A Near Field Communication Detection System for Drug-Drug Interactions

BY

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THESIS

Submitted as partial fulfillment of the requirements
for the degree of Master of Science in Electrical and Computer Engineering
in the Graduate College of the
University of Illinois at Chicago, 2016

Chicago, Illinois

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In memory of Ibrahim Alhlafy, my best friend, brother, and mentor. You left unforgettable fingerprints, and I wish you were here with me. You will always be missed!

ACKNOWLEDGMENTS

I would like to thank my advisor Prof. Piergiorgio Uslenghi for his support with my M.S. study since the first day I met him in Iraq. He was the reason behind making my dream come true to study at UIC, and was there whenever I needed help. I also would like to express my sincere gratitude to the rest of my thesis committee: Prof. Loay Abusalah and Prof. Dima Qato for their enormous and endless care and support with my study. They have a lot of patience, motivation and immense knowledge that provided me guidance in all areas that helped me accomplish my research goals; Prof. Rashid Ansari, for his continuous assistance and support which pushed me to widen my research from various perspectives.

I also would thank my mentor, my friend and previous advisor Dr. Firas Al-Saidi at Al-Nahrain University in Baghdad, for believing in me and for his inspiring ideas and untiring support that made it easier for me to overcome any problem in the way of my study and made me enjoy myself in the process.

Last but not least, a number of people who were the reason behind my accomplishments and success who I also would like to thank: my family for their love, patience, and spiritual support throughout my study abroad and my life in general; my friends Mustafa Al-Jobory, Samir Al-Safar, Gema Amaya-Santos, Andrew Adado for being there for me through my hard times, and for believing in me all the times throughout my entire journey of study.

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LIST OF ABBREVIATIONS

ADR	Adverse Drug Reaction
CAS	Chemical Abstracts Service
CCID	Chip/Smart Card Interface Devices
DAC	Digital to Analog Converters
DDIs	Drug-Drug Interactions
FDA	Food and Drug Administration
I^2C	Inter Integrated Circuit
IDE	Integrated Development Environment
JDK	Java Development KIT
LCD	Liquid Crystal Display
NDC	National Drug Code
NDEF	NFC Data Exchange Format
NFC	Near Field Communication
OCR	Optical character Recognition
OTC	Over-the-Counter
RFID	Radio Frequency Identification
SCL	Serial Clock line
SDA	Serial Data line
SRAM	Static Random Access Memory

LIST OF ABBREVIATIONS (continued)

SPI	Serial Peripheral Interface
TTL	Transistor-Transistor Logic
USB	Universal Serial Bus

SUMMARY

Adverse Drugs Reactions (ADRs) and their subset Drug-Drug Interactions (DDIs) are one of the important problems occurring in hospitals and healthcare centers around the world. A lot of studies and researches around the world focused on this problem to show their prevalence that is high, and their side effects that can be dangerous, and sometimes fatal. Other studies tried to find solutions to detect this problem in order to avoid it based on the use of reporting systems, online databases and other sources. These solutions were promising so far, but they did not pay a lot of attention to come up with an easy solution that can be used at the patient level.

The objective of this thesis is to find an easy and convenient solution to help detect DDIs in a patient oriented way that does not need any knowledge to decipher the information. The system is based on the use of Near Field Communication (NFC), where the drugs will be identified by NFC tags attached to their containers having all the DDIs information related to them. The consumers will be able to check for the presence of DDIs among these purchased drugs by scanning them using a Patient Terminal which is a small device designed for this purpose, and showing the results in a user friendly interface without the need of internet access.

This design used a known unified identifier to unify the different names and brands of drugs that are being purchased in the market from Over-the-Counter (OTC) to prescription drugs, as well as the different names of these drugs that are used in other regions and countries. The reason is to be able to detect any possible DDI for drugs from different areas and regions without depending on their names. Due to the large amount of data, different steps have been taken for compression, making it possible to store these data in a relatively small memory size NFC tags.

SUMMARY (continued)

The first version was described in this study, and afterwards other improvements and prototypes have been discussed for consideration as a future work. Finally, the system has been tested and worked successfully using samples of real drugs data.

1. INTRODUCTION

1.1 Drug Interactions

A drug is a compound, group of compounds or other substances that has a physiological effect when ingested or introduced to the human body in any other way. So far, it has been known that for all the drugs to be effective on the human body, there is always the potential of generating benefits, as well as risks in which it can be put in other words, the desired and undesired effects of these drugs.

As observed and noticed throughout the time, different patients have different responses to drugs, and to have a better understanding of that, it has to be mentioned that any particular response to a drug at the effect sites of the human body is caused by the concentration of that drug, and its metabolites, and with having that, it is more beneficial to divide the relationship between drug administration and responses into [1]:

1- The pharmacokinetic phase: relating drug administration to concentrations within the body produced over time.
2- The pharmacodynamic phase: relating the desired and undesired response produced to concentration.

Based on the divisions above, the response to a drug will differ from one person to another due to genetics, age, disease, and the presence of other drugs [1].

1.2 Adverse Drug Reactions

Adverse Drug Reaction (ADR) is an injury or a side effect that is caused by taking drugs, and this will happen due to a lot of reasons, such as these drugs will interact with food, dietary

substances, or other drugs, where we can call it Drug-Drug Interactions (DDIs). A Drug-Drug Interaction (DDI) happens when patients are asked to take several drugs at the same time. These drugs might be Over-the-Counter (OTC), or prescribed drugs, and in either ways it is very possible that an interaction can happen between them. Drug-Drug Interactions (DDIs) can be put in different categories, depending on the underlying mechanism, such as Figure 1.

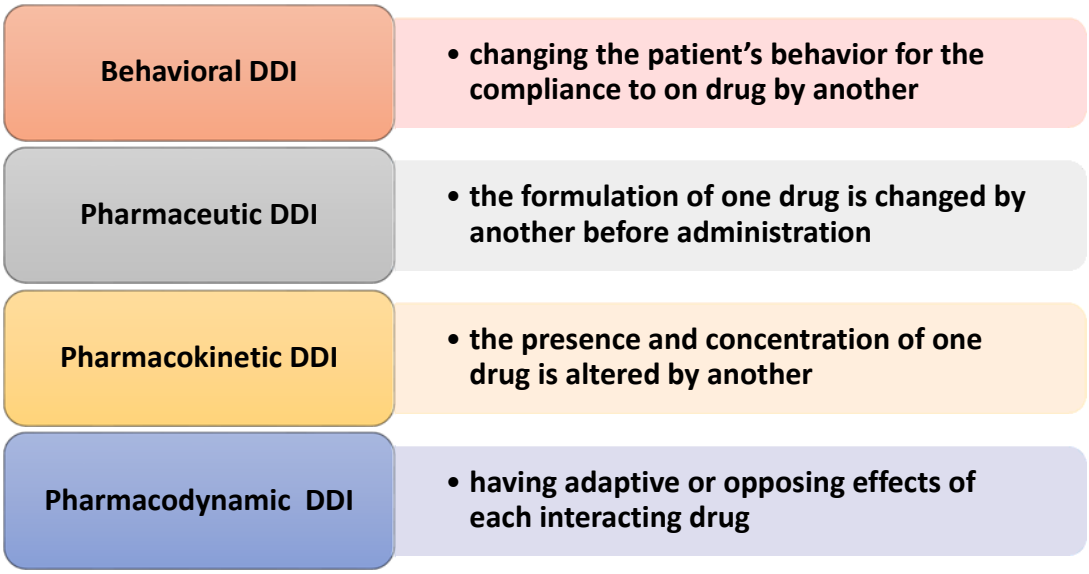


Figure 1. Drug-Drug Interactions categories

Based on the above categories, DDIs can be intentional beneficial or unintentional harmful, clearly the unintentional ones are of concern and what is focused on due to the fact that

they almost constitute 10%-20% of the overall ADRs [2]. These unintentional harmful DDIs cause a lot of problems such as partial or complete abolishment of treatment efficacy, or other problems, such as serious and fatal adverse events that lead to urgent hospitalization and care. Drug-Drug interactions (DDIs) attract general attention and focus towards the importance and danger of this problem, especially with the large number of researches and studies that haves been done to find out possible new DDIs, and enhancing the post-marketing monitoring of new or old drugs to better safeguard the public health, and even a counter action it has been stated that a number of these interacting drugs that are noticed on post-marketing, have been suspended from the market [3] [4].

1.3 Adverse Drug Reactions (ADRs) and the elderly people

While the effect and impact of ADRs has been given the required attention and been shown clearly enough through time for general adult population, the same attention had not been given enough for the elderly population who have a higher possibility to be exposed to different kinds of diseases and illnesses[5]. Having that, this will increase their needs to taking more drugs than other people with other age subgroups, leading to the fact that says they will be more subjectable to face the problem of DDIs, and the main reason behind that is the gradual physiological changes related with age, affecting the pharmacokinetic and pharmacodynamics properties of a variety of medications [6].

A lot of studies that included large numbers of elderly drug users have been done to obtain enough information and generate statistics about incidents of ADRs and DDIs experienced with the adults and elderly populations, helping getting the knowledge of how frequent they

happen, and what is the effect caused by them. One of the studies that used the data provided by a family health care unit in Brazil, showed that among a group of elderly people, a DDI had occurred with 39% (for people with 2-3 concurrent drugs), 88.8% (for people with 4-5 concurrent drugs) and 100% (for people with 6-7 concurrent drugs). TABLE I shows these statistics [7].

TABLE I

DRUG-DRUG INTERACTIONS STATISTICS FROM THE FISRT STUDY

Number of concurrent drugs	DDI percentage
2-3	39%
4-5	88%
6-7	100%

A second study is concerned with the prevalence of DDIs used a sample of 3005 residing elderly people, showed that about 30% of them are using 5 drugs concurrently, and that 4% of them are having the risk of a major DDI [8]. This study also stated that these 4% (1 out of 25) persons (or approximately 2.2 millions) in USA who are potentially having the risk of a Major DDI will also have this risk increase respectively with age, leading to hospitalization and urgent care.

TABLE II

EXAMPLES OF POTENTIAL MAJOR DRUG-DRUG INTERACTIONS AND THEIR SIDE EFFECTS FROM THE SECOND STUDY

Interacting drugs	Effect of interaction
Albuterol - Atenolol	Decreased effectiveness
Albuterol - Metoprolol	Decreased effectiveness
Warfarin - Simvastatin	Increased risk of bleeding/rhabdomolysis
Clopidogrel - Warfarin	Increased risk of bleeding
Lisinopril – Potassium	Increased risk of hyperkalemia
Aspirin - Warfarin	Increased risk of bleeding
Niacin - Atorvastatin	Increased risk of myopathy or rhabdomolysis
Garlic - Warfarin	Increased risk of bleeding
Niacin - Simvaststin	Increased risk of myopathy or rhabdomolysis
Ginkgo - Aspirin	Increased risk of bleeding

The last study that has been reviewed showed that 1 out of 30 urgent hospital admissions of patients with age of 65 and older, is caused by ADR, and almost half of these ADRs are suspected to be DDIs, and the mortality rates were higher with the persons of old ages [9].

Having all of these statistics from the above studies and results from other studies shows that there is actually a serious problem of DDIs that can happen to everyone, but most likely its occurrence is of a high frequency in the elderly population. This problem needs to be solved by means of providing the professional experience by clinicians, pharmacists or others who is in the in the field of health care. Another way to help is by relying on technology that comes on a variety of forms from the use of devices designed to help detect this problem or the use of the online resources when the professional experience is not provided at a certain time due to a different reasons.

2. DRUG-DRUG INTERACTIONS WITH RELATED LITRATURE

The attention given to the problem of DDIs (especially for the elderly people) was of a high importance due to its dangerous and sometimes fatal side effects which make taking serious actions and solutions as soon as possible a vital and an important thing to avoid or reduce this problem. In this chapter, some of the reasons that cause the problem of DDI will be discussed. After that, some of the studies that came with different solutions will be reviewed as well showing some of their drawbacks that led to proposing a system that will help with detecting the problem of DDIs in the end of the chapter.

2.1 Prescriptions Problems

Reducing the risk of a DDI can be done as a first thought with the medical help and advice provided by clinicians and doctors. Although these specialists already have the required knowledge to provide health care by means of medical advice or prescribing medications to the patient, room for having medication prescriptions errors and faults in general practice and hospitals still exists, leading to some undesired or dangerous and sometimes fatal side effects in which affects the patient's safety and the quality of the healthcare [10].

Prescribing errors made by doctors can be caused by a variety of reasons and factors that may affect separately or all together the decision of the prescriber. According to a study done in Scotland for a period of 14 months targeting junior doctors in eight hospitals, a significant number of these doctors were responsible for making prescriptions errors (40 doctors for 100 errors), these errors were categorized into different categories [11]. Work environment and workload was one important aspect that leads to pressure and then making mistakes. Another

factor was the lack of experience and practice that makes rushing in making decisions and prescribing medications a very common thing [11]. Next reason was the lack of proper communication between the team of doctors that led to errors in prescribing by a member of the team, or failing to detect an error made by one member by another member. Another cause that was found, is the poor documentations for some medications that will make it hard to prescribe the safe combination of medications, and finally, the poor information about what medications are being taken by the patients also identified as one of the important reasons behind errors in prescriptions in this study [11]. Another study that has been done at Hospital de Clínicas de Porto Alegre in Brazil for a period of two years to classify and categorize the types of medications errors and their seriousness, and it has been found that 48.25% of them were prescribing errors made by doctors, even though most of these errors has been detected and identified by nurses working there, but the possibility of not detecting these errors and giving the patients these prescriptions is very high [12]. Last but not least, with a study that has been done in Pakistan focused the percentage of DDIs observed in community and hospitals, it has been found that among 1014 prescriptions in total for a group of patients with age of (4-85) years, 40% of them had one interacting combination or more with 13% major, 17% moderate and 10% minor interactions [13].

Prescriptions errors made by specialists as shown above are very common but may be avoided by eliminating the reasons that caused them at least to some extent , but even by doing so, purchasing OTC drugs by patients makes the problem of DDI even more serious. By Purchasing OTC drugs, the patient does not have the scientific background or practice that may

help him/her to identify a potential DDI between two or more OTC drugs or between OTC and prescribed drugs in order to avoid it, and what makes this problem even more critical when the patients are old adults who possibly have more medical problems and use more medications or do not pay attention like the other age groups, as one of the studies showed that more than half of the major DDIs are caused by non-prescription drugs or what is called OTC drugs purchased by the elderly people[14] [7].

2.2 Literature Review

Currently, a lot of researches and studies have been done to improve the efforts in the area of DDI detection, some of them were based on reporting systems, Electronic medical records, online healthcare social media and others. Most of these studies showed some promising results but they also have some weak points and drawbacks.

2.2.1 Food and Drug Administration's Reporting System

One of the studies that used the Food and Drug Administration's (FDA) reporting system which is a database containing information about ADRs submitted to FDA [15], and used these information to build classified models to look for pairs of drugs in order to predict DDIs [16]. Another study investigated two models to detect DDIs from the FDA's reporting systems [17]. There are a lot of other reporting systems (like the FDA's system) all over the world and they surely made a big contribution to studies meant to help with the problem of DDIs and that is why these reporting systems were useful sources. However, there is a major problem, and it is that a lot of interesting cases of ADRs are not reported to these systems in a high ratio (under-reporting)

due to some delays in reporting, the passive nature of these reporting systems, or other difficulties, which leads to not being able to detect these particular cases or ADRs [18].

2.2.2 Electronic Medical Records

Other studies used Electronic Medical Records (standard medical history of a patient by one provider) to help with the problem of DDI [19]. One study used Drug utilization reports of some patients between 2006-2009 at a cancer center in Singapore and these reports were checked with the use of an internet based oncology database to identify DDIs [20]. However, getting these Electronic Medical Records is not an easy thing because of the privacy issues and to use them at a particular institution requires approval, and mostly they are available only to researchers or personnel who have cooperation with that institution [21].

