RFID: A Trustable Security Tool in Pharmaceutical Industry

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ABSTRACT

Security and safety are two main features desired in pharmaceutical chain supply but to attain the same is a challenging task. With the expectation of improved supply chain visibility for consumer goods, the RFID (Radio Frequency Identification) technology has been attracting considerable attention by manufacturers as well as government procurement agencies. RFID technique showed potential to store and retrieve data using radio waves to automatically identify people or objects. Automatic identification of product in much shorter time as compared to manual registration and high level of accuracy have attracted channels of distribution to adopt RFID technique as effective tool to counterfeit drugs. The technique is gaining trust with advancement in technology.

Key Words: Counterfeit, supply chain, tracking medication.

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INTRODUCTION

Counterfeiting is rapidly growing worldwide problem that affects a great number of industries and harm societies in many ways. According to the research by Robin Koh et al the counterfeiting problem have proliferated many folds[1]. Counterfeit is a drug which is sold in the market under a product name without authorization and it claims to be the original or genuine product[2]. With emerging counterfeit product market, the genuine producers are emphasising more to secure and authenticate pharmaceuticals. Proper identification of various materials such as raw materials, packaging materials, finished pharmaceutical products etc. is very important factor of quality assurance in pharmaceutical industries. RFID system can be utilised to assess the counterfeit medicines from the original one. The technology is considered to be the next wave of IT revolution[3,4]. RFID is perhaps the latest addition to the Auto Identification landscape which promises to revolutionize the way we track and manage our inventory. The technology has been around for more than 50 years; however, it has not been widely used. Since 2003, when Wal-Mart announced its intention to introduce an RFID application, it has brought new business opportunities to many information companies[5]. The impact of counterfeit drugs on any company's share price can be well observed from the incident of decline in share prices of Eli-Lilly from April 2002-july 2002 after news of counterfeit Zyprexa, due to loss of investor confidence. It took More than 1 year for the share price to return to previous levels[2].

APPLICATIONS

The commercial applications of RFID technique have started expanding significantly. Its applications are not a new phenomenon. The British Royal Air Force (RAF) used RFID-like technology in World War II to distinguish between enemy and friendly aircraft[6]. Most recently, it is gaining importance and popularity in many areas such as marathon races. But slow adoption and deployment of technique may be due to infrastructure availability, awareness and user friendliness. There is large number of sectors where the technology finds its application:

- Toll collection on highways
- Pharmaceutical industries
- Research labs
- Libraries
- Passport identities
- Crime investigations
- Banking

- Anti-theft systems

- Retail business

- Monitoring of product flow

- Wildlife studies by animal tracing

- Military applications[4]

(Monitoring of friendly force, equipments, Biological & chemical attack detection etc)

US DOD and Wal-Mart are the two biggest contributors to the development of RFIDs. Wal-Mart claims around 6% of supply chain cost savings due to the implementation of RFIDs. Wal-Mart was one of the earliest adopters of RFIDs along with the Department of Defense. Organized retail in India is growing at a very high rate, the main drivers being the huge population and a fast growing economy[5, 14].

HISTORY

History of radio frequency identification technique goes back to the history of electromagnetic and radio waves which form the basis of this technique but a significant landmark in this field was laid down by "Harry stochman" who published his paper on communication by means of reflected power[7].

- 18th century witnessed the beginning of fundamental understanding of electromagnetic energy.

- 1846: James clerk Maxwell published theory on electromagnetic[8].

- 1887: Hertz became the first to transmit and receive radio waves.

- 1896: First successful transmission of radiotelegraphy across Atlantics as demonstrated by Guglielmo Marconi.

- 1906: First continuous radio wave generation & transmission of radio signals by F.W. Alexanderson.

- 1948: Harry Stockman published a landmark paper "communication by means of reflected power[7]. But for stockman's vision to reach a reality took 30 years due to absence or inferiority of other techniques required in this regard such as high efficiency transistors, integrated circuits, microprocessors.

- During 1950's several technologies related to RFID were explored like "Identification Friend or Foe: IFF" for aircraft.

- 1964: Theory of loaded scatterers by 'Harrington'[9].

- 1970: Notable advancements were realised at research laboratories and academic institutions like Los Alamos scientific laboratories, North-Western University and Microwave institute foundation in Sweden.

