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A Review Paper on Embedded System for Automated Monitoring Of Foot Ulceration in Diabetic Patients Using Flexi Force Sensors

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Abstract

Diabetes complications damage the neurology of the body often referred as 'Diabetic neuropathy'. It results in severe nerve damage, causing the development of high pressure areas in the feet and may ultimately cause ulcerations. This paper discusses about the detection of foot neuropathy as possible, from a home based environment using a smart and low-cost foot pressure and foot movement analysis and blood flow stimulation system, which a patient can wear at any place to monitor the planter pressure distribution. Flexi force sensors are used to measure the pressure in different areas of the foot and it is displayed on a hand held device. A proposed circuit is used to measure the pressure on the foot with the help of force sensing resistors. The pressure on the foot is acquired by the sensor. DAQ is done by Graphical User Interface using 'Lab VIEW'. As per the Normalized Peak Pressure (KPa) values, normal and diabetic neuropathy patients foot pressure values are classified. A healthcare mobile app with algorithmic analysis, analyzes the acquired data from the sensors to intelligently empower furthermore superlative monitoring and care. This method can help diagnose foot ulceration at an earlier stage which can prevent further ulceration.

Key words: Diabetic Neuropathy, Diabetic Foot Ulceration, FlexiForce Sensors, LabVIEW GUI, IoT for healthcare.

I. INTRODUCTION:

Globally, approx. 422 million adults have diabetes, out of which 85-90% have Type 2 diabetes. Diabetes prevalence is increasing rapidly and the number is projected to almost double by 2030. Increases in the overall diabetes prevalence rates largely reflect increased risk factors for type 2, notably greater longevity and being overweight or obese. The WHO estimated 1.5 million deaths in 2012, making it the 8th leading cause of death. Diabetes doubles the possibilities of having cardiovascular diseases. About 75% of deaths in diabetics are due to coronary artery disease. The major long-term complications relate to damage to blood vessels [1].

Untreated, diabetes can cause many complications. Acute complications are diabetic ketoacidosis and nonketotic hyperosmolar coma; and serious long going complications are heart disease, stroke, kidney failure, foot ulcers and damage to the eyes. Damage to the nerves of the body, referred to as 'diabetic neuropathy', is the most common complication of diabetes. The symptoms may include numbness, tingling, pain, and altered pain sensation, which can lead to damage to the skin. It can further cause diabetes-related

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foot problems (such as diabetic foot ulcers) that may be difficult to treat, occasionally requiring amputation. Additionally, proximal diabetic neuropathy results in painful muscle wasting and weakness. Our main motive of working on this topic is to help diabetic patients recognize whether they have diabetic foot ulceration an earlier stage which can prevent furthermore complications [1].

Body sensor network systems can help people by providing healthcare services such as medical monitoring, memory enhancement, medical data access, etc. Continuous health monitoring with wearable or clothing-embedded transducers and implantable body sensor networks increase detection of emergency conditions in at risk patients. These systems prove useful in remotely acquiring and monitoring the physiological signals without the need of interruption of the patient's normal life and thereby improving life quality. This is possible when we connect the Body sensor network system with the 'universal global neural network' in the cloud which connects various things(devices) referred as 'Internet of Things' [9].

The IoT intelligently connects devices and systems which comprise of smart machines interacting and communicating with other machines, environments, objects and infrastructures and the Radio Frequency Identification (RFID) and sensor network technologies. An enormous amount of data can be generated, stored, processed for useful actions that can "command and control" the 'things' to make our lives much easier and safer. In most countries internet access is available so that the transferring of the information becomes easier and less costly. Through a widely distributed locally intelligent network of smart devices, IoT potentially provides extensions and enhancements in transportation, logistics, security, utilities, education, healthcare and other areas, providing a new ecosystem for app development [8].

IoT-enabled devices empower remote monitoring in the healthcare sector possible to keep patients safe and healthy, and empower physicians to deliver superlative support and care. As a result, healthcare costs have reduced significantly and treatment outcomes have improved. Applications of IoT in healthcare benefit patients, families, physicians, hospitals and insurance companies. Wearable devices like fitness bands and other wirelessly connected devices like blood pressure and heart rate monitoring cuffs, glucometer etc. give patients access to personalized attention. We can tune them to remind calorie count, exercise check, appointments, blood pressure variations and much more. IoT has changed people's lives, especially elderly patients, by enabling constant tracking of health conditions. This can majorly impact people living alone and their families. On any disturbance or changes in the routine, alert mechanism sends signals to family members and concerned health providers [9].