2.2.3 Consumer Contributed Contents

Consumer contributed contents can be used as a useful source to help, like one of the studies used online healthcare social media (informative free public source) as a consumer contributed contents to construct a heterogeneous healthcare network with the use of some logistic prediction models to detect DDIs [22]. To effectively detect DDIs using Consumer contributed contents, the contents should have enough data to serve this purpose, like the healthcare social media (in the previous study) should have active discussion between consumers about the drugs causing that particular DDI, because if there is no active discussion, the DDI will not be detected.

2.2.4 Computerized Systems

Most of the reviewed studies (e.g. using reporting system) did not mention or focus on the final interface that will show the results or signals of DDIs and kind of implied on using the memory of the professionals to keep tracking them, but having a lot of such cases will make tracking these signals a big challenge, so there should be some ways that will make the professionals or consumers to have access of these information, and for that a lot of other studies have proposed some solutions. One of the studies proposed to detect signals of DDI in reporting system by using a computerized system consists of a local database with data synchronized with these reporting systems, and computer software that will serve as the processing unit and the main interface for inputs and outputs [23]. One of the drawbacks of this system again is using these reporting systems mentioned before that may encounter some under-reporting issues, and another thing is that the authors did not mention how to make this system accessible by consumers to make them able to check the presence of DDIs by themselves, that is why such solution need to found as another line of defense for detecting DDIs in case the previous solutions or techniques will fail to do so.

2.2.5 Internet Solutions

One study came with a promising solution for drugs checking based on the internet of things and knowledge-based system to detect ADRs and allergy interactions, and this system consists of the consumer or patient's terminal to scan drugs or other products, and this terminal is mainly any device with barcode scanner or Near Field Communication (NFC) adapter (e.g. cellphones, PCs , etc.), while the other part is a Pharmaceutical Information System which is

basically a database holding the patient's Electronic Medical Record, letting the patient or consumer check a drug by scanning it, and the system after all will warn the person if this product is compatible or not using the cellphone or PC's screen [24]. This system proposed to add the feature to detect DDIs as a future work.

Another means for Consumers to check for DDIs is using online Pharmacological Databases (e.g. Micromedex, DrugBank, etc). one of the problems in this study is that the consumer should have a device (e.g. cellphones) with NFC technology, and not all the phones are equipped with this technology, and even if the second option will be used (scanning the barcode with the camera), it is still not a good option because that means that the Pharmaceutical Information System should have a list of all the possible barcodes of all the drugs, which is something very challenging because different companies use different barcodes around the world and some of them use same barcodes for different drugs and vice versa[25].

Using online recourses is beneficial like **1)** using the online Pharmacological Databases, **2)** using smartphones Apps provided by pharmacies to scan the barcodes of these drugs and check for potential DDIs, or **3)** using other solutions like what has been used in the last study mentioned above. The problem with these online recourses is that the user needs to have internet access and have devices with integrated adapters in order to get results (e.g. NFC, Cameras) which is something that maybe hard to achieve for everybody. Some of the researches that have been done showed that about 15% of Americans and about 4.4 billion people worldwide are still offline or do not use the internet at all [26][27]. Another research showed that in 2011, 83% of U.S. adults have a cell phone of some kind, and that only 42% of them own a smartphone [28]. These

numbers may vary from one place to another all around the world, but this at least gives some idea about the possibility of not having a smart devices, or not being online. Another thing that has not been mentioned or given enough attention is that drugs have different names in different regions or countries, so in order to successfully detect DDIs of these drugs from different regions, all of these names should be saved and synchronized in the proposed systems in order to achieve that, which is something challenging and needs a lot of efforts [29] [30].

2.3 The Motivation behind This Thesis

The drawbacks in each proposed solution in section 2.2 was the motivation behind this study. Our goal is to introduce an easy solution to detect DDIs by almost anyone with or without any medical experience (e.g. clinicians, home nursing individuals, other participants in the health care field and most importantly the patients themselves). This solution will focus on giving the user a quick warning about the presence of DDI rather than showing any other details about the patient or their medical history records. Afterwards the patient can double check with the specialist about a possible error in the prescription that led to this DDI. This can happen offline and without the need to be connected to the internet or any database.

3. A DRUG-DRUG INTERACTION NEW DETECTION METHODOLOGY

As seen in the previous chapter, few methods and systems have been introduced to help detecting the problem of DDIs by both professional individuals (e.g. Clinicians) or non-professionals (e.g. consumers), but they may have the problems like the lack of experience (especially elderly people), and maybe the lack of access to information. In this chapter, a proposed simple solution based on the NFC technology will be proposed to help with this problem, and it is user friendly, plus it does not need any kind of experience to interact with in order to get the final results. In the next section, a brief information about the NFC technology will be reviewed to help understanding the next chapter. In the subsequent sections, the proposed solution will be briefly explained and illustrated along with its strength.

3.1 Near Field Communication

Radio Frequency Identification (RFID) technology and its next generation Near Field Communication (NFC) have been introduced for the past few years and became widely used, due to their uses in the tap-and–go payments, the using of public transportation, the peering of two devices and exchanging of the secured data between two close devices (e.g. smartphones), making it one of the must to use technologies with various aspects in the future. Radio Frequency Identification (RFID) and Near Field Communication (NFC) share some properties together, like both have two nodes of operation, an initiator and a target [31].

Radio Frequency Identification (RFID) has a lot of standards based on the operating frequencies and some other features, like ISO/IEC 14443, ISO/IEC 15693, ISO/IEC 18000 series and ISO 11784/11785, while the NFC is only a subset of that, using mostly the standard ISO/IEC

14443 which has an operating frequency of 13.56 MHz [32][33]. Near Field Communication (NFC) added more security in order to authenticate before the actual data transfer which makes it even more preferable, and it works in a close range (up to 10 cm) which makes it more private and secure than RFID that can operate in a range up to 3 meters, making NFC have low power consumption comparing to RFID [34].

Near Field Communication (NFC) is based on a structure called NFC Data Exchange Format (NDEF), which is a standard data format that is used for the data exchanged between an NFC device and any other NFC device or tag, usually it is called NDEF message. Each message contains sub messages called a Records, and each one of these records can have different types, ID, length and payload. All of these records data will be distributed into a memory layout, this layout consists of sectors, and within each sector there is a number of blocks where the actual data will reside, this number of blocks varies according the to the used tag. An NDEF record comes into different types, such as a text record (stores text), and URI record (stores websites address) [31].

There are a lot NFC tags in the market today, but all of them can be characterized under four main types of tags standardized by NFC forum, based on the control protocols. Three of these types (Type 1, 2 and 4) are based on the ISO-14443A standard, but Type 3 is based on ISO-18092 standard. Most of these types differ in their memory sizes and the transfer speed. There is another type which is not standardized by NFC Form but it is compatible with ISO-14443A called MiFare Classic, which is one of the most used types these days, and will be used in a proposed system in the following sections.

3.2 A New Drug-Drug Interaction Detection System

A lot of the DDIs information is available online from various databases sources, like DrugBank and Micromedex. In order to get any information, an internet access is needed, plus a help from a professional maybe needed to enter the drugs names that need to be entered manually and to decipher some of the results to the patient or the consumer. The proposed prototype of this system is designed with an easy interface to help with the problem of DDI, and it can be used easily by both young and elderly people. This system consists of two parts, which are the **Pharmacy Terminal** where the DDIs information will be encoded in small tags attached to the drugs' containers by a pharmacist or a patient, and the **Patient Terminal** where these drugs will be scanned next by the patient with a device to detect the presence of any DDI. Figure 2 shows the system's diagram.

3.2.1 Pharmacy Terminal

The pharmacy will provide each drug container with an NFC tag (NFC target) attached to it, every tag will have:

1. The drug information
2. A list of the drugs that will interact with this drug.

These tags will be encoded inside the pharmacy using a Software/Hardware Solution, and for this, a prototype has been created which consists of computer application connected to a

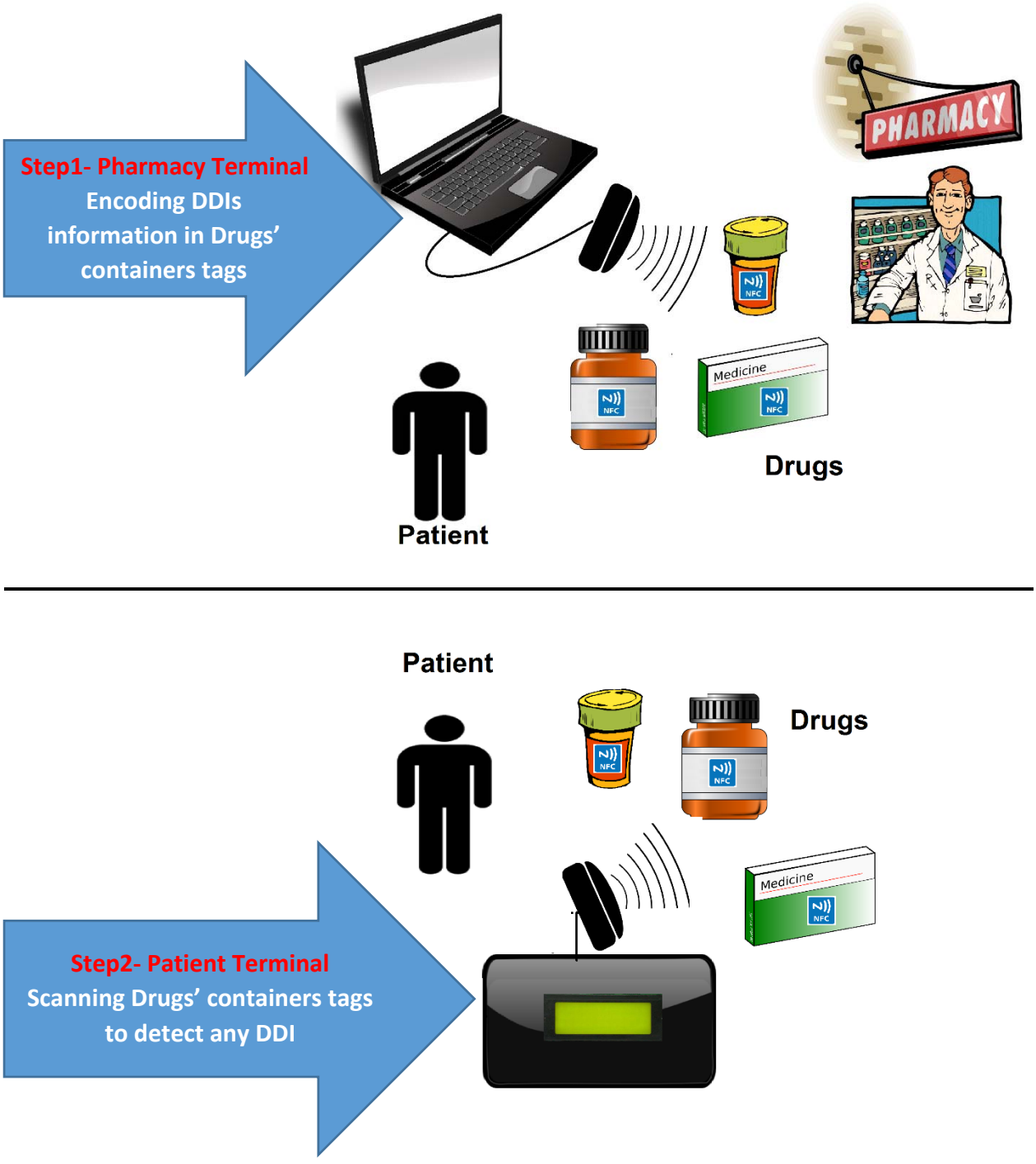


Figure 2. The new DDI detection system diagram

local database of DDIs, and this local database gets the information from a main online database (e.g. Micromedex, DrugBank) where all the DDIs are stored. Once the user (pharmacist or a consumer) enters two letters or more of the drug name, a list of the potential drugs names will pop up based on these two letters that can be in the beginning, the middle, or the end of the drug name to help this user find the drug name without any errors. This computer application is connected to an NFC Reader/Writer adapter that does the actual encoding of these tags, and this adapter connects to the computer using the Universal Serial Bus (USB). The encoding can be done either by a pharmacist, or by the consumer with easy steps, and attaching these tags to the containers can be optional but recommended to avoid any confusion in the future. Figure 3 shows the Pharmacy Terminal diagram.

3.2.2 Patient Terminal

The Patient Terminal is based on a central device or box with an NFC reader (NFC initiator), microcontroller, small screen and some functions buttons. This device can be purchased by a patient, home nursing professional, or any other expert or non-expert in the medical field. The device works as follows and as shown in Figure 4.

1. Two Drug containers or more with an NFC tag attached to each, containing all the DDI information related to that particular drug as mentioned above, are scanned by this central device, one by one.
2. A “CHECK” button should pressed to start analyzing the data and show if there is any possible DDI result on the screen, and will be given as the number of DDIs found within the entire group of scanned drugs.

3. A “NEXT” button should be pressed to show the final result which consists of pairs of names of any two interacting drugs, side by side with the severity of this interaction. The consumer will be able to navigate through these pairs, till he/she will reach the last pair from the results, then it will start over with the first pair again.
4. A “RESET” button which can cancel all the previous operations.

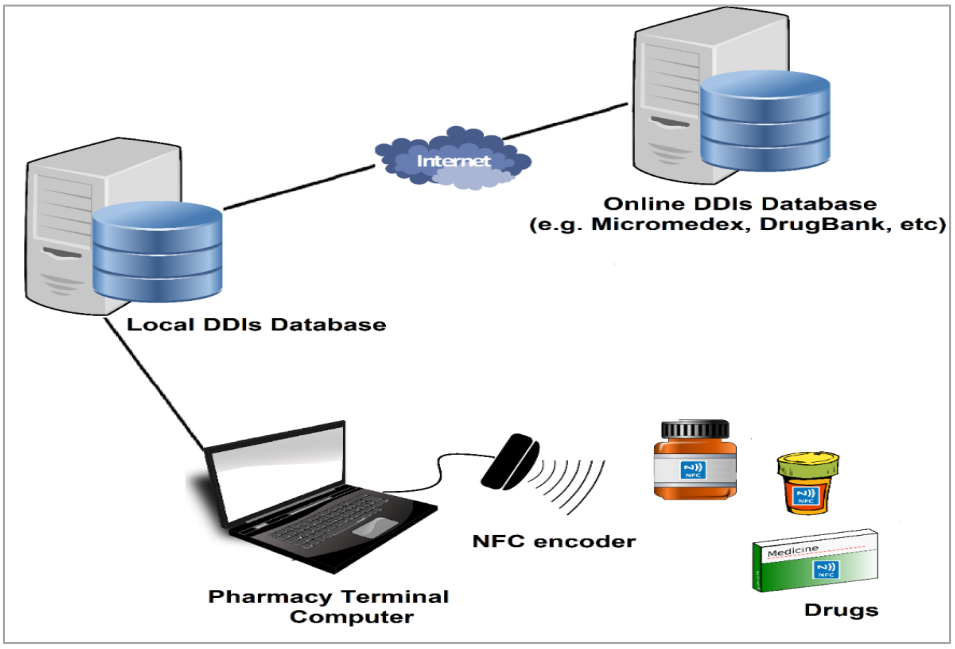


Figure 3. The Pharmacy Terminal diagram showing the main encoder’s database connection