- 1980: implementation of RFID technology.

- 1987: First commercial application began in Europe for collecting tolls.

- 1991: World's first open highway electronic tolling system opens in Oklahome.

- 1992: Walls et al defined the "information systems design theories"[10].

- 2004: USFDA approved a RFID tag for implantation in humans for assessing a person's health record.

- Ostbye et al.[11] evaluated an infrared/RFID system in a tertiary hospital and found that system can successfully locate hospital equipments.

- Cavalleri et al. (2004)[12] Presented a prototype of using wearable RFID tag for automated staff and patient identification.

- Li et al. (2005)[10,13] adopted RFID and mobile technology to implement mobile healthcare service system for positioning and identifying persons and objects. System demonstrated that patient's location and bio-information could be collected using RFID devices.

- Janz et al. (2005)[14] Showed RFID application for emergency department of a hospital. They presented in their study the technological and behavioural challenges encountered during the implementation of an RFID patient tracking system at the Elvis Presley Memorial Trauma Unit of the Shelby County Regional Medical Center (the MED), located in Memphis, Tennessee. They reported that data collected from tagged patients could improve medical processes, decision-making, and resource management.

- Fisher and Monahan (2008)[10,15] Indicated that many hospitals have begun to adopt RFID applications to track inventory, identify equipments and manage the personnel.

Evolution of RFID tags

- **1976:-** 12-b read only tags, build using CMOS logic chips & hybrid thick film. Circuitry covered half of the tag area.

- **1987:-** 128-b read only tags, built using a custom CMOS integrated circuit. Circuitry covered a quarter of tag area.

- **1999:-** 1024-b read-write tag, built using single custom CMOS integrated circuit. Circuitry covered insignificant tag area.

The 21st century has come up with major advancements in technology to improve accuracy, efficiency and to counter various risks associated with technology. Advances in microelectronics, embedded software and microwave circuits integration are setting new milestones to develop much advance wireless systems and are expanding the application field for RFID. The pace of development in RFID technology continues to accelerate[4]. Verichip tag is important application as it consists in human tagging. Today's new approach under consideration is "Internet of things", which enable the internet to reach out into real world of physical objects. The combination of RFID and GPS was recently introduced by China to ensure the online traceability of containers travelling between shanghai and savannah[16].

COMPONENTS

RFID will require considerable process redesign at all stages in the value chain where the technology is applied[5]. All RFID systems are composed of 3 main components.

1. RFID tag/ Transponder
2. RFID reader/ Transceiver.
3. Data processing system or backup database.

The tag is located on object to be identified and act as data carrier. Transceiver may be able to both read data from and write to transponder. The data obtained is then processed and checked for authentication.

The Transponder is a tag which acts as data carrying device consisting of a coupling element and an electronic microchip(Figure 1). Whenever the tag is within interrogation zone of a reader, it gets activated and responds to reader for data sharing. Power required for activation is supplied through coupling unit. The data capacity of transponder normally ranges from few bytes to many kilobytes. The smallest one is 1-bit which is just sufficient to give 2 signals states 0 and 1 where 0 implies that transponder is in the field while state 1 shows that transponder is not in the field[17].
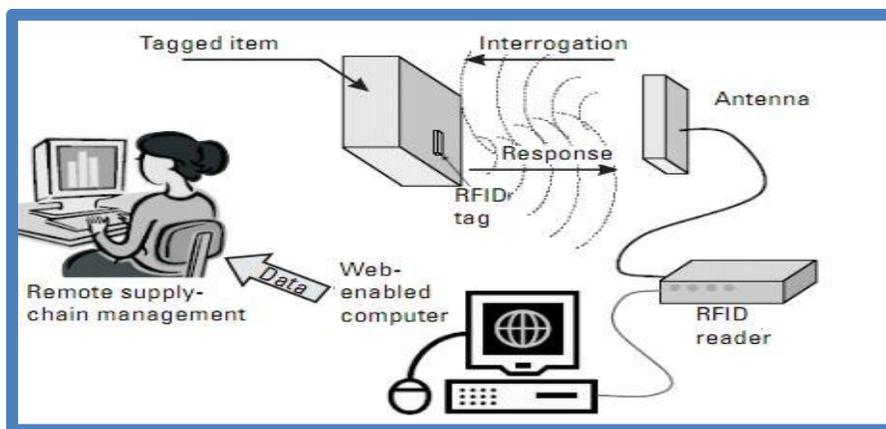