The major advantages of IoT in healthcare include: 1) Cost Reduction 2) Improved Treatment 3) Faster Disease Diagnosis 4) Proactive Treatment 5) Drugs and Equipment Management 6) Error Reduction [11].

By using wearables and other monitoring equipment embedded with IoT, the heath of the patients can be tracked and monitored more effectively. Physicians can track patients' adherence to treatment plans or any need for immediate medical help preventing infections. Healthcare apps compile large amount of health data from numerous sources such as Electronic Health Records (EHRs), medical imaging, wearable technology, medical devices, pharmaceutical research, genomic sequencing and so on [8].

II. GENERAL SURVEY OF THE DISEASE

Diabetes is a medical condition in which the sugar content in the blood rises to a high level. Diabetes mellitus (DM) is a group of metabolic diseases in which the subject has high blood sugar levels over a prolonged period with symptoms of frequent urination, increased thirst, and increased hunger. Insulin is needed for metabolism of sugar. The pancreas either doesn't synthesize insulin, or the cells in the body

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don't utilise the synthesized insulin. There are three major types of diabetes: Type 1 DM, Type 2 DM, Gestational diabetes. Type1DM - previously referred to as "insulin-dependent diabetes mellitus" or "juvenile diabetes", is a condition when the body fails to produce enough insulin and the cause of Type1DM is unknown. Previously referred to as "non insulin-dependent diabetes mellitus" or "adult-onset diabetes", Type2DM begins with insulin resistance [1].

In Diabetes, the body cells don't respond to insulin properly; which may result in a lack of insulin as the disease progresses. Primarily, it is due to excessive body weight and not enough exercise. Gestational diabetes happens when pregnant women without a previous history of diabetes develop a high blood glucose level. Diabetes of any type increases the risk of long-term complications that typically develop after years, may be a decade or two, but may be the first symptom in those who have otherwise not received a diagnosis before that time. Major long-term complications relate to damage to blood vessels. In Diabetes, there is double risk of cardiovascular disease; about 75% of deaths in diabetics are due to coronary artery disease. Untreated, diabetes can cause many complications. Acute complications include diabetic ketoacidosis and nonketotic hyperosmolar coma. Serious long-term complications include heart disease, stroke, kidney failure, foot ulcers and damage to the eyes [1]. Due to low insulin, the sugar is not metabolised and it stays in the blood for a very long time. Due to this the sugar content in the blood rises. Sugar attracts bacteria. Sugar in the blood provides breeding grounds for bacteria and thereby infection. Usually on having an injury, the human body pushes the RBC aside and WBC accumulate around the injured areas of the body to do the healing process. However, when the sugar content in the blood is high RBC cannot be pushed aside and WBC are unable to gather together to proceed with the healing process. Also sugar being sticky makes soft things rigid. Because of the excess sugary blood inside, the skin becomes rigid; may easily get a cut or a wound after coming in contact with anything hard. And in this case the healing process also doesn't function normally. Since the feet are always in contact with the ground, they are more prone to get injured as compared to the rest of the body. Hence ulcers may develop in the feet [A].

