ADVANCED DESIGN AND IMPLEMENTATION OF A MULTI-FUNCTIONAL THERAPEUTIC ELECTRICAL STIMULATOR

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ABSTRACT

This thesis presents the design, development, and intensively testing results of a two-channel, multi-functional Electrical Stimulation device (ES device), intended for therapeutic and rehabilitation applications. The proposed ES device is designed to be locally produced and offer performance comparable to or better than imported devices, addressing the high costs and limited accessibility of current clinical equipment. The system integrates a microcontroller-based pulse generator, a user-friendly interface, and an advanced driving stage, enabling the generation of twelve essential waveforms and two special functions. These waveforms address a range of therapeutic applications, including muscle rehabilitation, pain management, neuromuscular re-education, and other clinical interventions. The designed ES device seamlessly aligns with and adheres to international medical standards (IEC 60601-1, IEC 60601-2-10, and IEC 60601-1-2) to ensure safety, precision, and clinical efficacy. The proposed device has also successfully complied and certified with the stringent regulatory certification requirements of the Thailand Food and Drug Administration (FDA). Extensive tests have been conducted to validate the accuracy, stability, and performance of the device's output, as well as the usability of its interface. The results demonstrate that the proposed ES device meets the required technical specifications and performs effectively in various simulated clinical scenarios. This work contributes to reducing dependency on imported technologies and supports the growth of local medical device innovation and commercialization.

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CHAPTER 1

INTRODUCTION

1.1 BACKGROUND, SIGNIFICANCE AND PROBLEM STATEMENTS

Background: Physiotherapy is constantly advancing, and new technologies are playing a key role in improving treatment outcomes. Electrical Stimulation (ES) devices are commonly used for muscle rehabilitation, pain relief, and therapeutic exercises. However, many of the ES devices used in clinics today are imported, which leads to high costs and limited access to the latest technology. This situation highlights the need for locally developed ES devices that can match the performance of imported ones while being customized to meet the specific needs of local medical and educational institutions.

As the demand for physiotherapy equipment grows, developing a local ES device could provide many benefits. It would promote self-reliance in medical technology and offer healthcare providers a more affordable and accessible solution. Moreover, having such devices available locally would greatly improve practical education in physiotherapy, giving students the chance to use advanced tools. In addition, integrating these devices into training programs would help boost the growth of the physiotherapy field.

Significance: This research focuses on designing and developing a locally produced ES device that can perform as well as or better than imported equipment. By creating a high-quality and cost-effective device, this project aims to support the use of advanced science and technology within the country, reducing the reliance on imported medical tools.

The device will also enhance the hands-on education of physiotherapy students by giving them access to modern, locally made equipment. It will also benefit academic research and the training of physiotherapists, helping them become skilled in using state-of-the-art therapy tools. Beyond education, the device has commercial potential, with the possibility of mass production, which could boost the economy by cutting down on costly imports.

Problem Statement: Although ES devices are widely used in rehabilitation and therapy, most of them are imported, leading to high purchasing and maintenance costs. This reliance on foreign-made equipment adds to the financial burden of healthcare providers and limits access to the latest technological advancements.

The lack of locally produced ES devices also means fewer opportunities for customization to meet specific therapeutic needs or for use in local education systems. This results in fewer practical learning experiences for students and professionals in physiotherapy, limiting their exposure to advanced technology.

This research aims to solve these issues by developing an ES device that rivals imported equipment in terms of performance, features, and safety. The device will meet relevant medical standards and be developed with input from local physiotherapists to ensure it meets clinical needs. Ultimately, the project seeks to create a prototype that is ready for commercial production, reducing reliance on imported technology and supporting the growth of local medical device manufacturing.

1.2 OBJECTIVES

(1) Develop a locally-produced ES device that matches or surpasses the performance and functionality of imported devices.
(2) Reduce dependence on imported ES devices, decreasing costs and increasing accessibility for healthcare providers.
(3) Customize the ES device to meet the specific needs of local medical and educational institutions.
(4) Provide affordable and high-quality ES devices for clinical use, contributing to self-reliance in medical technology.
(5) Enhance hands-on education for physiotherapy students by offering modern, locally-manufactured ES devices for practical learning.
(6) Integrate the ES device into academic and clinical training programs to improve the skill development of physiotherapy professionals.
(7) Promote the use of locally-produced medical technology through commercialization, supporting economic growth and reducing reliance on foreign technologies.
(8) Ensure the developed ES device adheres to relevant medical standards, ensuring safety, accuracy, and clinical effectiveness for professional use.

1.3 SCOPE OF WORK

(1) Design and develop an ES device with functionality comparable to or exceeding imported devices.

(2) Customize the device to meet the specific therapeutic needs of local healthcare providers and educational institutions.
(3) Develop at least 12 essential waveform types to provide versatile therapeutic options for muscle rehabilitation and pain management.
(4) Utilize a microcontroller (dsPIC33EP512MU810) to control and process the functions of the ES device, ensuring efficient and reliable operation.
(5) Implement and integrate key components, including the control unit, pulse generator, and driving stage, into a fully functional prototype.
(6) Evaluate the prototype for real-time pulse generation to ensure the device meets therapeutic and safety requirements for clinical use.
(7) Facilitate technology transfer and commercialization, preparing the prototype for mass production and market entry.
(8) Ensure the device complies with relevant medical standards, focusing on safety, accuracy, and performance.

