vLoadt
Label	VLoadt as a function of time for constant decay rate
Units	$\frac{\text{mol}}{\text{mL}}$
Equation	$N_t = N_o e^{-kt}$
Description	<p>N_t is the viral load at user-defined time t ($\frac{\text{mol}}{\text{mL}}$)</p> <p>$N_o$ is the initial viral load ($\frac{\text{mol}}{\text{mL}}$)</p> <p>$k$ is the elimination constant (d^{-1})</p> <p>t is the time (d)</p>
Source	hobbie1970
RefBy	IM: calofPredictedVL and IM: calofElimConst

Detailed derivation of viral load at user-defined time t:

Using the First-Order rate Law in [TM: expElim](#), we have:

$$\frac{dN}{dt} = -kN_o$$

Where N_t denotes the viral load at user-defined time t , N_o denotes the initial viral load and k denotes the elimination constant. When rearranging for integration, we have:

$$\int_{N_o}^{N_t} \frac{1}{N_t} dN_t = - \int_0^t k dt$$

Performing the integration, we have the required equation:

$$N_t = N_o e^{-kt}$$

Data Definitions

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

Refname	DD:viralLoad
Label	Viral load
Symbol	N
Units	$\frac{\text{mol}}{\text{mL}}$
Equation	$N = \frac{n}{V}$
Description	N is the viral load ($\frac{\text{mol}}{\text{mL}}$) n is the number of virions (mol) V is the volume (mL)
Notes	The viral load describes the concentration of a virus within the body at a certain time. It assumes that the volume of blood is constant with respect to A: constVolume .
Source	--
RefBy	IM: calofPredictedVL and IM: calofElimConst

Instance Models

This section transforms the problem defined in [Section: Problem Description](#) into one which is expressed in mathematical terms. It uses concrete symbols defined in [Section: Data Definitions](#) to replace the abstract symbols in the models identified in [Section: Theoretical Models](#) and [Section: General Definitions](#).

Refname	IM:calofElimConst
Label	Calculation of elimination rate
Input	N_t, N_o, t_t
Output	k
Input Constraints	$0 < N_t < N_o$ $N_o > 0$ $t_t > 0$

Output Constraints	$k > 0$
Equation	$k = \frac{\ln(N_o) - \ln(N_t)}{t_t}$
Description	k is the elimination constant (d^{-1}) N_o is the initial viral load ($\frac{\text{mol}}{\text{mL}}$) N_t is the viral load at user-defined time t ($\frac{\text{mol}}{\text{mL}}$) t_t is the time duration between initial and secondary viral load test (d)
Notes	The constraint $N_o > N_t > 0$ is required for the nature of the problem with respect to A: proportional . Due to the input constraint, the $k > 0$ is established due to A: alwaysElim . Using this instance model, the goal of the software in GS: detElimrate can be achieved. In addition, this constraint is used to achieve a functional requirement seen in FR: Verify-Output .
Source	--
RefBy	IM: calofPredictedVL

Detailed derivation of elimination constant:

Using the relationship for the viral load seen in [DD: virallLoad](#) with respect to time in [GD: vLoadt](#), we have:

$$N_t = N_o e^{-kt_t}$$

Where N_t denotes the viral load at user-defined time t , N_o denotes the initial viral load and k denotes the elimination constant. When isolating for the elimination constant, we have:

$$\frac{N_t}{N_o} = e^{-kt_t}$$

To isolate further, the natural logarithm is applied:

$$\ln\left(\frac{N_t}{N_o}\right) = -kt_t$$

After using the logarithmic quotient property, we have the required equation:

$$k = \frac{\ln(N_o) - \ln(N_t)}{t_t}$$

Refname	IM:calofPredictedVL
Label	Calculation of elimination rate
Input	N_o, k, t_p
Output	N_p
Input Constraints	$N_o > 0$ $k > 0$ $t_p > 0$
Output Constraints	$0 < N_p < N_o$

Equation	$N_p = N_o e^{-kt_p}$
Description	N_p is the predicted viral load at time t ($\frac{\text{mol}}{\text{mL}}$) N_o is the initial viral load ($\frac{\text{mol}}{\text{mL}}$) k is the elimination constant (d^{-1}) t_p is the time duration of chosen prediction period (d)
Notes	The constraint $N_o > N_t > 0$ is applies when determining future values from the in initial infection with respect to A: initialInf as well as A: alwaysElim . Using this instance model, the goal of the software in GS: predictVL30 can be achieved. In addition, this constraint is used to achieve a functional requirement seen in FR: Verify-Output .
Source	--
RefBy	