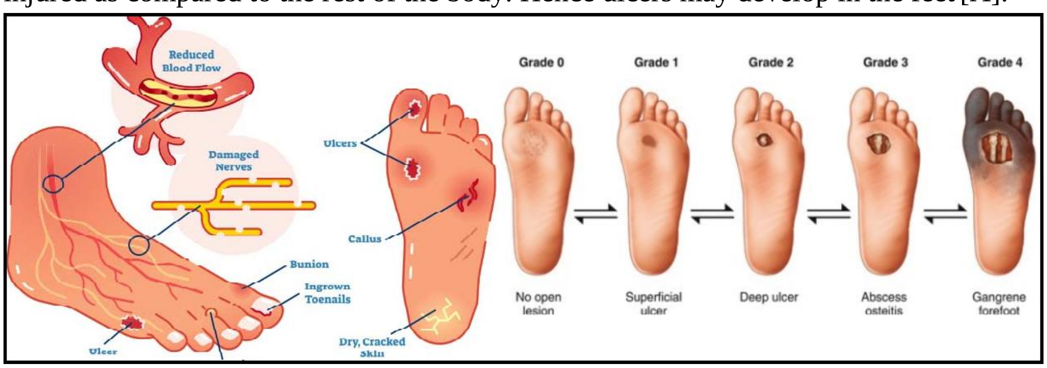

Fig 1. Diabetic Foot Ulcers - Step-by-step[2]

Mostly, ulcers are found under the big toes and the balls of the feet, and they can affect the feet down to the bones. Diabetic foot ulcer is a major complication of diabetes mellitus, and probably the major component of the diabetic foot [4]. Wound healing is an innate mechanism of action; key feature of wound healing is stepwise repair of lost extracellular matrix (ECM) that forms the largest component of the dermal skin layer. Diabetes impedes the normal steps of the wound healing process. Many studies show a prolonged inflammatory phase in diabetic wound which causes a delay in the formation of mature granulation tissue and a parallel reduction in wound tensile strength [3].

Diabetic neuropathy is often developed due to metabolic and neurovascular factors. Peripheral neuropathy leads to loss of pain or feeling in the toes, feet, legs and arms due to distal nerve damage and low blood flow. Painless trauma develops. Blisters and sores show up in the numb areas of the feet and legs such as metatarso-phalangeal joints, heel region. Due to this pressure/injury goes unnoticed and eventually become portal of entry for bacteria and infection [2].

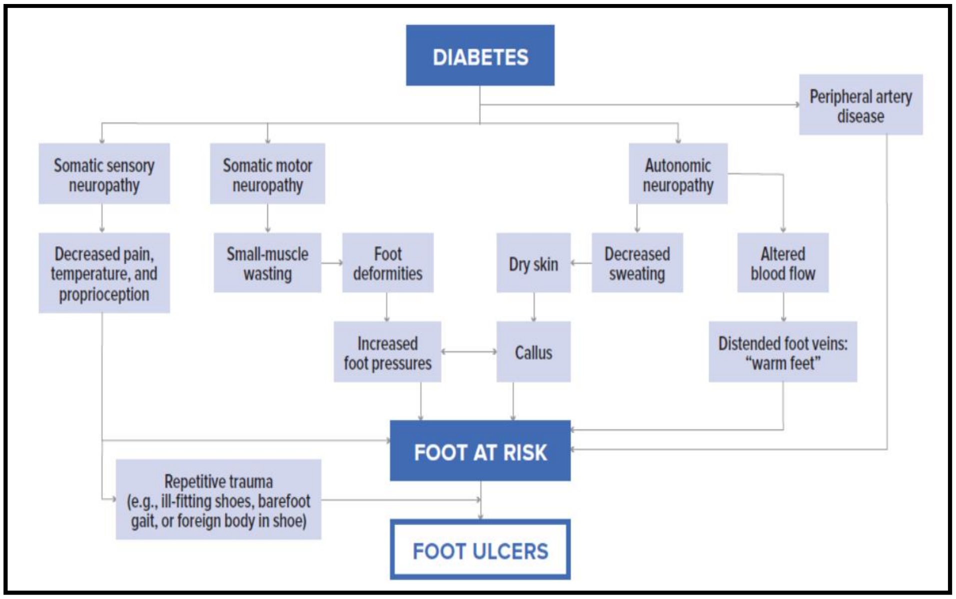

Fig 2. Pathways to Diabetic Foot Ulceration[2]

Diabetes may lead to neurovascular complications, where increase in pressure among the foot regions may develop. Patients often face loss of pain/temperature sensations in their feet, resulting in inadequate pressure under their feet, during walking or standing. This may cause injury in the feet and painless trauma and ultimately ulceration. Repetitive injury results in bone changes, causing the foot to become deformed. A detailed study of the pressure distribution on the sole of the foot in static position is needed. It is important to develop low cost planter foot pressure system' to measure foot pressures that can differentiate between normal subjects and diabetic patients. These pressure profiles i.e. pressure concentrations can help in writing proper orthotic prescriptions [5].