Figure 1. Components of RFID technology

Depending on the power supply transponders are of two types. Passive transponders[4] do not have their own power supply and required power must be withdrawn from the field of reader. In case of active transponders the power for operation comes from a battery incorporated with transponder[4]. Voltage supplied by antenna is used to activate the transponder which is always high enough to operate the circuit. This implies they are always active being powered by a constant source of energy. These tags generally have a higher read range and offer read/write facilities. The pitfalls of this are these tags are generally more bulky in size and weight compared to the passive tags (due to the weight of the battery) and are more expensive. In absence of external activation the transponder is switched into power saving mode to prevent unnecessary discharge from battery. Inductively coupled transponders are always operated passively and in order to use this low power as effectively as possible a schottky detector with impedance matching is typically used as rectifier. The frequency generated from the reader activates the passive device and it reflects back the information stored in the tag. However these tags have a comparatively lesser read range and are not writeable. The lack of need of an external power source makes these tags virtually of unlimited life.

The chip size is determined by its memory capacity[17]. Permanently encoded read only data carriers can only define the identity of an object and further data is stored on central database. But in case of writable systems, EEPROM or RAM technology is required.

Tag Antenna is designed to couple or radiate electromagnetic energy and may be used to both transmit and receive electromagnetic energy. The LF range where the read distances are small, tag antenna comprises of a coil to which chip is attached. In UHF range where read distances are larger, the reader and tag are coupled by electromagnetic wave in free space to which tag and reader are tuned by appropriate antenna structures[4]. In general tag antenna should be as small as possible (lehpamer: RFID design principles). The simplest RFID tag will broadcast its ID serial number (its electronic product code, EPC) to any nearby reader.

Reader activates and interrogates the tag and also connected to a host computer. Readers may be fixed or may be handheld terminals. It has components like antennas, transceivers and a processor to decode the data. Readers typically operate at single frequency[4].

Reader antenna acts as bridge between reader electronics and electronic wave in space. Highly directional, high gain antennas are used for large read distances. Tags are small and thin enough to be embedded in paper, already commercially available.

RFID frequency band[16] Desired frequency band of operation depends on the regulations of the country where tag will be used Table1. In terms of communication, RFID has 4 frequency bands.

- LF & HF: Less than one meter communication distance.

- UHF & Microwave: 3-10 meters reading distance.

Table 1. ISO standard of RFID frequency Band

Band	Frequency	ISO standard
LF	125kHz	18000-2
	134kHz	
HF	13.56 MHz	18000-3
UHF	Europe: 400MHz, 865-869MHz	18000-7
	USA: 902-928MHz	18000-6
	Japan: 952-954MHz	
Microwave	2.45 GHz	18000-4
	5.8 GHz	

EPC global is the organization which sets standards for the use of RFID system globally. EPC code consists of 4 parts. Header specifies the format of code. In a 96 bit format code this part is typically of 8 bits which means 256 possible combinations. EPC Manager guarantees a kind of uniqueness to the product. In a 96 bit format this part is typically of 28 bits which means 268,000,000 possible combinations. Object class indicates type of object. In 96 bit format this part is typically of 24 bits which means 16,000,000 combinations. Serial number differentiates between the products of same type. In a 96 bit format it is typically of 36 bit which means 68,000,000,000 possible combinations.

IMPORTANCE IN PHARMACEUTICAL SECTOR

Identification and movement tracking is very essential for the management of a pharmaceutical unit. RFID technology can play a significant role in management. Various kinds of activities such as material control, access control in critical areas, entry and exit to pharmaceutical building, critical processing steps, to restrict movement of equipments and analytical instruments can be overlooked by deploying RFID system. Most of the major pharmaceutical companies like Pfizer and Glaxo SmithKline are already tracking their high value items through the use of RFIDs in the US. Hence the system can help in following purposes:

- Product anti-counterfeiting.

- Automatic identification.

- Anti-forgery detection.

- Auto-inventory.

- Monitoring and controlling flow of materials.

- Effective management of medicines in hospitals.