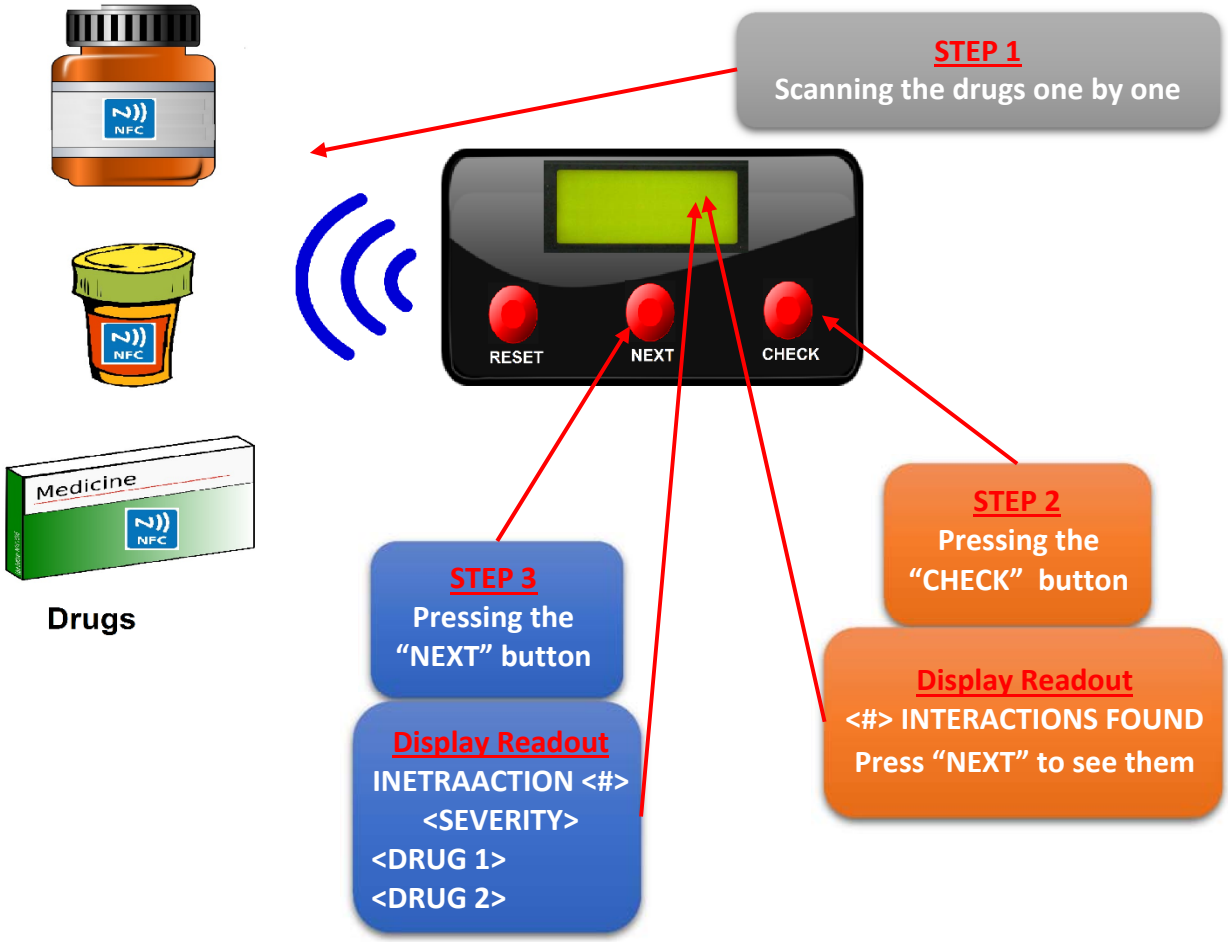


Figure 4. The Patient Terminal diagram showing the steps of scanning

3.3 System's Benefits

The proposed solution is very easy to use by almost everybody. Below are some features for the proposed system:

- Helping the person who is in charge for tag encoding (pharmacist or consumer) to find the right drug easily with a list of suggestions while typing the name of the drug, reducing the chance to have any error.
- The central device does not need any special experience or training to make it work. The patient just scans the drugs and the results will appear, which makes it easy to deal with, and this is a great advantage for elderly people reducing the possibility for them to make any mistakes or having any difficulty to make it work.
- If it will be implemented in all pharmacies or drugs suppliers, a unified system will be created, this will make the consumer be able to purchase drugs from different pharmacies without worrying about the different naming or barcoding system used in these pharmacies, leading not to being able to detect DDIs. The new local databases of these pharmacies or drugs suppliers will be consistent and synchronized with the main DDIs database like Micromedex where a high quality information of drugs and it is used and trusted by clinicians in more than 3500 medical institutions around the world due to an ongoing comprehensive reviews and studies done by professionals in the medical field [35].

- No need to have internet access to detect any possible DDI while using the proposed system. The reason behind that is as mentioned above, every tag attached to a drug container have complete list of drugs interacting with it, and this data will be checked and analyzed by the central device (patient terminal) to determine the presence of a possible DDI between these drugs, so these tags can be considered as local small databases for every drug.
- The tags can always be reused again and again by simply rewriting another drug's information in it. This will be beneficial for the patient in order not to purchase another one and it will be beneficial for the pharmacy to reuse them for another drug.
- Different names for the same drug in different regions or countries will not cause a problem in detecting DDIs. The reason behind that is that a unique identifier will be used for every drug during the actual data analysis at the moment of pressing the "CHECK" button in the central device to show the potential DDIs.

4. SYSTEM IMPLEMENTATION AND RESULTS

This proposed system was created to help with the problem of detecting DDIs that are still occurring nowadays with rates that lead to raising the awareness of finding some practical and easy solution to help improve detecting these DDIs. Some solutions were proposed to be used by professionals, but solutions for people with no experience such as elderly people had not given the required attention, so for that reason a system that can be used with easy steps was much needed. After briefly describing the new proposed system in the previous chapter, in this chapter, a detailed description of the system main two parts (Pharmacy Terminal and Patient Terminal) will be shown in both the hardware and software sides, but first comes a brief description of one of the main parts that the system's two parts (Pharmacy and Patient Terminals) depend on, which is the use of a unique identifier.

4.1 Using a Unique Identifier

To make this prototype effectively work , all the drugs that have a potential DDI with a particular drug need to be encoded inside the NFC tag and attached to that particular drug's container. There are a lot of drugs today in the market, this includes prescription drugs and OTC drugs and other supplementary products, all of these drugs and products need to be encoded in NFC tags which is something challenging. If we look at the different generic and brand names as well, it will be even more challenging and that is due to the memory size limitation of these tags. The brand name drug is usually manufactured by pharmaceutical company under their trademark, while the generic name drug is manufactured by any generic name company, and in order for them to receive the FDA's approval, this generic name drug should be equivalent to a

specific brand name drug, in terms of the ingredients and contents [36]. This means that there are a lot generic and brand names that will lead to the same drug again in terms of active ingredients and contents, at the same time there are a lot of different names that will lead to the same drug (generic or brand name), these different names are used in different regions or countries. Having all of these facts will make it easier to encode all of these different drugs into the NFC tags, but in order to be able to do that, a unique identifier should be used for a particular drug combining all of these different naming used in brand or generic names all over the world under one umbrella.

Creating a new unique identifier for every single instance of a drug is applicable to some point, but one of the challenges that will appear is to have a consistent database of this new unique identifier all around the world, which is a non-trivial task, plus it is time consuming. A lot of currently used codding for drugs has been investigated, such as the National Drug Code (NDC) which is a universal drug identifier for drugs in the United States. The NDC code structure shown in Figure 5 consists of 10 digits put in three parts as follows [37]:

- Labeler Code: this code assigned by FDA to identify a labeler, manufacturer or a producer of the drug.
- Product Code: this code identify the strength dosage form and formulation of a specific product, each manufacturer have its own codes.
- Package size code: this code identifies the size of the package (20 pills, 40 pills, etc.)

As mentioned above, the NDC code will not be helpful because there is a possibility that a certain drug entity will have different NDC codes due to a different labeler or package size, which will lead to the same problem of encoding too much codes into the NFC tags to cover all the drugs that will interact with a particular drug, so a real unique identifier is still needed.

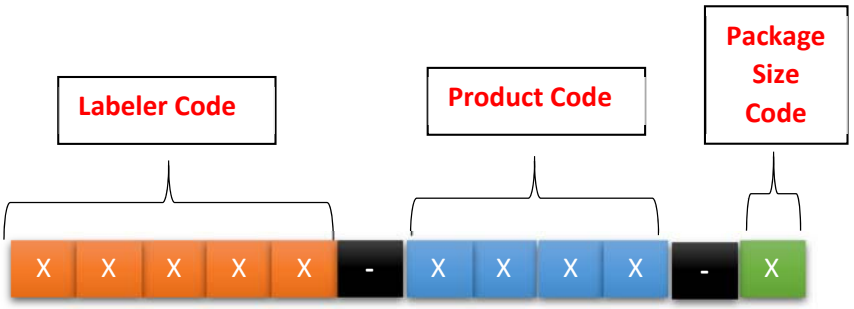


Figure 5. National Drug Code structure

The Chemical Abstracts Service (CAS) number is a unique 10 digits number assigned to every organic or inorganic substances, and it has been identifying substances since 1957 to the present, like chemicals, metals, nuclear partials, and drugs, beside that it does not cover these substances only in the united states, but in the whole world. The number consists of up to 10 digits divided into three parts as shown in Figure 6 [38].

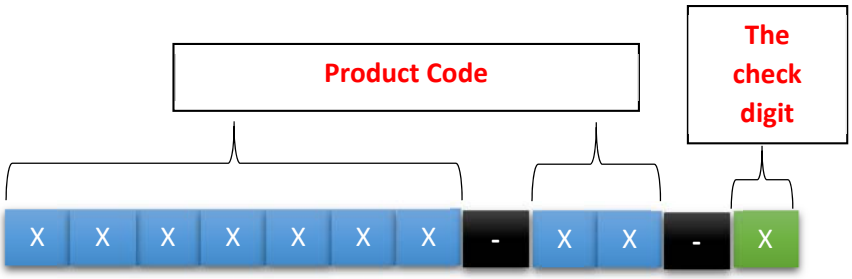


Figure 6. The Chemical Abstracts Service Number structure

The actual number is the 9 digits on the left, while the last digit is a check digit used to check the validity of the actual number through a specific equation, but it will not add anything important to help in the identifying process. Having the number will limit the amount of data needed to be encoded in the NFC tags because now every drug is identified by one number, regardless of the multiple brand or generic names it has, or whether it is an OTC or a prescription drug. Because of all of the above, the CAS number was used as the unique identifier in this prototype.

4.2 Design and Architecture

As seen by the previous chapter, there are two parts of this prototype system, the Pharmacy Terminal and the Patient Terminal, and what follows will explain in details the hardware/software design and architecture of both.

4.2.1 Pharmacy Terminal Hardware Design

In this prototype, the pharmacy end hardware consists of three parts: NFC Tags, Processing Unit, and Encoding Device.

The first part is the NFC tags that will be attached to the drug container. Inside these Tags, the drug ID along with a list of all the drugs interacting with this particular drug will be encoded. The type of tags used in this prototype was a combinations of both MiFare Classic 1Kbyte and 4Kbyte tags (Figure 7), and that was due to the memory capacity that was needed to encode all the DDIs in this tag, and to be more precise it was mostly based on the drug called "Warfarin" which is used to prevent blood from clotting and causing veins blockage [39]. Warfarin has the biggest DDI list with other drugs according to experts in the pharmacology field who were asked as part of the investigation that has been done to help build in this prototype.

Figure 7. Near Field Communication sample sticky tag with a drug container

The second part is the processing unit with the user interface, which in the case of this prototype is a computer (laptop). This laptop holds the interface software that will be used by the user (pharmacist or patient) to encode the NFC tags attached to the drugs containers with the DDI information related to the particular drug. In addition to that and for the sake of testing and checking, it will hold the local database for DDIs in which is connected to the interface software. This computer does not need any special specifications.

The third part is the NFC reader/writer **device** that will be connected to the main computer via a USB port, doing the actual encoding of the NFC tags. The used device was the ACR122U USB NFC reader/Writer, which is an affordable powerful device that is easy to use. This Reader/Writer is a USB PC-linked contactless smart card reader/writer based on the 13.56 MHz transfer frequency, furthermore it is a plug and play device and this is because of its compliance with Chip/Smart Card Interface Devices (CCID), which will make it able to interface with different systems and applications without problems. Furthermore, today's applications of this device are a lot, they vary from network authentication, access authentication, public transportation, banking and payment transactions [40]. Figure 8 shows the Pharmacy Terminal's three parts connected together.

4.2.2 Pharmacy Terminal Software Design

The software resides in the described computer in section 4.2.1. It consists of two parts: the DDI database server, the main encoding software.

The first part is the DDI database server which is a local database server that will reside in the pharmacy, either in a separate computer, or in the same computer that will have the main

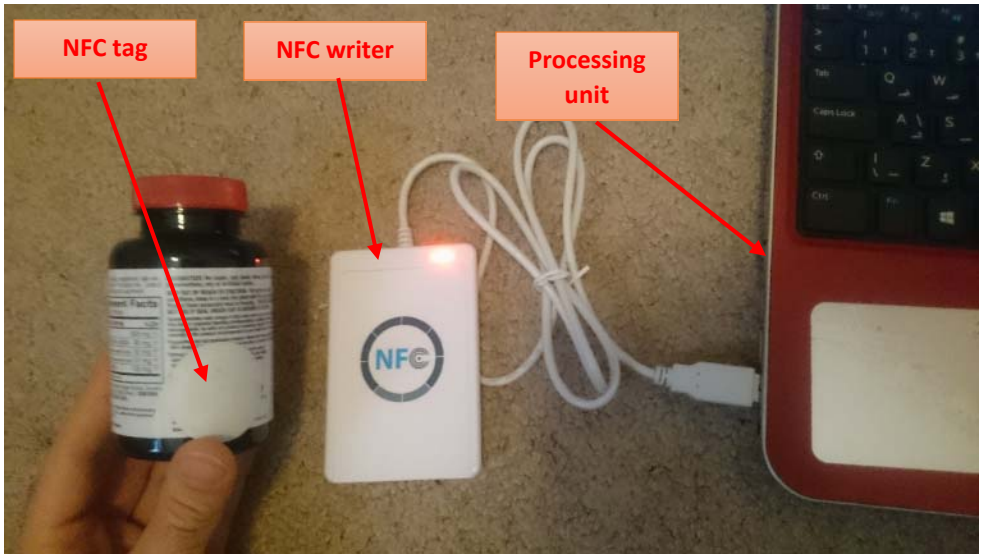


Figure 8. Pharmacy Terminal parts

encoding software, depending on the size needed for this database and the preference of the pharmacy. In this prototype system, the used server for this database is MySQL Server, which is one of the most popular database servers. The reason behind using it is due to the fact it is mostly open source, free, not expensive (depending on the features), and finally it is an industry standard.

The used MySQL server is part of the XAMPP package, which is an Apache distribution consisting of the most common web development technologies in a one package like MySQL and Apache web server, with everything build with PHP, and it also contains a control panel for the purpose of starting, stopping, and error debugging of these servers [41].

In order to configure the database in terms of creating, deleting, modifying tables, adding and deleting records, either the PHP configurations web page within the apache server could be used or the NetBeans Integrated Development Environment (IDE) after being connected to MySQL server. The later was used for both this purpose, and building the main interfacing software.

The prototype database consists of two tables, the first table named “drugs”, and in this table there are three attributes (columns). TABLE III shows the attributes and their data types of the “drugs” table.