Detailed derivation of predicted viral load at time t:

Using the relationship for the viral load seen in [DD: viralLoad](#) with respect to time in [GD: vLoadt](#), we have:

$$N_t = N_o e^{-kt_p}$$

Where N_t denotes the viral load at user-defined time t , N_o denotes the initial viral load and k denotes the elimination constant. When predicting the viral load after 30 days, the elimination constant found in [IM: calofElimConst](#), is used instead of N_t therefore we have:

$$N_p = N_o e^{-kt_p}$$

Data Constraints

[Table:InDataConstraints](#) 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 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. 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.

Var	Physical Constraints	Typical Value	Uncert.
N_o	$N_o > 0$	$10.0 \cdot 10^6 \frac{\text{mol}}{\text{mL}}$	10%
N_t	$0 < N_t < N_o$	$5.0 \cdot 10^6 \frac{\text{mol}}{\text{mL}}$	10%
t_p	$t_p > 0$	$30.0 d$	10%
t_t	$0 < t_t < t_p$	$1.0 d$	10%

Input Data Constraints

Properties of a Correct Solution

[Table:OutDataConstraints](#) shows the data constraints on the output variables. The column for physical constraints gives the physical limitations on the range of values that can be taken by the variable.

Var	Physical Constraints
k	$k > 0$
N_p	$N_p > 0$

Output Data Constraints

Requirements

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

Functional Requirements

This section provides the functional requirements, the tasks and behaviours that the software is expected to complete.

Input-Values: Input the values from [Table:RegInputs](#).

Verify-Input-Values: The software will ensure that the inputs are not out of bounds and in accordance with the data constraints especially regarding the [A: initialInf](#) and furthermore, [A: alwaysElim](#). If any inputs are out of bounds, an error message is displayed.

Calculate-Values: Software calculates the initial elimination rate of HIV virus and the predicted viral load after the chosen prediction period.

Verify-Output: The output values will be cross referenced with the result constraints. This requirement is related to the assumptions: [A: initialInf](#) and [A: alwaysElim](#).

Output-Values: Output related requirements including the elimination rate and predicted viral load to satisfy the goals of Diagnose.

Symbol	Description	Units
N_o	Initial viral load	$\frac{\text{mol}}{\text{mL}}$
N_t	Viral load at user-defined time t	$\frac{\text{mol}}{\text{mL}}$
t_p	Time duration of chosen prediction period	d
t_t	Time duration between initial and secondary viral load test	d

Required Inputs following [FR: Input-Values](#)

Non-Functional Requirements

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

Verifiable: The Drasil generated python code is tested using static and dynamic code analysis, linting, unit and system testing and continuous integration methods outlined in the Verification and Validation plan of Diagnose.

Understandable: The code will be generated using the Drasil Framework into modules to address each requirement.

Reusable: The code will be created using Drasil. The framework has data libraries of scientific theories, concepts, quantities and units commonly used in scientific problems. The created knowledge libraries of Diagnose can be reused as required.

Maintainable: 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 throughout the documentation of Diagnose to measure maintainability. The traceability will be measured by ensuring the connections are recorded and identifiable.

Portable: The code is able to be run in different environments.

Likely Changes

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

More-Inputs: The software may be expanded to include more inputs from the user to increase the accuracy of the output. This change may alter assumptions: [A: allProductive](#) , [A: neglectSick](#) and [A: neglectDrugs](#).

More-Outputs: The software may be expanded to include more outputs like assessing the progression to AIDs or a suggestion for therapy.

Unlikely Changes

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

Determine-elimination-rate: The goal of determining the elimination rate of the virus will not likely change.

External-input: There will always be a source of input data external to the software.

Unchanging-input-constraints: The input constraints will not likely change.

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" should be modified as well. [Table:TraceMatAvsA](#) shows the dependencies of assumptions on the assumptions. [Table:TraceMatAvsAll](#) shows the dependencies of data definitions, theoretical models, general definitions, instance models, requirements, likely changes, and unlikely changes on the assumptions. [Table:TraceMatRefvsRef](#) shows the dependencies of data definitions, theoretical models, general definitions, and instance models with each other. [Table:TraceMatAllvsR](#) shows the dependencies of requirements, goal statements on the data definitions, theoretical models, general definitions, and instance models.