- Tracing of drug in crime investigations.

Product anti-counterfeit tool[1]

Availability of counterfeiting products has become a great challenge to pharmaceutical industry. Generally there are number of intermediates in chain of distribution starting from manufacturing units to company's warehouse, main distributors, wholesalers, retail pharmacists. Counterfeiting is more prevalent in developing countries due to limited control over flow of drugs through supply chain[2]. Fake items get entry to market at these intermediate levels. Some drugs have high market value which attracts adulteration crimes. For example Pfizer Inc. spent $5 million to implement an RFID system for tracking Viagra[18]. Purdue Pharma L.P began RFID tagging OxyContin and an explicit way to identify and authenticate products is needed in supply chain because the counterfeits can be very similar or even identical to genuine items. RFID has recognized potential in anti-counterfeiting. RFIDs also help in better handling of the product returns in-case there are any issues with a particular batch (Fig. 2).
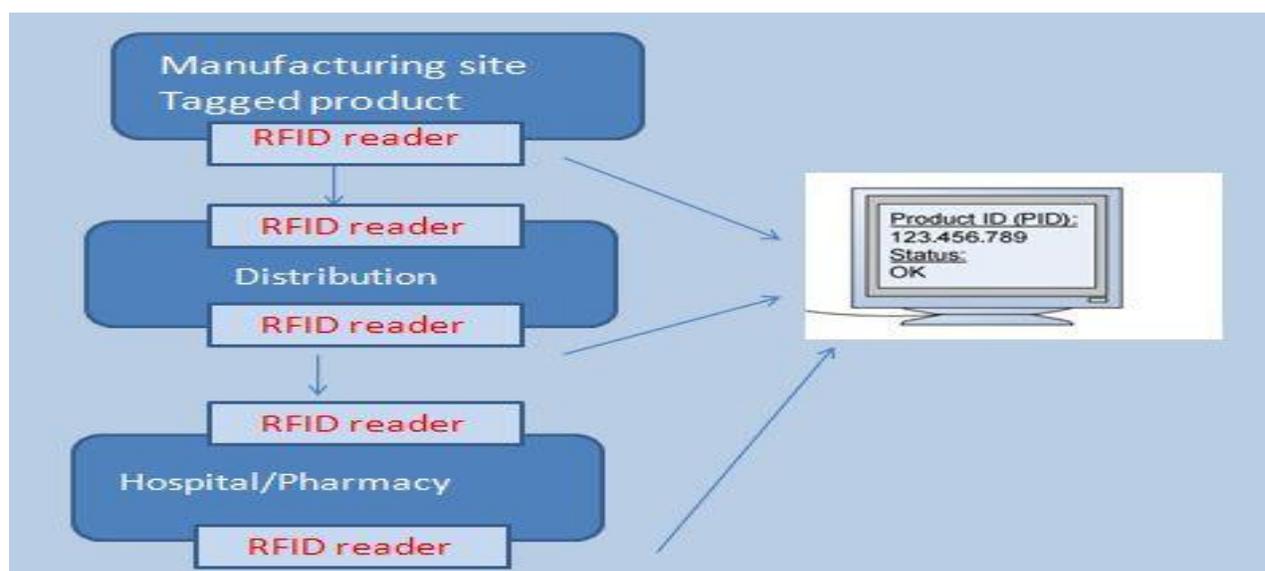

Figure 2. Functions of RFID Reader

Container identification

The chemicals are transported in high quality containers. Fatal consequences can occur if unsuitable container is selected or product information is not properly labelled. Using RFID transponders large amount of data related to container and filled material can be recorded and can also be changed when required (authorised writing)[17]. The container tag must be resistant to damp, impact vibration, dirt, radiations and acids.

Inventory and warehouse management

The entry and exit of raw materials and finished goods can easily be tracked by RFID technology. The materials handled in pharmaceutical industry can be classified and placed at different

locations. By analyzing the aggregate customer demand patterns with the help of RFID tracking at retailers and stores, a Company can easily sense the demand trends. This will help in proper demand planning. The method used for tracking pallets and cases in warehouses by bringing every pallet or case in line of sight of the reader is a very labor intensive process. RFIDs do not require the reader to be in the line of sight of the tags, thus reducing the labor requirement greatly in the warehouse. With greater accuracy in tracking, there is greater visibility of the Inventory.