TABLE III

ATTRIBUTES AND THEIR DATA TYPES OF THE “DRUGS” TABLE

Attribute	Type
Id	Integer
Name	Text
CAS	Text

The “Id” column can be a random integer assigned to every drug that will be put in this local database, and it may vary from one pharmacy to another, and if it does, this will not affect

the process of checking for DDIs, because it will totally depend on the second table called “Interactions” which is the main table in this prototype. TABLE IV shows the attributes and their data types of “interactions” table

TABLE IV

ATTRIBUTES AND THEIR DATA TYPES IN “INTERACTIONS” TABLE

Attribute	Type
Id1	Integer
Id2	Integer
Severity	Integer

“Id1” and “Id2” represent the first and the second drugs in this DDI pair and they are linked to the records of the first table to get their CAS number information. “Severity” is a number that represents the severity level of that DDI pair. This is shown in TABLE V. It does not matter which drug should be “Id1” or “Id2”, or if both “Id1-Id2” and “Id2-Id1” pairs are in the table, because the main encoding software will take care of these duplications or mistranslations if they exist.

TABLE V

SEVERITY LEVELS AND THEIR ASSIGNED NUMBERS

Severity level	Assigned number
Minor	0
Moderate	1
Major	2
Contraindicated	3

The second part is the main encoding software which is the main element in the pharmacy terminal, and this software will be the interface of the encoding process of the NFC tags, either by a pharmacist, or by the consumer. This software was built in Java programming with Java Development KIT (JDK) 1.8 platform, using the NetBeans IDE which is one of the most powerful programming environments designed by ORACLE [42]. The library that was used to interface with the ACR122U NFC reader/writer was the “nfctools” library, developed by Adrian Stabiszewski and his team for the purpose of NFC reading and writing tags [43]. The library was modified in a certain way and new classes were created to meet all the functions needed to build this encoding software prototype. As seen in the previous sections, this software will do the following steps which will be shown also in the flowchart in Figure 9:

- Let the user enter the name of the drug to get its DDI information, and if the name is entered partially (two letters and more) a pop up menu will show up containing all the suggestions close to the needed drug to let the user choose from them, to eliminate the chance of having errors, and also if nothing will show up, it means that this drug does not have any DDI. This search can be started over by pressing a button called “Refresh”.
- After locking up the name, a button called “Write” should be pressed, and by doing so, the name of this drug will be matched with a record in the “drugs” table to get its “Id” and “cas” values.
- The “Id” from “drugs” table will be matched with all the values of “Id1” or “Id2” in the “interactions” table to get the list of all the drugs’ IDs interacting with this drug, along with the severity of every DDI. If there is any duplication in pairs due to database building errors, for an example there is the pair **drug A – drug B** with the pair **drug B – drug A**, this duplication will be considered as one automatically.
- This list of the interacting drugs IDs will be matched again with the “drugs” table to get their CAS numbers defined in the “cas” attribute.
- Finally, the information that will be encoded into the tag are: **1)** the name of the drug **2)** the CAS number of the drug **3)** and the CAS numbers of all the drugs interacting with the main drug along with the interaction severity level.
- If the writing operation is not successful, the person will be asked to put the tag again to repeat this operation.

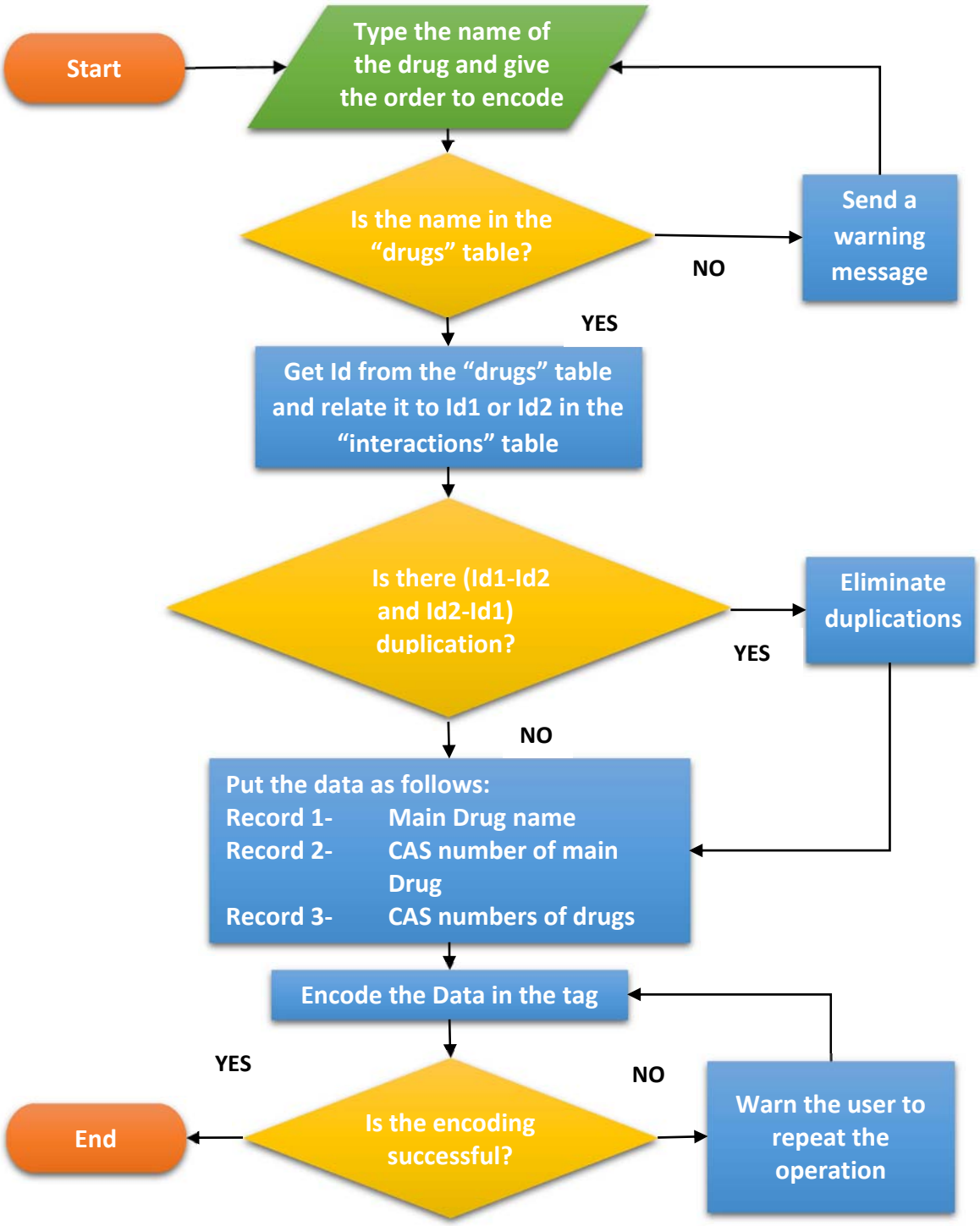


Figure 9. Pharmacy Terminal encoding process flow

4.2.3 Near Field Communication's tag Data Structure and Compression

As illustrated before, the NDEF message consists of one or more records, and to make things more organized, the data collected in the last step of the encoding software process will be put in three records, as part of the full NDEF message that will be encoded into the tag. The used records types were text records which are the simplest and the default types. The brief structure is illustrated in Figure 10.

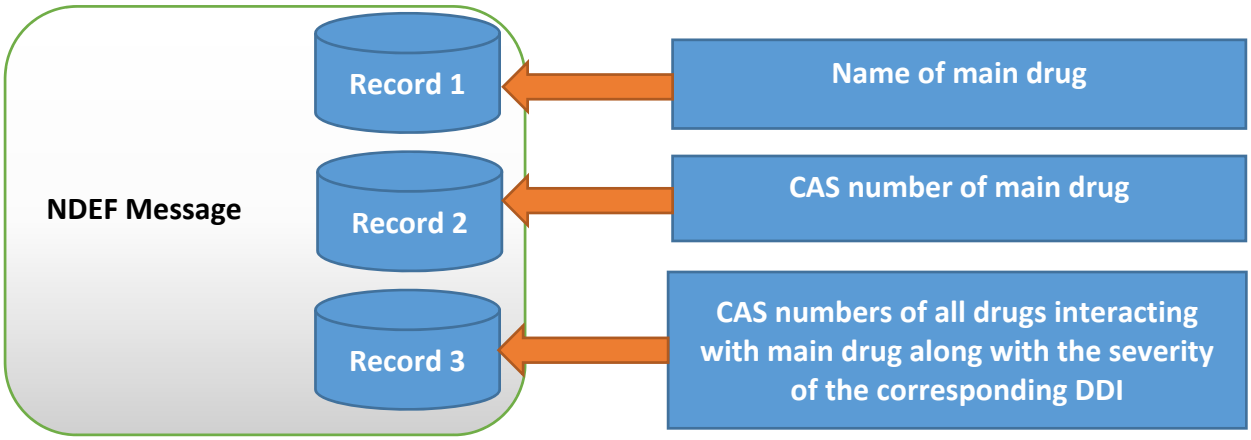


Figure 10. The NFC Data Exchange Format message brief structure

One of the main challenges that has been faced in building this prototype is the limitation of the memory size of the NFC tags, especially if the list of drugs interacting with the main drug is large, which is almost 466 DDIs for "Warfarin" when checked with Micromedex.

As illustrated before, the CAS number attribute in the “drugs” table is of a Text type, this is due to the presence of the hyphens in the structure of the number (XXXXXXX-XX-X), and as explained before, the last digit is used to check the validity of the whole number, meaning that it will not add any useful identifying information. Even if the CAS is having digits, they will be treated as text (characters) not decimal, which means that every digit (including the hyphens) will be 1 byte. If this CAS number will be used as text with hyphens, this will cost 12 bytes (10 digits + 2 hyphens), which is something that may seem trivial if the CAS number list in record 3 is small, but it will be non-trivial if the list is big, causing a problem of not being able to fit everything in the tag. Additionally, as part of record 3 structure, every CAS that represents a potential interacting drug having a DDI with the main drug, should be accompanied with the severity level of this DDI, and since the “severity” attribute in the “interactions” table is integer it means that this is an extra 4 bytes (integers in Java are 4 bytes), adding even more difficulty and making this process more challenging. As a reason of that, a series of steps were taken inside the main encoding software to make the encoding process more reliable and the usage of the memory more efficient, the following are the steps in order:

1- Removing the hyphens from the CAS number leaving only 10 characters (new CAS size = 10 bytes).
2- Removing the last check digit (character) of the CAS number, leaving only 9 characters (new CAS size = 9 bytes).
3- Converting the CAS in step 2 from text type (characters) to integer type (decimal number), leaving only 4 bytes and that is because integers in Java are 4 bytes having a maximum

decimal value of 4,294,967,295, so the maximum value of CAS (999,999,999) can fit without problems (new CAS size= 4 bytes).

The above CAS number structure was used in both record 2 and 3, but using it in record 3 is what made the encoding size efficiency better due to the presence of a CAS number multiple times (list of interacting drugs). The compression efficiency per 1 CAS number achieved from this compression was 66.66 %. That means 66.66% of the bytes used originally for 1 CAS number was removed. The compression efficiency were calculated as in Equation 4.1:

$$efficency = \frac{uncompressed\ size - compressed\ size}{uncompressed\ size} = \frac{12-4}{12} * 100\% = 66.66\% \quad (4.1)$$

As part of record 3, the severity level of every DDI should be encoded as well, and since there are only four severity levels (minor, moderate, major and contraindicated) then there is no need to use the full 4 bytes of the integer type defined for the “severity” attribute in the “interactions” table, so this size should be reduced to increase the compression efficiency. There were two methods with different results that had been used inside the main encoding software to reduce the size occupied by the “severity” attribute.

Method 1: The severity level was converted from a 4 bytes integer data type to 1 byte data type to encode the four possible severity levels (00000000, 00000001, 00000010, 00000011), after that every level will follow its corresponding interacting CAS number (DDI) as shown in Figure 11.

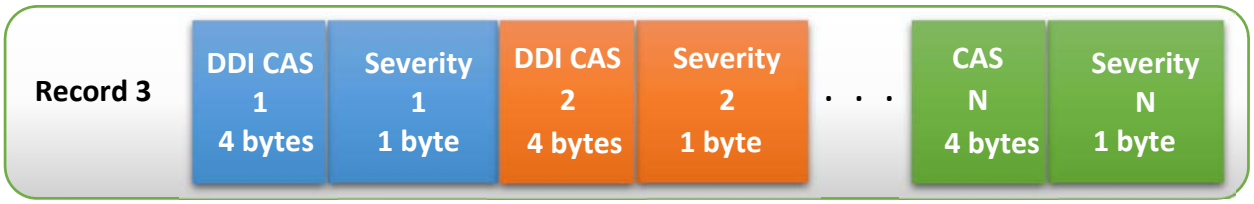


Figure 11. Record 3 structure according to method 1

The compression efficiency was increased to 68.75% using this method. Equation 4.2 shows how the compression efficiency was calculated per (1 CAS number + severity level):

$$efficency = \frac{uncompressed\ size - compressed\ size}{uncompressed\ size} = \frac{16-5}{16} * 100\% = 68.75\% \quad (4.2)$$

Method 2: The severity level of every interacting CAS number (DDI) will be converted from the original 4 bytes integer to only 2 bits for the four possible levels (00, 01, 10, 11), and by having this, the severity level of four consecutive interacting CAS numbers (DDIs) will be encoded in 1 byte, and after that the byte will be places after these four DDIs, as shown in Figure 12.

The compression efficiency was increased to 73.43% using this method, which is higher than the previous method so it was used according to that. Equation 4.3 shows how the compression efficiency was calculated per (1 CAS number + severity level):

$$efficency = \frac{uncompressed\ size - compressed\ size}{uncompressed\ size} = \frac{16-4.25}{16} * 100\% = 73.43\% (4.3)$$

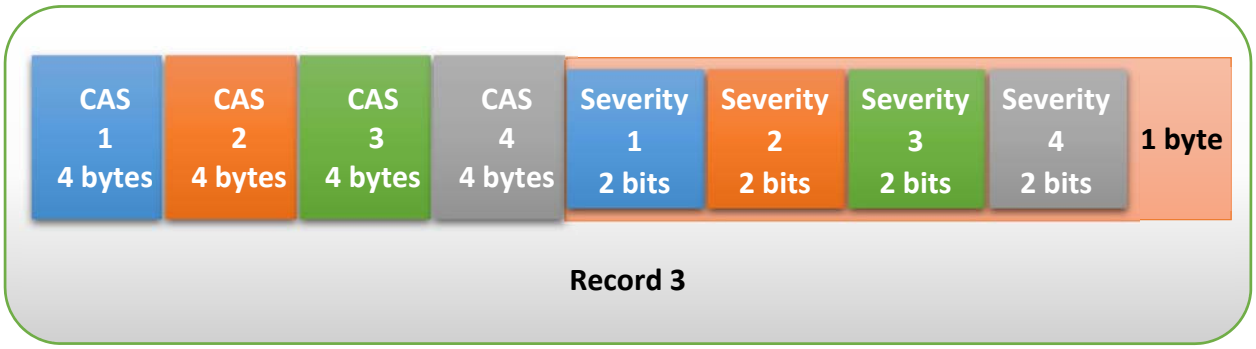


Figure 12. Record 3 structure according to method 2

After compressing both the CAS number along the DDI severity level, all of the data were encoded in three records as mentioned before, and all of them were of a text type records. A text record is designed to store text in its payload, meaning that every character is 1 byte, and this is how the name of the main drug was encoded into record 1 using a predefined class function when the record was declared in the source code, this function will take the text as it is and put it in the record's payload as 1 byte per character, the function was part of Stabiszewski's encoding library used for this prototype. For record 2 and 3 the encoding process was different. The reason behind that is that the text record is expecting a normal text to be used at the moment of the record declaration through the pre-defined function in the library. In order to overcome this issue, a new class function was created to accept bytes array at the moment of the record declaration instead of original text format that the text record would receive as an input, something needed especially after using the compression techniques explained before and

arranging the data into consecutive bytes, so the easiest way was to deal with the record in bytes instead of text. Figure 13 shows the final structure of data in the NDEF message.