	A: initialInf	A: constGrowth	A: constVolume	A: constConditions	A: allProductive	A: alwaysElim	A: neglectDru
A: initialInf							
A: constGrowth							
A: constVolume							
A: constConditions							
A: allProductive							
A: alwaysElim	X						
A: neglectDrugs							
A: neglectSick				X			
A: proportional							

Traceability Matrix Showing the Connections Between Assumptions dependence of each other.

	A: initialInf	A: constGrowth	A: constVolume	A: constConditions	A: allProductive	A: alwaysElim	A: neglectDr
DD: viralLoad			X				
TM: expElim							
GD: vLoadt							
IM: calofElimConst						X	
IM: calofPredictedVL	X					X	
FR: Input-Values							
FR: Verify-Input-Values	X					X	
FR: Calculate-Values							
FR: Verify-Output	X					X	
FR: Output-Values							
NFR: Verifiable							
NFR: Understandable							
NFR: Reusable							
NFR: Maintainable							
NFR: Portable							

LC: More-Inputs					X		X
LC: More-Outputs							
UC: Determine-elimination-rate							
UC: External-input							
UC: Unchanging-input-constraints							

Traceability Matrix Showing the Connections Between Assumptions and Other Items

	DD: viralLoad	TM: expElim	GD: vLoadt	IM: calofElimConst	IM: calofPredictedVL
DD: viralLoad					
TM: expElim					
GD: vLoadt		X			
IM: calofElimConst	X		X		
IM: calofPredictedVL	X		X	X	

Traceability Matrix Showing the Connections Between Items and Other Sections

	DD: viralLoad	TM: expElim	GD: vLoadt	IM: calofElimConst	IM: calofPredictedVL	FR: Input-Values	FR: Verify-Input-Values	FR: Calculate-Values	FR: Veri Out
GS: detElimrate									
GS: predictVL30									
FR: Input-Values									
FR: Verify-Input-Values									
FR: Calculate-Values									
FR: Verify-Output									
FR: Output-Values									
NFR: Verifiable									
NFR: Understandable									
NFR: Reusable									
NFR: Maintainable									
NFR: Portable									

Traceability Matrix Showing the Connections Between Requirements, Goal Statements and Other

Values of Auxiliary Constants

There are no auxiliary constants.

References

- [1]: Fischer, Ulrike R. and Weisz, Willy and Wieltschnig, Claudia and Kirschner, Alexander K. T. and Velimirov, Branko. *Benthic and Pelagic Viral Decay Experiments: a Model-Based Analysis and Its Applicability*. June, 2004. <https://aem.asm.org/content/70/11/6706>.
- [2]: Hobbie, Russell K. and Roth, Bradley J. *Exponential Growth and Decay*. January, 1970. https://link.springer.com/chapter/10.1007/978-0-387-49885-0_2.
- [3]: Libretexts Contributors. *14.4: The Change of Concentration with Time (Integrated Rate Laws)*. August, 2020. [https://chem.libretexts.org/Bookshelves/General_Chemistry/Map:_Chemistry_-_The_Central_Science_\(Brown_et_al.\)/14:_Chemical_Kinetics/14.4:_The_Change_of_Concentration_with_Time_\(Integrated_R](https://chem.libretexts.org/Bookshelves/General_Chemistry/Map:_Chemistry_-_The_Central_Science_(Brown_et_al.)/14:_Chemical_Kinetics/14.4:_The_Change_of_Concentration_with_Time_(Integrated_R)
- [4]: Perelson, Alan S. and Neumann, Avidan U. and Markowitz, Martin and Leonard, John M. and Ho, David D. *HIV-1 Dynamics in Vivo: Virion Clearance Rate, Infected Cell Life-Span, and Viral Generation Time*. June, 1996. <https://science.sciencemag.org/content/271/5255/1582.full.pdf>.
- [5]: Weisstein, Eric W. *Exponential Decay*. June, 1996. <https://mathworld.wolfram.com/ExponentialDecay.html>.
- [6]: William C. Shiel Jr. MD. *Definition of T cell*. December, 2018. <https://www.medicinenet.com/script/main/art.asp?articlekey=11300>.