III. SYSTEM DESIGN

A. BLOCK DIAGRAM

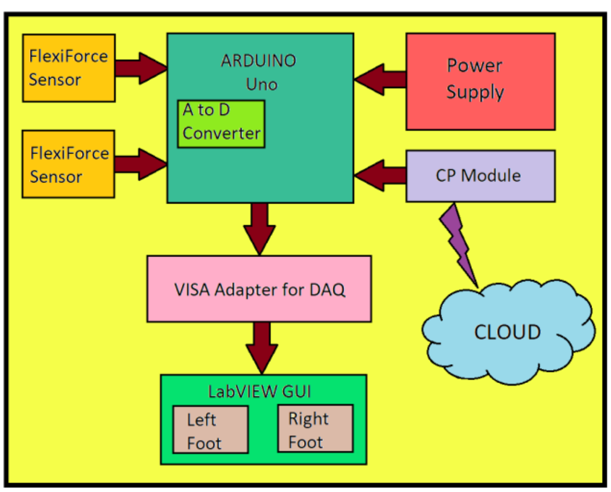

Fig 3. Proposed Block Diagram Of The System

B. SYSTEM COMPONENTS

a. Sensors:

There are various sensors available in the market for body pressure measurement – viz. Piezoresistive strain gauge, capacitive sensors, electromagnetic sensors, peizo-electric sensors, potentiometric sensors, thermal sensors, resonant sensors, force balancing sensors, etc. A pressure sensor usually is as good as a transducer; it generates a signal that is a function of the pressure imposed. Body pressure sensors provide valuable insight into the design performance of surfaces in contact with the human body. Out of all the available sensors, we have picked force sensing resistors called as Flexi Force Sensors for sensing the body pressure. FlexiForce sensors are used for measuring the force between almost any two surfaces. They are durable enough to stand up to most environments and ideal for integrating into OEM products. Their thin, flexible profile allows them to measure forces where larger, bulkier technologies can't. 4 key uses for FlexiForce sensors are: they detect and measure Force from an applied load, rate of change of a force load over time, force thresholds to trigger appropriate action, contact and/or touch. We had to survey an average human foot to formulate the placement of sensors according to the pressure areas to avoid excess use of sensors and thereby make it cost-effective

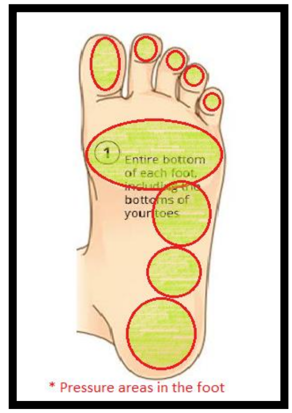

Fig 4. An Average Human Foot

b. Arduino UNO with ATMega328:

Arduino is a quick functioning, easy to handle, electronic prototyping platform composed by the Arduino board and the Arduino IDE. Arduino proves to be a tool for developing interactive objects, taking inputs from a variety of switches or sensors and controlling a variety of lights, motors and other outputs. It is very flexible; it offers a variety of digital and analog inputs, *SPI*, serial interface, digital and *PWM* outputs. Arduino it can be connected to computer via USB and can be communicated using standard serial protocol. It is cost efficient and comes with free authoring software.

c. VISA DAQ Adapter:

DAQ i.e. Data acquisition is application program interface; it fetches data from the hardware. DAQ is required to measure real world physical conditions and converting them into digital numeric values that can be read and manipulated by a computer. DAQ apps are usually controlled by software programs e.g. LabVIEW in this experimental setup. The components of DAQ are: 1) Sensors 2) Signal Conditioning Circuitry 3) Analog to Digital Converters.

d. LabVIEW:

LabVIEW is systems engineering software for projects with the requirements - testing, measurement and control with quick accessibility to hardware and data insights. LabVIEW provides a platform for graphical programming approach so that every aspect of your application, including hardware configuration, measurement data, and debugging can be visualized; it proves to be highly beneficial for designing smart machines or industrial equipments. Graphical user interface allows users to interact with electronic devices through graphical icons and audio indicator instead of text based user interfaces; GUIs were introduced in reaction to the perceived steep learning curve of command-line interfaces.