Finally and after using the above data structure and compression technique, the approximate needed size for encoding the interactions data of "Warfarin" was calculated since it has been known that it will have worst case scenario (largest list of DDIs). These calculations were done for record 3 (since record 3 will consume almost the whole memory) to have an approximation for the size needed by that drug. Warfarin has 466 DDIs as recently checked with Micromedex, so by multiplying 466 by 4.25 (bytes needed per DDI), 1980.5 bytes will be needed, with extra bytes for record 1 and 2, beside some headers and tag information encoded by the manufacturer which are burned inside sector 0, and because of all of above, the Mifare classic 4Kbyte was used to cover the worst case (Warfarin), and even more if there will be ever a drug with a larger DDI list.

4.2.4 Patient Terminal Hardware Design

The Patient Terminal (central device) consists of three main hardware parts connected to each other by a number of jumpers through a breadboard, these parts are: 1) the microcontroller board, 2) the NFC reader adapter, 3) and the LCD screen.

The first part is the microcontroller board: which is main processing unit where all the data will be fed to it as the input, analyzed, and then the results will be shown as the output. There are a lot of microcontrollers in the market nowadays that can achieve the needed task. Most of them are having difficulties of attaching modules to them with the extra hardware needed, or programming these boards can become a nightmare especially because most of these

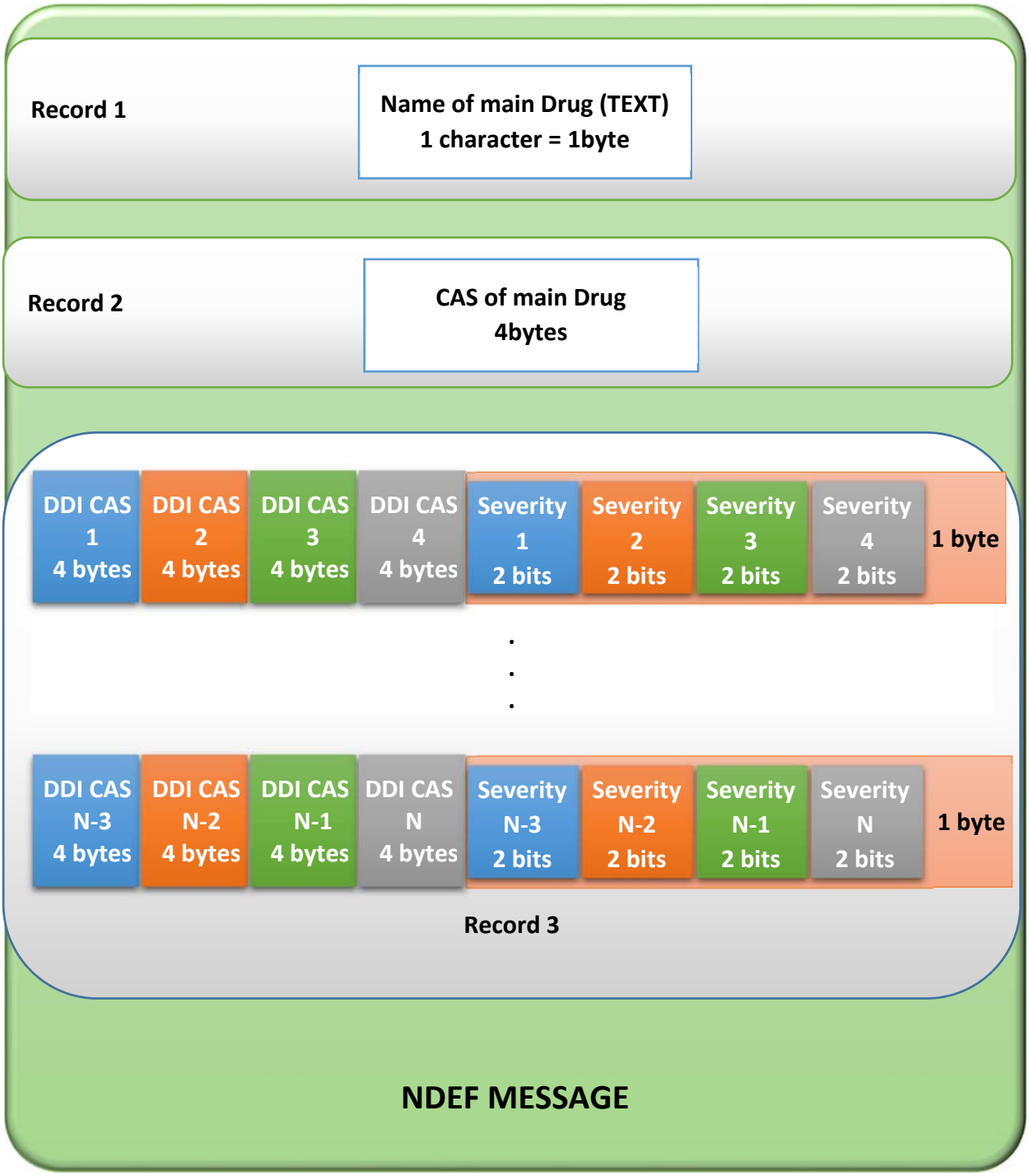


Figure 13. The NFC Data Exchange Format message final detailed structure

programming languages are low level languages. Arduino boards open new scopes in the microcontrollers era, because these boards are open-source platforms making them affordable and easy-to-use. These microcontrollers use a high level programming language (C/C++ in this case), making the nightmare of having infinite source code for small projects almost disappear, plus they have a lot of compatible shields and modules that adding them will be as easy as a blink of an eye [44].

The microcontroller board used was the Arduino DUE which is one of most powerful microcontrollers in the Arduino family, one of the reason behind that is that it is the first board using a 32 bit processor (Atmel SAM3X8E ARM Cortex-M3 N/CU) with an 84 MHz crystal oscillator, improving the overall speed, features and functionalities [45]. The Arduino DUE has a lot of ports and pins that can be used for a wide scope of different functions, such as 54 digital input/output pin, 12 analog inputs with 12 bits of resolution, two Digital to Analog Converters (DAC) outputs and much more.

When any Arduino will be programmed, the SRAM will play a vital role because this is where are all the data that will be read (e.g. data from NFC tags) and all the variables will be manipulated and saved when the program will start. There are other smaller and simpler Arduino boards like UNO or MEGA, etc., but their SRAM is small (2 or 8 Kbyte) and this will not help, especially if there are multiple drugs to be scanned and some of them are like “Warafrin” needing a lot of size. This means that the data will overflow and the program will have an unexpected behavior, so that was one of the main reason behind choosing the Arduino DUE because of its big SRAM size (96 Kbyte). There is only one disadvantage of using the Arduino DUE in which its

operating voltage or the Transistor-Transistor Logic (TTL) level voltage is 3.3 V not 5 V because most of the Arduino modules work with 5 V TTL, but this problem can be solved with using pull up resistors or voltage level translators.

The second part is the NFC reader: The PN532 is one of the most well-known NFC controllers in the market nowadays and it can be found in a lot of NFC modules. Some of these shields are "NFC Shield v1" and "NFC Shield v2" manufactured by Seeedstudio, "NFC/RFID Breakout Board" manufactured by Adafruit and the "NFC/RFID Shield" which is also manufactured by Adafruit, and the last shield has been used in this prototype with the Arduino DUE.

It is very possible that the other modules could have been used instead of this shield, but it was used simply because its library is compatible with Arduino DUE without modifying it or making some serious changes. The Shield uses a TTL level of 5 V, but even if uses the TTL level and knowing that the Arduino DUE is using the 3.3 V as TTL, this will not create a problem and no extra level translator will be needed for the interface between the DUE and the shield because the shield already has pull-up resistors on board that will handle this issue.

This Shield has many capabilities including reading/writing to tags, other features may be added in the future depending on the current development on the supporting libraries. The Adafruit shield support the Inter Integrated Circuit (I^2C) and Serial Peripheral Interface (SPI), but the default protocol that is used by the shield and does not need any hardware change was the I^2C [46]. One advantage of the I^2C protocol is using a shared bus that will allow deploying multiple shield to scan multiple tags at the same time, and these shields will have addresses and as long

as they are different there will be no collision. With the I^2C, two pins are used to communicate, the Serial Data line (SDA) and the Serial Clock line (SCL) rather than SPI that needs 4 wires, additionally the shield uses an interrupt pin to interrupt the Arduino when there is a tag detected instead of polling the shield by the software periodically to check for tags availability [47].

The third part is the screen: which is the output of the central device in which after scanning drugs, the DDIs will be shown in pairs on this screen as the result of scanning. The Liquid Crystal Display (LCD) is based on the famous Hitachi HD44780 driver which is a very common driver used with most of the basic LCDs. The used LCD consists of the following pins:

- V_{ss} & V_{dd}: for supplying power (ground and 3.3 V respectively)
- V_o: for adjusting the contrast of the characters on screen, usually connected to a potentiometer to adjust, or connected to a power supply for constant contrast.
- R_S: for selecting the register to perform a writing operation on, it could be an output register or an instruction register.
- R/W: which switch between reading from and writing to registers, active low is for writing.
- E: for enabling writing.
- D_0-D_7: data to be written or read.
- A & K: the anode and cathode of the backlit.

Having the hardware parts illustrated, they were connected together as it can be seen in the Figure 14 and Figure 15 and as the following:

- The Adafruit shield was connected to the Arduino board with 5 pins, the SCL and SDA pins in the shield were connected to the same pins on the board, digital pin 2 in the shield (used for interrupt) was connected to digital port 2 on the board, and finally the power supply pins (ground and the +5 V).
- The 20 x 4 LCD was connected using the 4-bit mode instead of the 8-bit mode, meaning that only 4 data lines were connected (D_4-D_7) which is enough to display most of the characters needed for this prototype, these lines were connected to the digital ports (3-6) respectively in the board. V_{ss} and VDD were connected to the ground and 3.3 V supply pins on the board respectively, Vo was connected to a potietionmeter which was connected to the ground and 3.3 V on the board to adjust the contrast of the characters on the screen. E and R_S were connected to digital ports 11 & 12 in the board respectively, R_W was connected to the ground (writing is active low), and finally the A & K (anode and cathode) were also connected to the +3.3 V and the ground pins on the board respectively.
- The three functions buttons were connected to digital ports 48, 50 and 52 in the board respectively from one side, and the other side was connected to 3.3 V pins on the board and to the ground via 220 Ohm resistors.