Limit unauthorised access

Some of the areas of manufacturing plant, materials and documents are critical and confidential and hence entry to such departments is carefully controlled in order to maintain secrecy and safety. RFID tag can be used for access control. Authorised personnel may be provided with a tag (on apparel, ID card, watch etc) and are allowed to enter in restricted area if approved by system suitability test (SST). RFID can be used in check the access to critical operations such as sterilization time, steam pressure; temperature etc by allowing the access to fully trained authorised personnel only.

R & D department

In research and development of drugs, number of specimen tubes and plates containing compounds for testing are stored in refrigerator. There is possibility to misidentify the item due to obscured label number[18]; even the barcode system fails due to frost. RFID system sharply reduces the time of picking as well as eliminates the problem of picking wrong samples.

Recording Process parameters during manufacturing

The quality of product largely depends upon various processing parameters such as time length which the product spends under certain temperature conditions. RFID system can be deployed to periodically record and transmit temperature, vibration and other permanent data. The quality of product can be better assured[18].

Medicine and equipment traceability in hospitals[19, 20]

RFID technology seems to be good solution to prevent thefts of equipments and supplies. Medical equipments with fixed RFID tag when brought outside the designated premises or if tag is removed without deactivation form server side, it will trigger alarm. Many hospitals have begun to adopt active RFID systems with the goal of locating pieces of equipment when medical staff needs them. Hence the time spent in "hunting and gathering" equipments can be saved providing more time in direct patient care. Hospitals can more efficiently utilize the equipment they have and lower expenses on equipment rental and purchasing[21]. At St. Vincet's hospital (Birmingham, Ala) surgical instruments are monitored to determine their location[20]. Many

hospitals have begun to adopt active RFID systems with the goal of locating pieces of equipment when medical staff needs them. Although the prior literature showing some signs of research and advancement in the study of RFID in healthcare industry, there is lack of a design science research into design and development of RFID system in general, and RFID based human management system, in particular[10].

Tracking medication from pharmacy to patient[19]

When tagged medication leaves the pharmacy, the patient information is updated at server system after proper authentication. On arrival to hospital it is again scanned by reader for authentication and all required information is updated such as: a) Type of medication. b) When the medication given to patient? C) Information about the nurse administering it etc. same information may also be stored to RFID enabled patient wristband and can be checked every time when needed. A patient in the provisional observation area may be waiting for examination report or intravenous drip. However, if such patient is made to wait for excessively long time without further attention from the medical personnel, the RFID will not be read for a predetermined amount of time. The information of the patient will be automatically sent to the management centre where the management of the hospital may respond accordingly, such as instructing the medical personnel to give further attention provide more medical service, or request the examination reports to be completed within a certain amount of time[18]. Such a study was conducted at "Jena University hospital, Germany, June 2006" [17, 19]. Such new technologies of monitoring, tracking, and identification aim to increase efficiency in hospitals but also tend to intensify the surveillance to which nurses and other hospital staff are subjected.

Patient identification

Every patient after admission to hospital is given a RFID wristband which stores patient's personal data such as registration ID, name, age, registration date, medical history etc which can easily be located, identified and accurate treatment can be provided to right patient at right time. RFIDs have been embedded in patient bracelets so that medical staff can electronically identify patients before surgery and before administering medications and blood transfusions. Additionally, these systems have been implemented in order to locate where patients are and to passively collect data on patients' movements through hospital. RFIDs can be embedded in the packaging of drugs. So whenever a patient takes a medication by removing a pill from the packaging, it can be detected and tracked. This information can be used by the doctors to check whether the patient is taking the medications properly. RFID systems are seen as valuable

because of their ability to collect data in real-time. As a result, these systems may have a valence toward surveillance.

FACTORS AFFECTING RELIABILITY

Read reliability is defined as probability that an RFID reader can detect and identifies an RFID tag when it is in the read range of reader's one of the antennas. Trace reliability is probability that a system successfully detects and identifies an object when it is present in designated area. There are numbers of factors that can impact read reliability such as material surrounding a tag, inter-tag distance, tag antenna distance, orientation of tag with respect to antenna, the number of tags in read range of antenna and the speed of tagged object [22].