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e. Power Supply:

Power supply is essential for controlling, regulating and distributing DC power throughout the system. It enables an electronic system to function properly by supplying and controlling its DC power. We can say that the power management subsystem function is analogous to the body's blood vessels function. The blood vessels in our body supply proper nutrients to keep the body alive; likewise, the power management subsystem supplies and controls the power to keep an electronic system alive. It employs a power supply that accepts a DC voltage input, typically 5 V, 12V, 24V, or 48 V and produces a DC output voltage

f. CP Module:

CP Module is used to extend communication to further Ethernet partners. CP Module is basically a communication processor card. It is used to get connected with the internet. It is beneficial for applications where internet connectivity is a needed. It is useful in IoT based projects to connect with the cloud to send and receive large amount of data.

g. Health Monitoring Mobile App:

With algorithmic analysis of the huge volume of data, mobile healthcare app can be put to great use to eliminate mistakes in medication, reduce wait time at medical clinics and hospitals, and provide better service and improved security. It allows users to upload prescriptions, place orders, provide delivery options and make payments. It calculates health conditions. It integrates the solution with IoT enabled devices to provide notifications and reminders. During surgeries, staff can monitor blood loss via a monitoring system, other patient vitals could be monitored via a mobile app, and the surgical team could even use an app to inform the family in the waiting room about the patients' progress/status. It can help schedule reminders on a mobile device to improve customer satisfaction and improve the bottom line by reducing missed appointments. Healthcare mobile app has the following key benefits: 1) Real-time communication support, 2) Easy to use interface, 3) Electronic health records, 4) User-friendly, 5) Responsive, 6) In-built system for doing medical calculations, 7) Back-end Systems and API Development, 8) Appointment Scheduling, 9) Emergency Department, 10) Navigation Provider. Such healthcare mobile apps help in remotely acquiring and monitoring the physiological signals without the need of interruption of the patient's normal life, thus improving lifestyle and saving the time in unnecessary doctor visits.