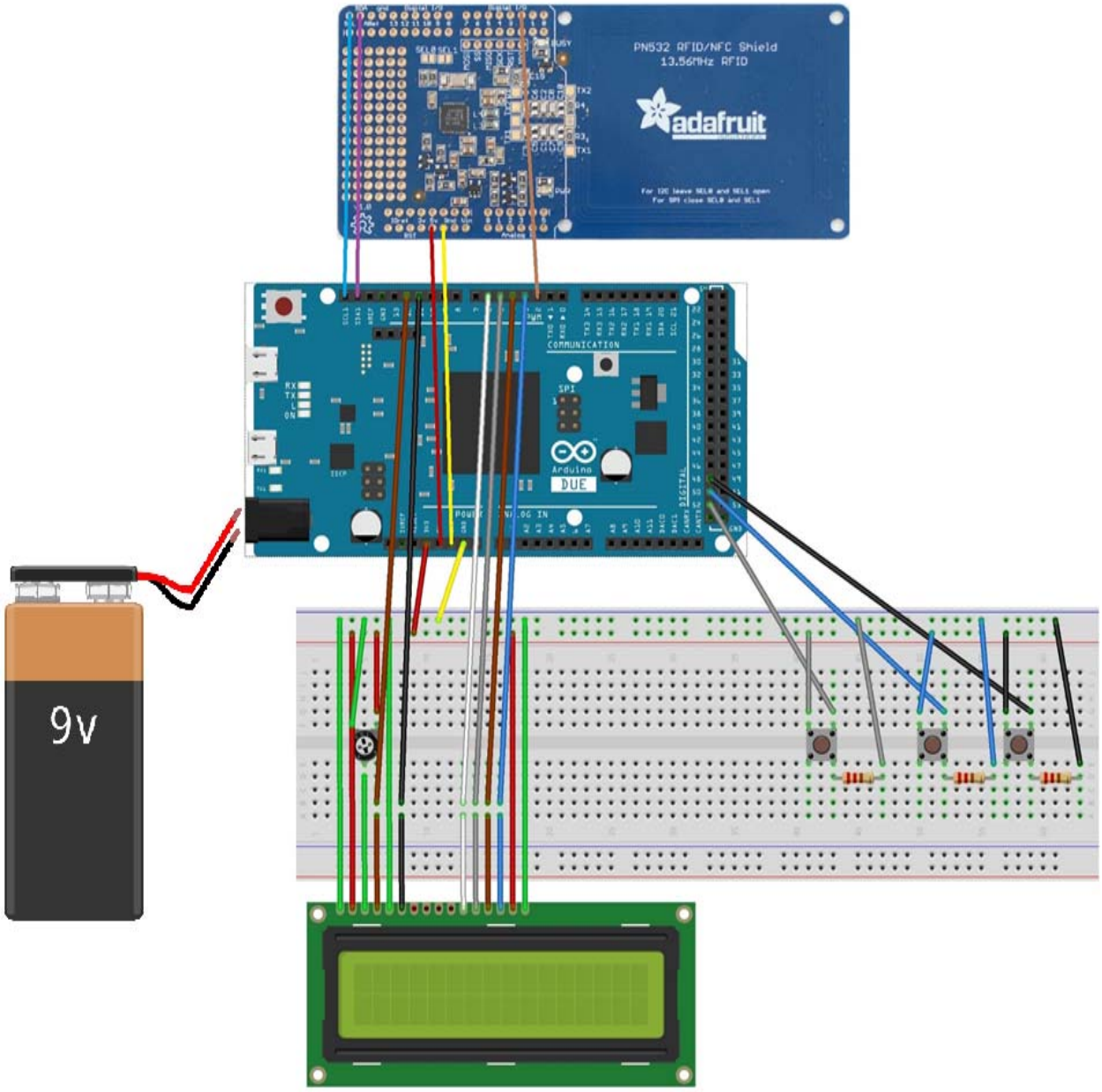


Figure 14. Patient Terminal circuit

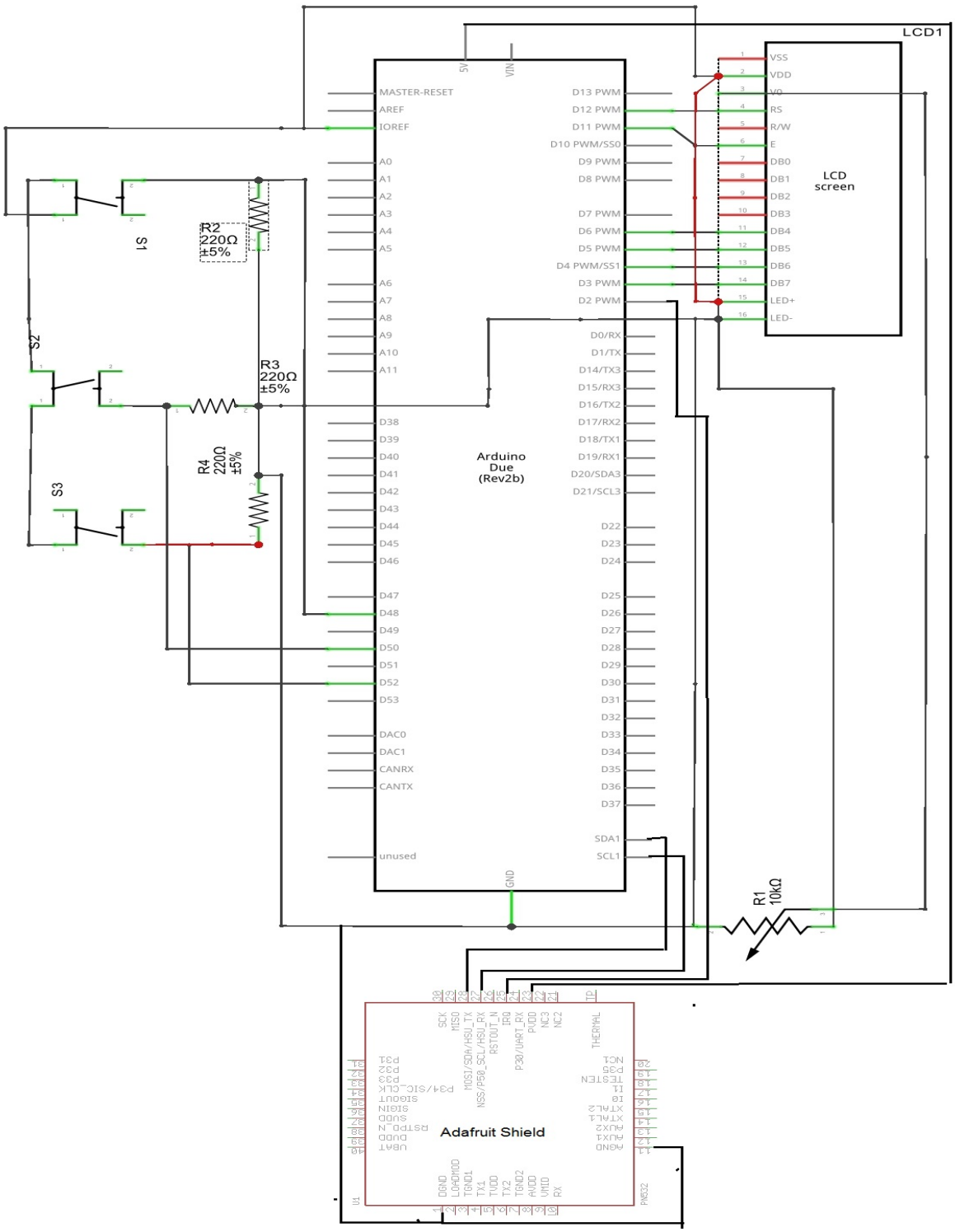


Figure 15. Patient Terminal schematic

4.2.5 Patient Terminal Software Design

As illustrated before, the using of a high level language with Arduino made it very easy to build big projects without having the fear of having a very long source code, something that would happen with assembly and any other low-level languages based microcontrollers. The Arduino IDE (called Sketch) is a programming environment software which makes it very easy to write programs (in C/C++) and upload them to any Arduino board through a user-friendly interface, and it comes with drivers for most of the Arduino boards expect the DUE, which has to be downloaded and installed manually in order to make it work [48].

To connect any module to the Arduino board, a library containing customized classes is needed for that module. Within these classes there should be some functions or methods that can be used by the end user when writing a program, making it much easier to communicate with that module. Some of these libraries are already included with the sketch such as the Liquid Crystal Library Which allows the Arduino to control any LCD based on the Hitachi HD44780 chipset, but for most of the other modules, their libraries should be downloaded and added to the sketch's libraries [49]. For the Adafruit NFC shield, the used library was the "Adafruit_NFCShield_I2C" written and developed by Adafruit industries [50]. This library handles the low level interface between the shield and the Arduino board, but it has a lack of any NDEF operation support and only has some low-level shield operations, making this a challenging and time consuming task. Luckily there is only one high level library called "NDEF" developed by Don Coleman designed to handle the NDEF messages and records [51]. This library interfaces the high-level NDEF operations with the low-level shield operations library (e.g. Adafruit_NFCShield_I2C),

making it easy to deal with NDEF records and their data in any desired way. The latest library was also modified to work with the “Adafruit_NFCShield_I2C”, and also some functions were created to deal the binary payload of every NDEF record, just like what had been done with the main encoding software in the Pharmacy Terminal. The main Arduino program will do the following:

- Waiting to scan the tag attached to drug containers, and after scanning, an indication on the screen will tell when to remove the tag and scan the next one. If the same drug will be scanned, a warning will pop up, and if there is any error in reading, the user will be alerted to rescan the drug again.
- In every scanned tag, three records will be read in the following:
    1. The first record (name) will be added to a names vector (Vector 1).
    2. The second record (drug CAS number) will be added to CAS vector (Vector 2).
    3. The third record (interacting CAS numbers) will be added to an interacting matrix (Matrix 1), while the severities will be added to another severity matrix (Matrix 2).

  Figure 16 shows the structure of these vectors and matrices.
- When scanning is completed, the “CHECK” button should be pressed to begin checking for the presence of any DDI. After pressing “CHECK”, each CAS number in Vector 2 will be checked for matching with a CAS number in every column of Matrix 1 except the corresponding column of that main drug, and if a matching will be found, both the names of the main drug and the interacting drug along with the severity of the interaction will

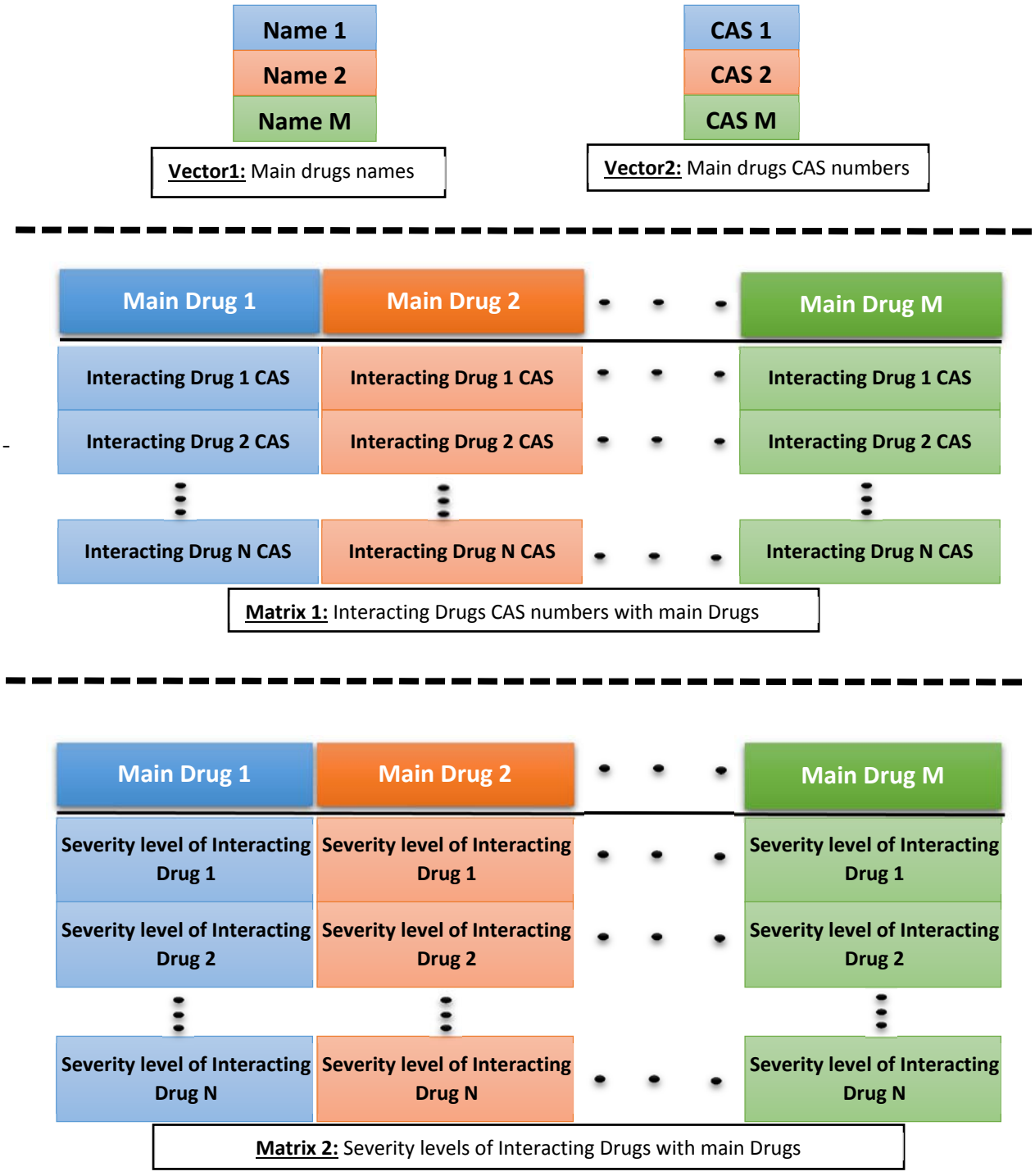


Figure 16. Structure of matrices and vectors used to analyze and detect Drug-Drug Interactions in the Patient Terminal

be saved temporarily for the final results, the names and severities will be taken from Vector 1 and Matrix 2.

- After checking is completed, a message will be printed on the screen shows how many DDIs has been found.
- Pressing "NEXT" will navigate through the results (in pairs) which will be pairs of interacting drugs along with their severities, and after finishing the last result, the first result will show up again.
- A third "button can be pressed to cancel any operation and start the device over.
- Checking the DDIs is in a bidirectional way, meaning that if there are two drugs **"A"** and **"B"** and they have interaction between them, if only one of them will have the other drug in its list, that would be enough to detect that interaction.

The three buttons were all defined as an interrupt in the Arduino board, and once any of them will be pressed, a new subroutine will start to accomplish the desired task. Figure 17 shows a flowchart of the process flow mentioned above.

4.3 The Results

After designing and implementing the system, it was tested with different examples to show how it works. MiFare 1k and especially the 4k tags were used for drugs having long list of DDIs. This Section will mostly show snapshots of the both the Encoding Software and the central device demonstrating different scenarios with brief explanation of each.

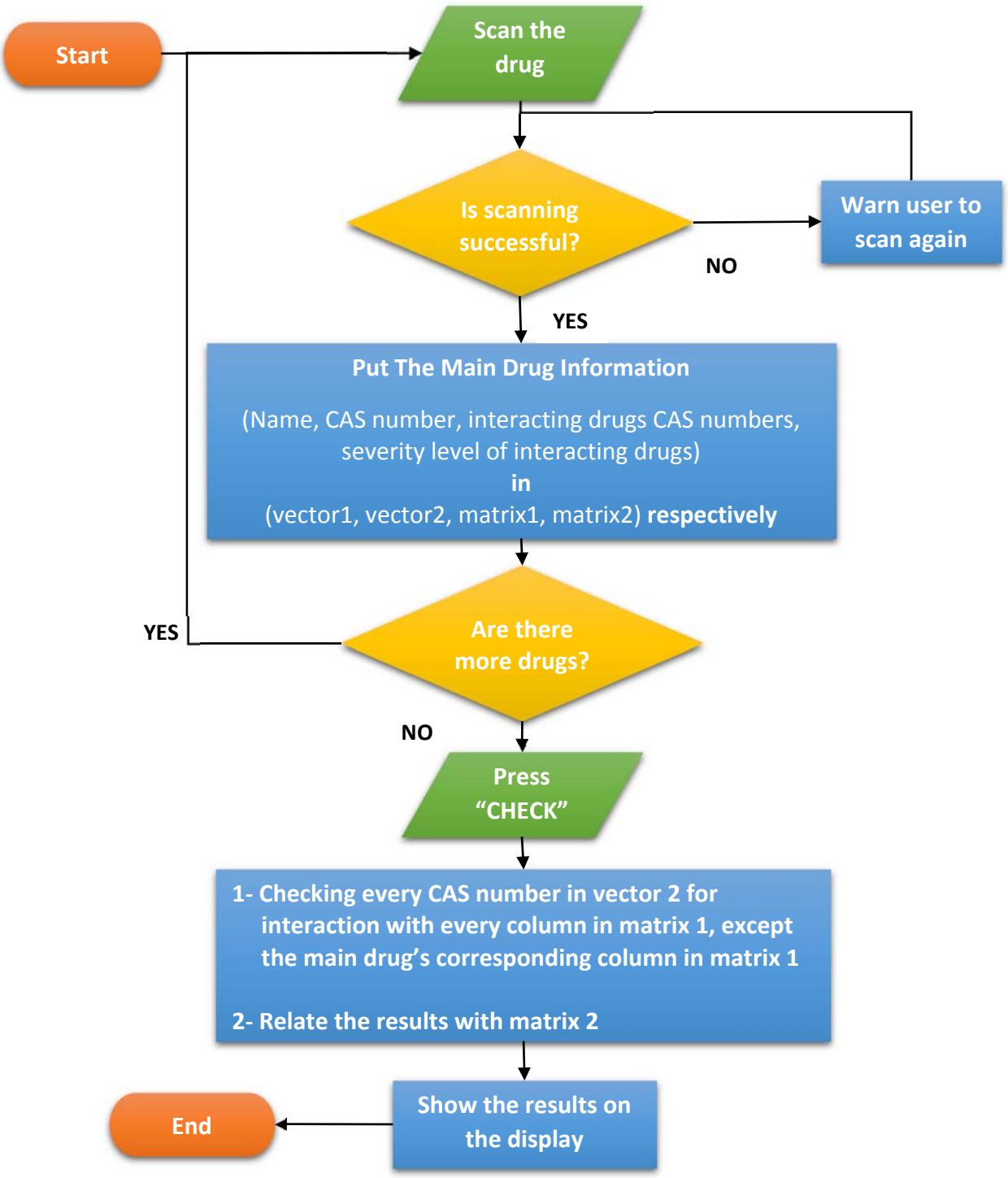


Figure 17. Patient Terminal Drug-Drug Interactions detection process flow

4.3.1 Pharmacy Terminal Testing

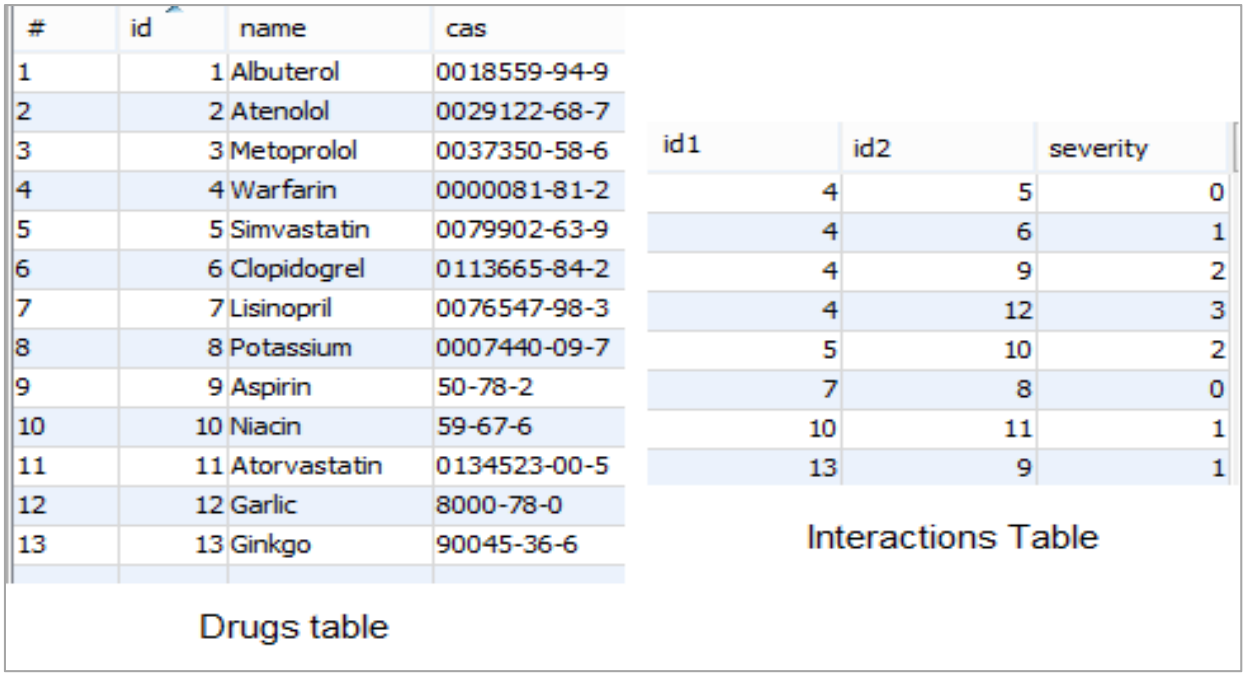
For the sake of testing, TABLE VI (showing he major DDIs of TABLE II in Chapter 1) was used to create the local interactions database with the help of Micromedex to obtain the CAS numbers of these drugs along with the severity levels of the interactions, but since it appeared that all the real severity levels for this table were the same (2 → major), these levels were changed randomly to make sure that the system can detect the difference for the sake of testing.