- Read range depends upon the frequency of operation. Read reliability at distance of 1 meter has been shown to be 100% which gradually reduces between 2-9 meters[22].
- Depending on the orientation, tag require at least 20-40 mm spacing for reliable working.
- When the tags are very close to each other and are perpendicular to antenna, tags would not work well or don't work at all.

Improving RFID reliability

In an experiment by Lin Zhong et al[22] reliability was checked in three different ways like (a) Multiple antennas per portal, (b) Multiple readers per portal, (c)Multiple tags per object. Results of study showed that multiple tags on different sides of object increase the probability of successful read by reader while in case of multiple readers per portal it was severely reduced.

BARRIERS IN IMPLEMENTATION

1) Social acceptance and trust of RFID is quite low.
2) Lack of awareness.
3) Insufficient security and security safeguard.
4) Deployment of RFID may lead to loss of many jobs.
5) Initial high cost of setting up system
6) Barriers for smaller companies like hidden organizational costs.
7) Lack of well established standards.

One important aspect is to protect the consumers from unwanted scanning of RFID tags that are attached to the items they are carrying. Tag contains not only the traditional information but also a unique serial number. So each consumer carrying such item can be tracked which presents a clear potential for privacy violations. Hospital nurses feel overly scrutinized by these tracking technologies. Nurses report that they would rather spend their time looking for equipment and

locating patients than spending it logging in and navigating the RFID system software, replacing RFID tags, and/or calling technology support when the system is not working properly. In cases in which the staff are being tracked by the RFID systems, nurses describe feeling like "big brother" is watching as they spend time with patients, take unofficial rest breaks between patients, and take official breaks during their shifts[15].

Blocker tags can be used to selectively block only selected subset of ID codes[23]. Another approach is to "KILL" the RFID tags before they are placed in the hands of consumers. Killed tag can never be activated. Another approach is use of a container known as 'Faraday Cage' made of metal mesh or foil that is impenetrable by radio signals.

CHALLENGES

1) Requirements for privacy and security according to specifications.

2) For globally operating systems, insufficient semantic interoperability of RFID system may restrict benefits from their deployment.

3) Setting up harmonized frequency policy.

4) To develop the processes for establishing guidelines and best practices.

5) Impact of almost permanent exposure to low intensity radio waves.

6) The analysis of market perspective and socio-economic aspect.

Depending on the frequency, some RFIDs are unsuitable for use where the water content is high whereas for some frequencies use of RFID in the proximity of metals is not recommended. Higher frequencies fail to penetrate objects with high water or metal content. Wireless transmission can be unpredictable at times and there might be interference with other RF signals from other devices. The frequency spectrum allocated is different in different countries. Therefore, in the case where international shipment of goods takes place, RF reconciliation needs to be done. The RFID cannot be used in biopharmaceutical supply chain due to mainly two reasons. First being unavailability of well documented proofs demonstrating non-thermal effects of RF[26]. Secondly FDA will not allow it per CPG section 400.210. But the studies performed on various products including Hormones, vaccines and immunoglobulin have shown non-thermal effect of RF under the frequencies used in RFID. This can be expected from mathematical point of view also. Typical protein size is 50Å. Typical highest RFID frequency is 2.4GHz; the wavelength of which would be nearly 50 Å. so from the protein's point of view we expect that the RF wave would not look like a wave at all. Readers generate huge amount of data, large portion of which is redundant. For multinational companies which are geographically distributed, managing data in real time and aggregation of data in central facility is difficult task. False

negatives occur when reader does not detect or read tag due to signal blocking, deep buried tag or improper orientation.

CONCLUSION

RFID technique promises to bring some major changes in pharmaceutical industry and is considered to be most reliable security tool to increase integrity in supply chain. It will continue to make inroads into healthcare via track-and-trace solutions. With the boom in organized retail, retail represents the most promising market vertical for RFID adoption. The price of the tags & readers, the low awareness of the critical benefits of RFID in the industry and key issues in implementation makes it virtually impossible for Small and Medium Scale Enterprises to adopt this technology. As the cost of using this technique reduces to affordable level, the scope and application will be ever increasing and pharmaceutical industry will be benefited economically to large extent. The combination of RFID with other technologies like GPS is expanding its field of application, one so called "Internet of things".

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