IV. SYSTEM WORKING

A. CIRCUITRY

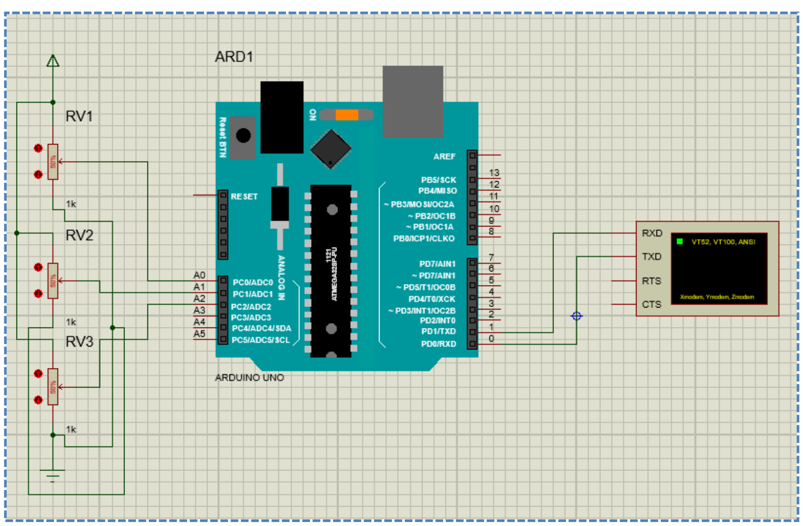

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Fig 5. Circuit Diagram

B. WORKING

In this experimental setup, the force sensing resistors receive the incoming analog inputs in the form of pressure from a subject under observation. We fix the thin and flexible Flexi Force Sensors on the sole of the footwear to measure the force between the feet and the footwear. The output from the sensors is fed to the Analog Input Pins of the Arduino UNO board with ATMega328 microcontroller. We use the Arduino IDE to write, compile and run the program and then burn this code on the Arduino UNO board using a USB cable that connects the Arduino UNO board with the computer through the USB Port on the Arduino UNO board. The Arduino UNO board conditions the received sensor signals and the conditioned signal is then converted into digital values that can be read and manipulated by the ATMega328 Microcontroller. The Tx-Rx Pins of the Arduino UNO board are connected with the Tx-Rx of the LabVIEW GUI by which the output signals from the Arduino UNO go as the input to LabVIEW. LabVIEW has inbuilt data analyzing algorithms that analyzes and compares the received data from Arduino UNO with a set of pre-fed values. LabVIEW GUI interacts with the Arduino UNO and Flexi Force Sensors to compare the pressure profile of the diabetic subject with the pressure profile of a normal subject and display the results graphically to ultimately diagnose whether the subject has Diabetic Foot Ulceration. Approximately, pressure range of 50 to 400 KPa is for normal subjects whereas pressure range above 600 KPa at metatarsal heads is for diabetic patients. We have used a CP Module to connect our experimental setup with the internet to get connected with the ‘global internet neural network’ – ‘Internet of Things’.

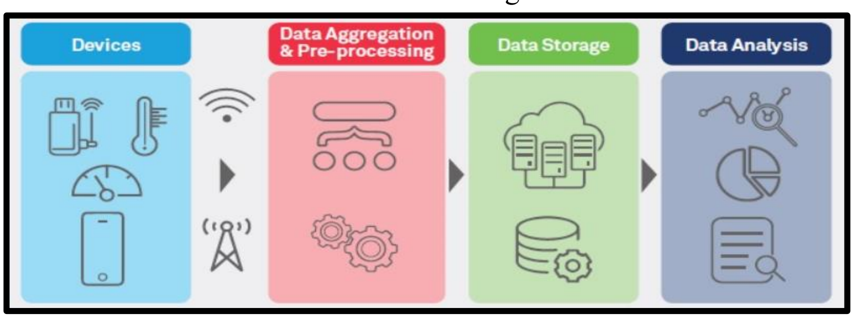

Fig 6. IoT Functioning Procedure

We connect the Process with the cloud to generate, store and process the gathered data, and intelligently connect devices and systems to gathered data from embedded sensors and actuators and the Arduino board. Mobile networks already deliver connectivity to a broad range of devices and this enables us to develop new services and application. Mobile App is used for surveillance and maintains a record of the Pressure profile as well as the entire medical history of the subject diagnosed with Diabetic Foot Ulcer keeping a track of the important body parameters like heartbeat rate, blood sugar, etc. Emergency condition is detected and an emergency signal is triggered to the nearest ambulance service and nearest hospital and doctor. Alert mechanism alerts family members and concerned health providers and family doctor. It can provide contact details, addresses, wait times and scheduling can help keep patient from going into crisis mode. It can keep a track of the discharge information, medication information, precautions, follow-up appointment information, emergency contacts, first aid tips, and more. This app analyzes the data acquired to show any improvement or decline in the patient’s condition. It aids in educating patients to identify symptoms and propose fitness activities, diagnostic testing, dietary suggestions, etc; and also schedule medicine and

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appointment reminders. Use of IoT makes this experimental setup a smart system for monitoring foot ulcers in diabetic patients

V. FUTURE SCOPE

We can add a GPS module using Arduino Uno to track the patient. To simplify the hardware, reduce wiring and make the setup light-weighted we can use wireless sensors and use WSN. Also we can add a wifi module to connect with the internet wirelessly instead of connecting it with the Ethernet. Also, the mobile app can be modified to help patients, employees and families to find waiting rooms, patient rooms, check-in stations, X-ray labs, cafeterias, etc; useful for telling them the way and their location. It can be enabled with an audio chatbot to answer the basic queries useful for visually impaired patients who cannot read.

VI. CONCLIUSION

Since health care services are an important part of our society, automating them may lessen some burden on humans and eases the measuring process. This experimental setup aids in the diagnosis of diabetic foot ulceration in a home based environment using a smart low-cost foot pressure and foot movement analysis and blood flow stimulation system, which a patient can wear at any time and any place to monitor the planter pressure distribution. Study shows an approximate pressure range of 50 to 400 KPa for normal subjects whereas pressure range above 600 KPa at metatarsal heads for diabetic patients.

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