TABLE VI

COPY OF TABLE II IN CHAPTER 1 SHOWS ONLY THE MAJOR DRUG-DRUG INTERACTIONS

Drug 1	Drug 2
Albuterol	Atenolol
Albuterol	Metoprolol
Warfarin	Simvastatin
Clopidogrel	Warfarin
Lisinopril	Potassiumc
Aspirin	Warfarin
Niacin	Atorvastatin
Garlic	Warfarin
Niacin	Simvaststin
Ginkgo	Aspirin

Figure 18 is a local database sample used in the test and it shows that Warfarin (id 4) has most of the interactions with different severity levels based on TABLE VI and the random severity levels, so it will be used along with its interacting drugs to encode the tags and test the system.



#	id	name	cas
1	1	Albuterol	0018559-94-9
2	2	Atenolol	0029122-68-7
3	3	Metoprolol	0037350-58-6
4	4	Warfarin	0000081-81-2
5	5	Simvastatin	0079902-63-9
6	6	Clopidogrel	0113665-84-2
7	7	Lisinopril	0076547-98-3
8	8	Potassium	0007440-09-7
9	9	Aspirin	50-78-2
10	10	Niacin	59-67-6
11	11	Atorvastatin	0134523-00-5
12	12	Garlic	8000-78-0
13	13	Ginkgo	90045-36-6

Drugs table

id1	id2	severity
4	5	0
4	6	1
4	9	2
4	12	3
5	10	2
7	8	0
10	11	1
13	9	1

Interactions Table

Figure 18. Screenshot of local interactions database sample used in test

Figure 19 shows the main screen of the encoding software with a brief description of its layout. Figure 20 shows the process of searching for a drug called “Simvastatin” (one of the interacting drugs with Warfarin) using suggestions by the search box.

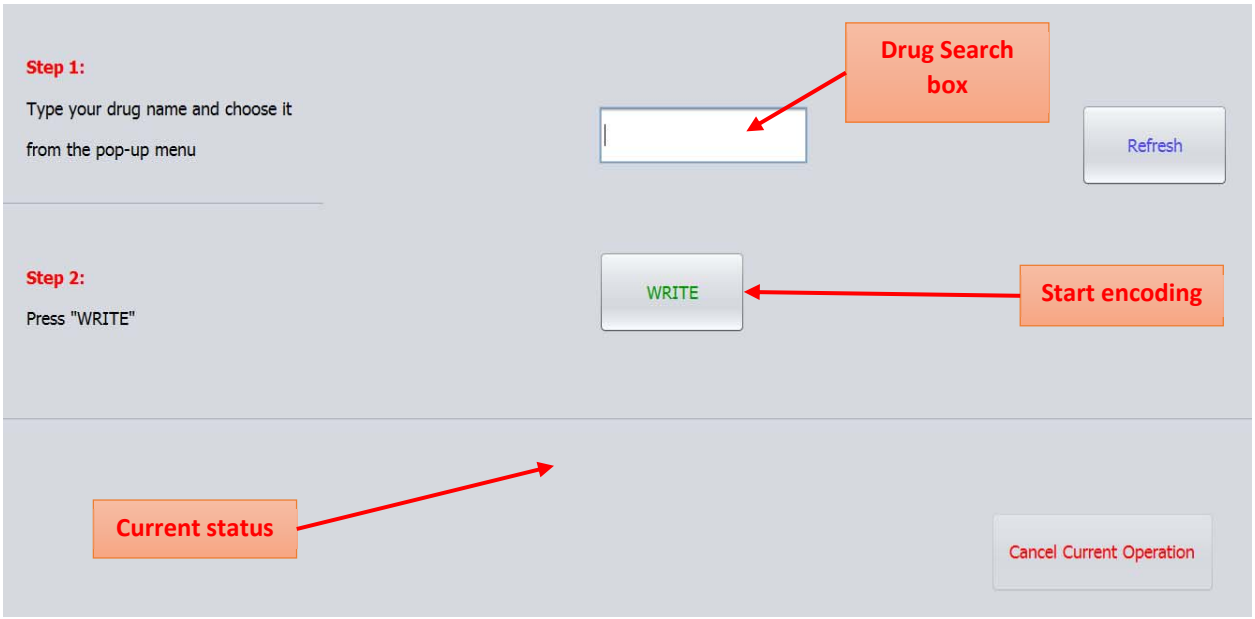


Figure 19. Screenshot of the main screen of the encoding software

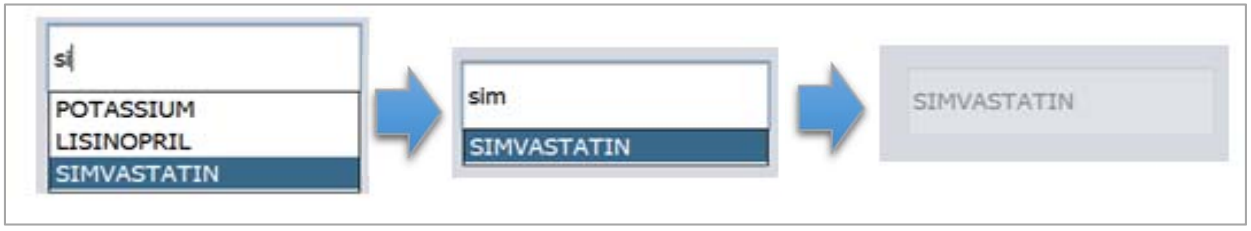


Figure 20. Screenshot of the encoding software search box showing the search process for a drug (Simvastatin in this example)

Figure 21 shows the successful encoding process of a drug (Simvastatin in this example) after pressing the “Write” button and putting the tag.

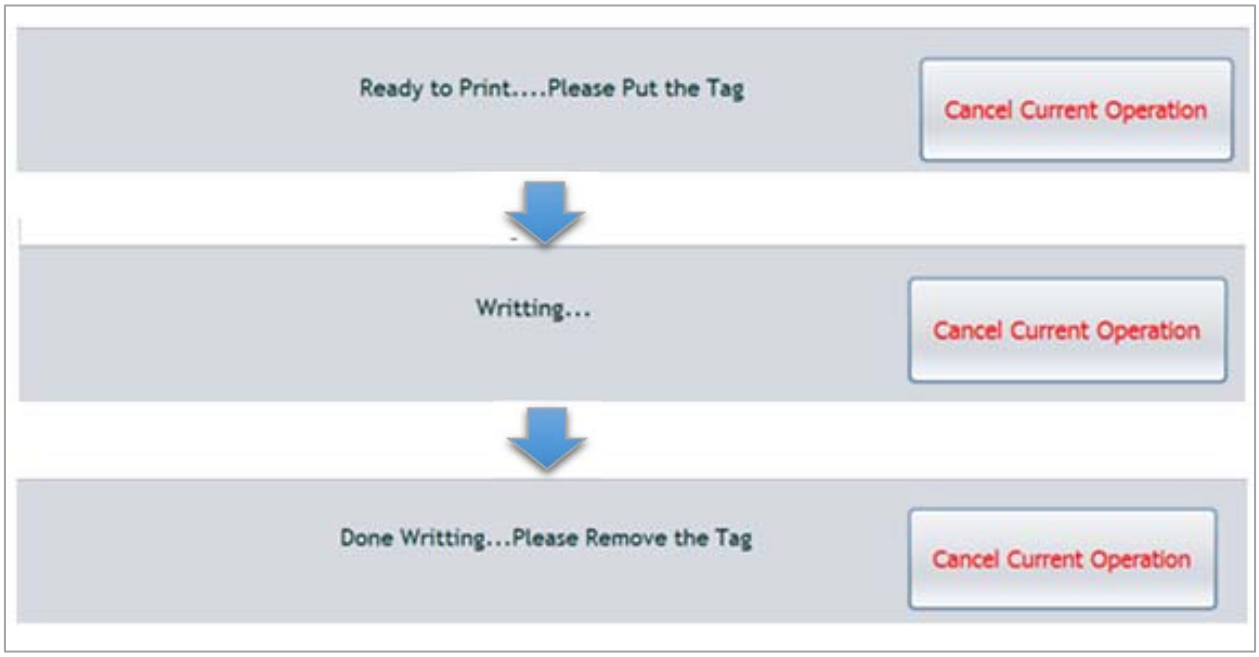


Figure 21. Screenshot of successful drug encoding operation

Sometimes the encoding operation may fail due to moving the tag away from the writing field during the encoding process or due to using a faulty tag, in this case the software will notify the user to retry again by putting the tag near the field again or using a new one till the operation will be successful as seen in Figure 22.

Figure 22. Screenshot of unsuccessful drug encoding operation

Figure 23 shows the NDEF message payload characters representation read by an Android App designed to get NFC tags information. As it can be seen the characters of encoded main drug name “Simvastatin” (with the upper caption) is clear because record 1 of the NDEF message was fed with normal text data (saving the name’s text directly) with one byte for one character, while the rest of the characters (with the lower caption) do not have a meaning in the text representation because record 2 and 3 were fed with binary data, and this is the text representation of these binary data. The bytes of these characters (record 2 and 3) will be converted to an integer and long data types later with the Patient Terminal (central device), only then they will have meaning, representing the CAS number of the main drug (record 2), and the CAS numbers of the interacting drugs with that main drug (DDIs) along with their severity levels (record 3). The same operation was repeated for “Warfarin” and the drugs interacting with it from the previous TABLE VI with random severity level. All this is shown in TABLE VII.

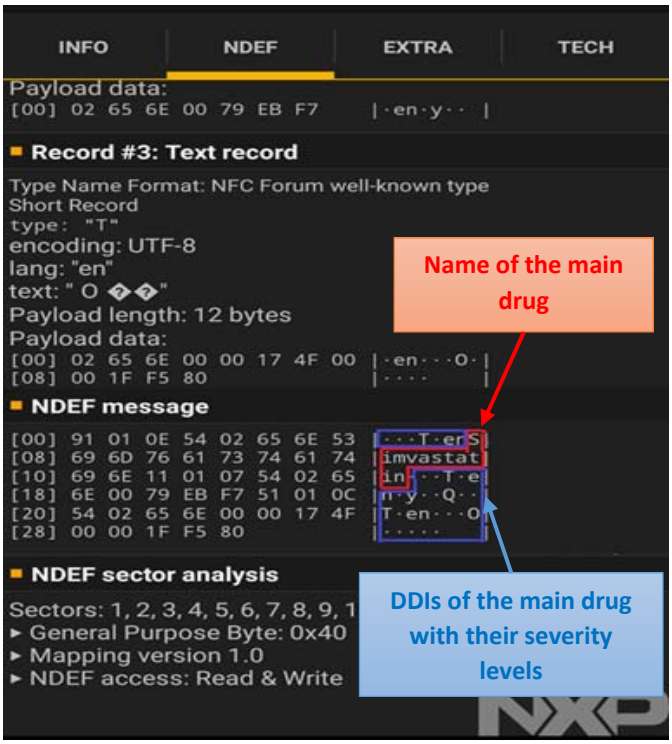


Figure 23. Screenshot of the encoded drug information in a text representation using an Android App

TABLE VII

INTERACTED DRUGS WITH WARFARIN USING RANDOM SEVERITY LEVELS FOR TESTING

Drug 1	Drug 2	Severity
Warfarin	Simvastatin	Minor
Warfarin	Clopidogrel	Moderate
Warfarin	Aspirin	Major
Warfarin	Garlic	Contraindicated

4.3.2 Patient Terminal Testing

The central device as shown before consists of the microcontroller (Arduino), NFC reader (Adafruit NFC/RFID shield), LCD screen, and functions buttons. Figure 24 shows the central device and the main screen when it is first turned on:

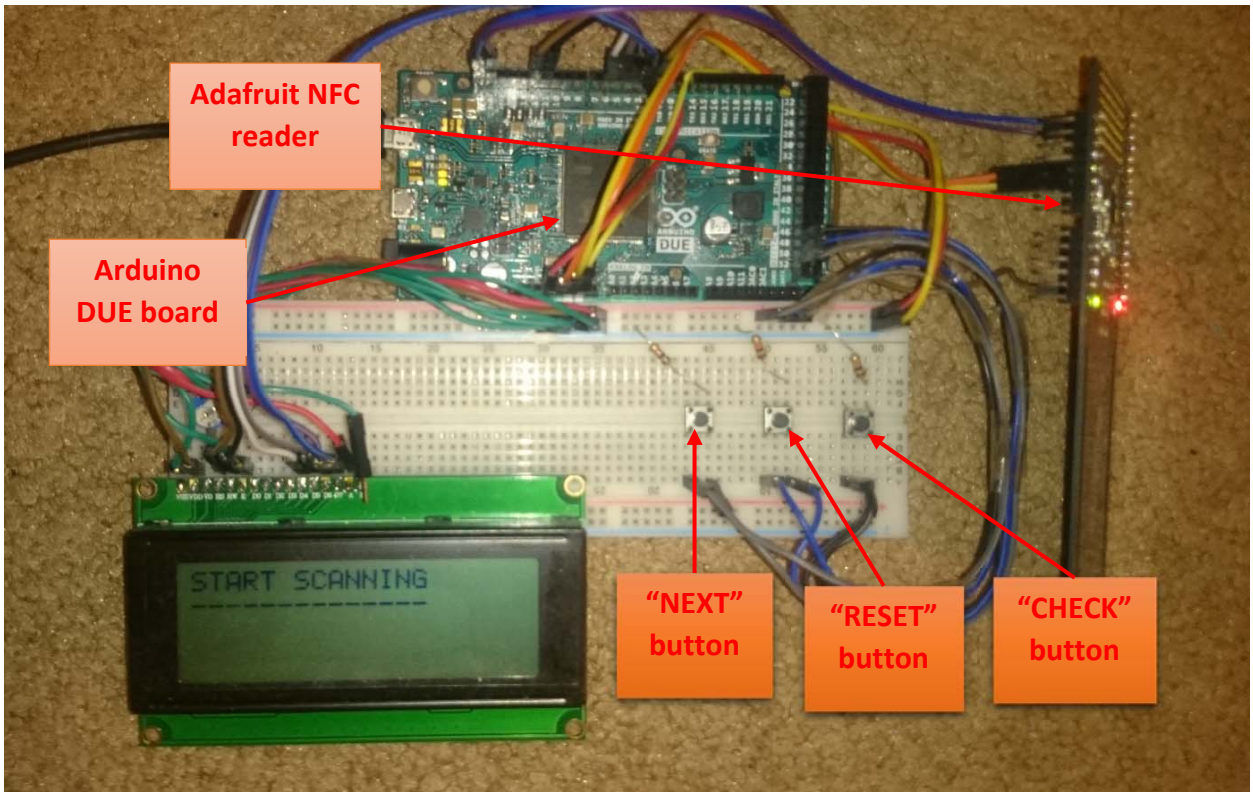


Figure 24. Patient Terminal connections with main display ON

After turning the device on, the drugs will be scanned one by one by placing the tag near the NFC reader field. after doing so, the “CHECK” button should be pressed to start checking for interactions and showing the result at the end as the number of interactions found. Figure 25 shows the screen messages during a sample scanning for “Warfarin”. Figure 26 shows the screen messages of the checking process after scanning all the drugs in TABLE VII by pressing the “CHECK” button to show the number of interactions found.

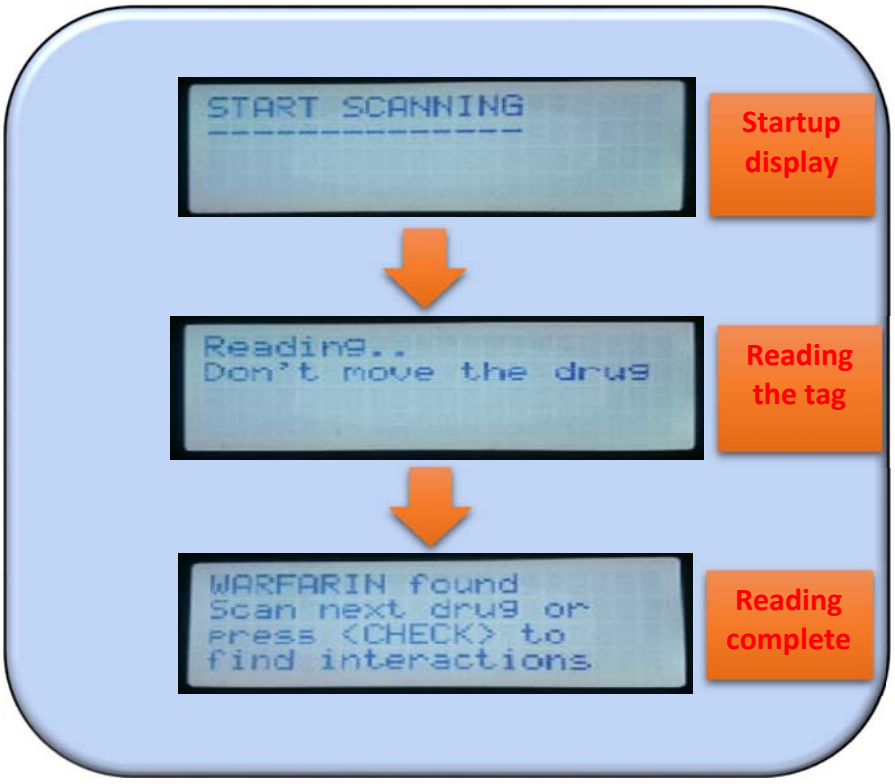


Figure 25. Display readout shows the scanning process of “Warfarin”

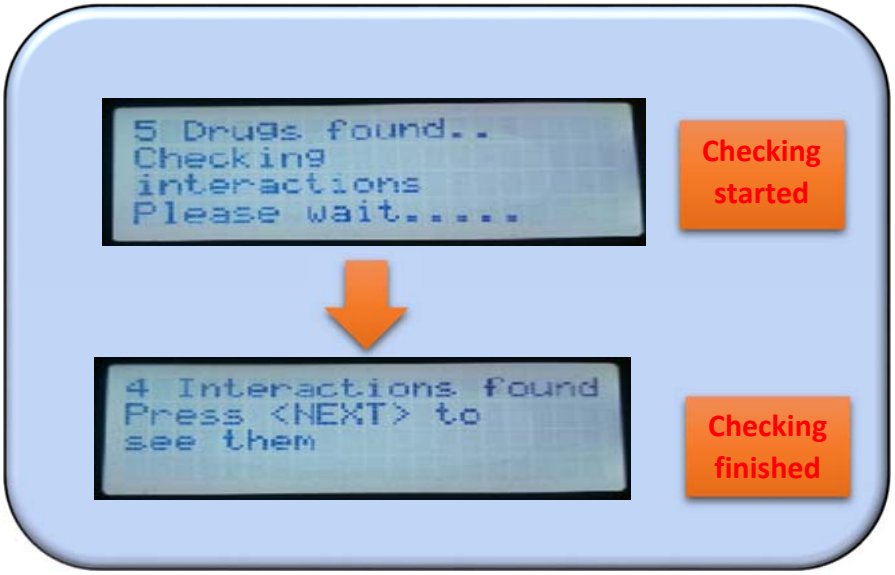


Figure 26. Display readout shows the checking process after pressing the “CHECK button

Finally by pressing the “NEXT” the interactions will be shown as pairs of two interacting drugs along with the severity level of that interaction, and the user can navigate among them. Figure 27 shows the 4 interactions with “Warfarin” according to TABLE VII.

Also the reading operation may have some errors due to moving the tag away from the reading field of the NFC reader or reading the same drug again accidently, so to avoid any confusion the user will be notified as shown in Figure 28.

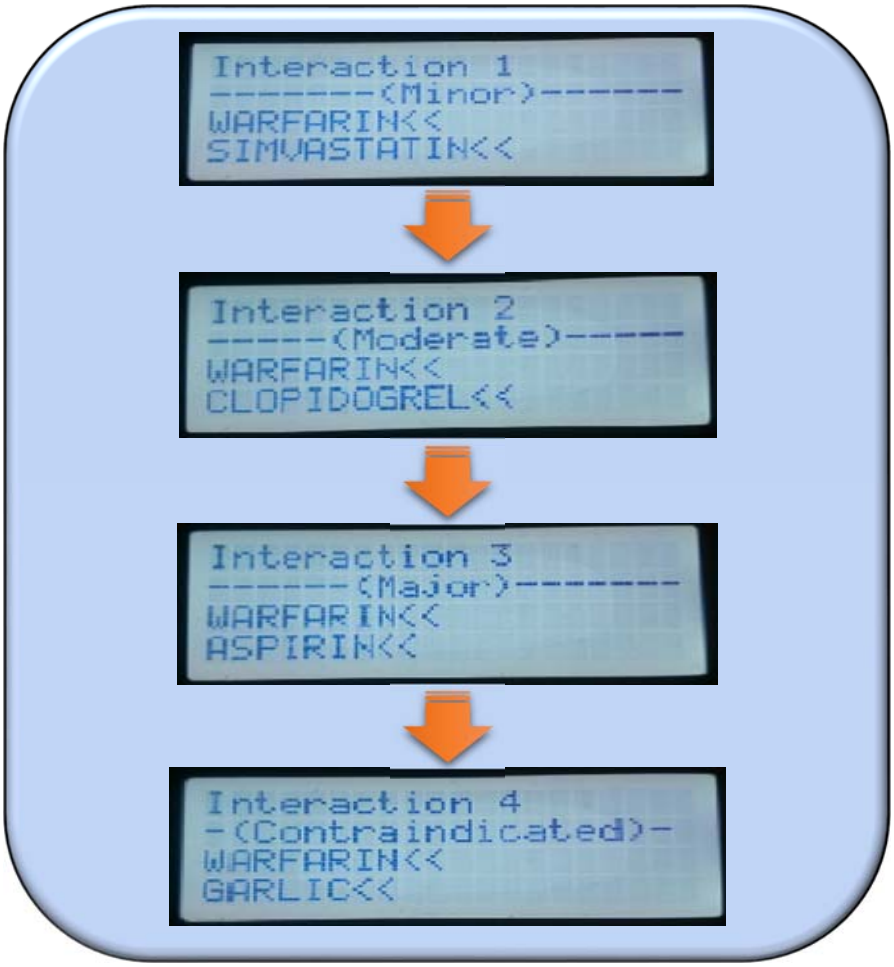


Figure 27. Display readout shows drugs interactions with their severity levels

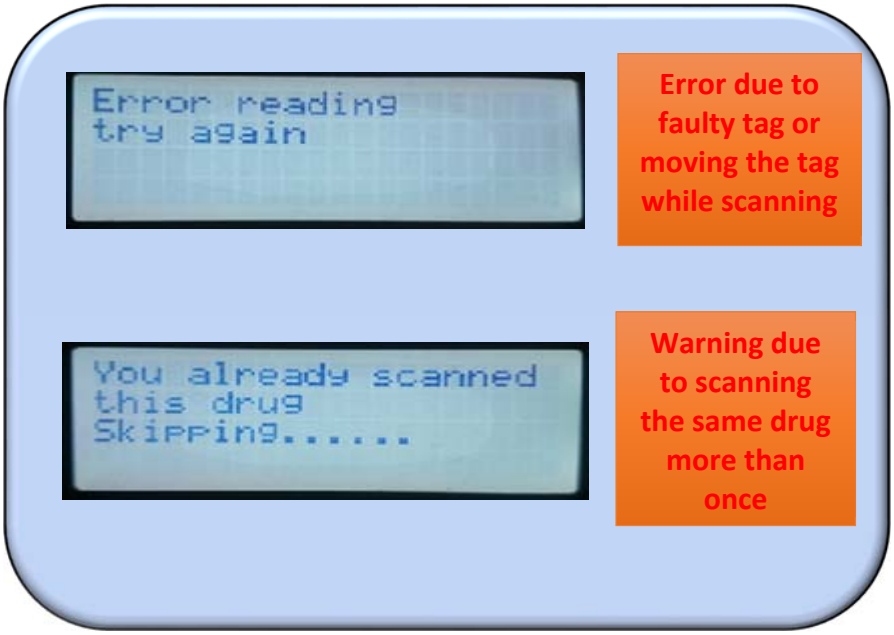


Figure 28. Display readout shows errors while scanning the tags

5. CONCLUSION, GUIDANCE FOR IMPROVMENTS AND FUTURE WORK

5.1 Discussion and Conclusion

Drug-Drug interactions (DDIs) can be caused when a patient uses two or more drugs at the same time having interactions among them. Few studies that are showing the high prevalence of DDIs (especially in the elderly people) have been reviewed. It has been shown in these studies that DDIs can happen due to various reasons such as prescriptions errors and the use of Over-The-Counter (OTC) drugs. Some promising solutions have been proposed by other studies to help detecting DDIs such as the use of online sources or reporting systems, but they were having some drawbacks such as access privacy, unavailability, or inaccuracy, but most importantly, none of these studies came with a convenient, easy to use solution at the costumer level with a simple user friendly interface that doesn't require internet access.

This thesis proposes a system to help detecting DDIs at the consumer level with user friendly interface and without the need to have internet access, making it very easy to be used for detecting DDI instantly anywhere and anytime. The system is based on the Near Field Communication (NFC) technology where drugs are identified by NFC tags attached to their containers. These tags will act as small databases for every drug containing data that will be used to detect any possible DDI for this particular drug. The system consists of two main parts, the Pharmacy Terminal where these tags will be encoded with the data in pharmacies or drugs' suppliers, and the Patient Terminal where these tags will be scanned by consumers to check for the presence of DDIs.

The Pharmacy Terminal consists of an NFC encoding software that resides in a computer with NFC encoder. This software is designed with a very simple and user friendly interface that will let the user find any drug easily and then encodes this drug's data into the NFC tag instantly. The encoding software is connected to a local database which will be connected to another main online database where all the interactions data will be stored (Micromedex in this case)

The Patient Terminal consists of an Arduino, an NFC reader shield, and a 20 x 4 LCD display. This terminal is designed in an easy-to-use way with a user friendly interface which will simply let the consumer scan the drugs one by one by the NFC reader and in the end the results will show up on the display telling the user if the scanned drugs have any interaction among them, along with the severity level of that interaction.

There are different names (brand or generic), and even different names in different countries that will lead to the same drug, so using these different names to check for DDIs will not be reliable because storing all of these data will take a lot of memory in the pharmacies' local databases, in the processing unit in the Patient Terminal, and most importantly in the NFC. For this reason an existing unique identifier was used to identify each drug instead of their different names, this identifier is called the Chemical Abstracts Service (CAS) Number. The encoded data of every drug tag will have the name of this drug along with its CAS number, and a list of the CAS numbers of all the drugs that have interactions with it, along with the severity levels of these interactions (4 possible levels). Knowing that sometimes this list might be long, different steps have been taken to compress the encoded data, such as changing the representation and

datatype of the CAS numbers (4 bytes in the new representation instead of 12 bytes in the old one), and appending the severity levels of these interactions in a memory reliable way (4 interactions followed by 1 byte of their four severity levels).

There are 3 pre-defined libraries that have been used in this system. The first library “nfctools” is used for the encoding software of the Pharmacy Terminal which is based on Java. Some classes of this library have been modified in a way to handle and encode the compressed data, to deal with the NFC message structure in a binary way, and to detect errors. New classes have also been added to “nfctools” to handle the connection with the database along with the front user interface. The other two libraries (Adafruit_NFCShield_I2C and NDEF) are based on the Arduino C/C++ and used for the Patient Terminal device. The first one (Adafruit_NFCShield_I2C) is used for the NFC encoder, and the other one (NDEF) is used to handle the NDEF messages. Some of the classes of these two libraries were also modified for the integration between each other, and to detect errors. New class have also been added which represents the main program that will get the data from the tags, analyze them, and then show the results on the display.

Finally, and for testing the system. In the Pharmacy Terminal, a normal laptop with NFC encoder has been used to encode the NFC tags. This same computer was used also as the local database, and some sample data have been inserted into this database from one of the studies that is showing some major DDIs of some drugs in Chapter 1. These drugs were scanned one by one using the Patient Terminal, and at the end, the DDIs along with their severity levels were successfully detected and results were shown on the display.

5.2 Improvements and Future Work

The main goal of this thesis to find an easy solution to detect DDIs that can be used at the consumer level without internet access was achieved, but still there is still room for future improvements and prototypes.

For the **Pharmacy Terminal**, there are different improvements that can be explored and accomplished in the future, some of these changes are:

1. Using an Optical character Recognition (OCR) or barcode reader to identify a drug in the pharmacy for the encoding software in order to start encoding the tag. Using a barcode scanner as mentioned above will need to link the local DDIs database with the pharmacy products local database where these barcodes are stored.
2. Modifying the encoding software to be able to distinguish between the different types of errors (e.g. faulty tags and moving the tag away while encoding).
3. Accomplishing the actual connection between the local DDIs databases in pharmacies and the main DDIs online database (e.g. Micromedex in this case) because this connection was hypothetical in Chapter 4.
4. Another prototype for encoding that will be explored in the future is the use of a designated NFC encoding machine to automatically encode the NFS tags and attach them to the drugs' containers. This machine can replace the current prototype.

For the **Patient Terminal**, there are different improvements that can be explored and accomplished in the future, some of these changes are:

1. Adding multiple NFC shields to the Arduino board to scan multiple drugs at the same time because the I2C allow that.
2. Adding LEDs, and voice shield, to the Arduino board to help people with disabilities using the device easily.
3. Adding a mini thermal receipt printer to print the results in case a patient wants to show them to his/her doctor.
4. Modifying the code to be able to distinguish between the different types of errors (e.g. faulty tags, moving the tag away while encoding, and having an empty tag).
5. Find a solution to update the tags in case there will be updates for the databases, such as using expiration dates for the tags to give the user a reminder to update these tags in the pharmacies. Another solution could be using WiFi shield to update the tags whenever there is any internet access, keeping the offline feature of the device working without any change.
6. Adding the patient's drugs allergy record into NFC tags which can be used by the patient as an ID to check for allergy interactions along with the other Drug-Drug Interactions.
7. Using "Raspberry Pi" board to add more speed and memory, especially if some of the above mentioned improvements will be accomplished

8. Creating a smartphone App that can be used as another version of the Patient Terminal and will do the same task, because some people may prefer to use their smartphones, and that was the reason behind using NFC instead of RFID in this system.

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