1.4 RESEARCH APPROACH

(1) Conduct a comprehensive literature review to explore existing ES devices, their applications, and limitations in the context of physiotherapy.
(2) Study relevant medical standards and regulations to ensure the developed device complies with safety, accuracy, and performance requirements.
(3) Analyze and gather key information from physiotherapists to define the necessary functions and features for the device, tailored to clinical needs.
(4) Design the system architecture of the ES device, including the control unit, waveform generator, and user interface.
(5) Develop the functional algorithms in for generating the required waveforms, ensuring precise pulse amplitude, frequency, and duration control.
(6) Design and construct the individual circuits for the various subsystems.
(7) Integrate the subsystem circuits into a fully functional prototype, ensuring seamless operation across all components.
(8) Test and validate the ES device through rigorous experimentation, including real-world clinical trials with physiotherapists, to ensure it meets therapeutic requirements.
(9) Optimize the prototype for commercialization, focusing on cost-effective production, scalability, and ease of use for healthcare providers.

(10) Prepare a detailed report and thesis, documenting the entire development process, results, and the potential impact of the ES device in the healthcare sector.

1.5 EXPECTED OUTCOMES

(1) A locally-produced ES device with performance and functionality equal to or better than imported devices, tailored for physiotherapy applications.
(2) A cost-effective and accessible ES device that can reduce dependency on expensive foreign technologies, providing economic benefits to healthcare providers.
(3) A customizable ES device that meets the specific needs of local healthcare institutions and educational programs.
(4) A fully-functional ES prototype with at least 12 essential waveforms, ready for clinical use in muscle rehabilitation, pain management, and therapeutic exercises.
(5) Use of the ES device in academic and clinical training programs, enhancing the skill development of students and professionals in physiotherapy.
(6) Adherence to medical standards, ensuring the safety, accuracy, and clinical effectiveness of the developed ES device.
(7) Support for local technological innovation, promoting the use of home-grown, high-tech medical devices in the healthcare industry.
(8) Transfer of knowledge and technology to the local industry, fostering the commercialization of the ES device and enabling its wider adoption in the healthcare market.

1.6 KEY CONTRIBUTIONS

The key contributions of this thesis lie in the development of a locally-produced ES device that matches or surpasses the performance of imported alternatives. By designing a device that complies with international medical standards and incorporating feedback from local physiotherapists, this work ensures that the device meets clinical and therapeutic needs. The thesis also contributes to reducing reliance on costly imported medical equipment by offering a cost-effective, high-quality solution for muscle rehabilitation, pain management, and physiotherapy.

Moreover, the device's integration into educational programs will enhance hands-on learning for physiotherapy students, providing them with access to modern,

locally-developed technology. This research promotes technological self-reliance by fostering the use of locally produced medical innovations, supporting the growth of the local healthcare and technology sectors. Additionally, the commercialization potential of the prototype paves the way for future mass production, benefitting the medical device industry and contributing to economic development.

1.7 THESIS ORGANIZATIONS

This thesis is structured into six main chapters as follows:

Chapter 1: Introduction outlines the background, significance, objectives, and scope of the research, along with the expected outcomes and contributions.

Chapter 2: Theoretical Framework reviews relevant literature on ES devices, clinical applications, technical parameters, and regulatory standards.

Chapter 3: Research Methodology describes the design and development of the ES device, covering system components such as the pulse generator, user interface, and safety measures.

Chapter 4: Experiments and Results presents the experimental results, including waveform tests, system accuracy, stability, and user interface performance.

Chapter 5: Discussion discusses the results, design limitations, challenges, and suggestions for future research.

Chapter 6: Conclusion summarizes the key findings, contributions, and potential for commercialization and further development.

CHAPTER 2

THEORETICAL FRAMEWORK

2.1 LITERATURE REVIEW

Electrical Stimulation (ES) is a therapeutic technique that involves the application of electrical impulses to stimulate nerves, muscles, or other tissues. ES devices have been widely used in modern clinical practice, particularly in physiotherapy and rehabilitation. Historically, the use of ES was primarily popularized within aging populations, where it was employed to address issues such as muscle atrophy, pain management, and mobility improvement [1]. However, in recent years, the application of ES has expanded far beyond its initial target demographic.

Today, the growing aging society is not the only group driving the increased demand for ES devices. The scope of ES applications has significantly broadened, reaching younger generations who face challenges such as muscle injuries, office syndrome, and other related conditions. With the modern lifestyle involving prolonged sitting and repetitive tasks, issues like neck and back pain have become prevalent even among younger individuals, prompting a rise in ES usage for both preventive and therapeutic purposes. Additionally, the versatility of ES in addressing various health concerns indicates its growing relevance in the foreseeable future, making it a valuable tool for enhancing the quality of life across diverse age groups.

This expanding interest and evolving demographic highlight the importance of developing adaptable, efficient, and user-friendly ES devices that cater to a broader spectrum of needs. This paper explores the current advancements in ES technology, examining its applications in both clinical and non-clinical settings, and discusses the trends shaping the future development of ES systems. ES technology has been extensively researched since 1791 and has since found widespread applications in various clinical treatments. Its use is particularly prominent in areas such as physiotherapy, pain relief, muscle strengthening, cardiac pacing, iontophoretic drug delivery, and functional electrical stimulation (FES) [1, 2]. The first commercially available ES device, introduced in 1969, facilitated motor function recovery for patients with motor nerve lesions [3]. Since then, ES technologies have undergone continuous development and refinement across multiple dimensions, leading to significant advancements in therapeutic applications [1-21].

ES devices typically employ a variety of waveforms, including square, rectangular, exponential, ramp, sinusoidal, triangular, and Gaussian. These waveforms are often referred to by specific technical names within the therapeutic field; for instance, rectangular waveforms are known as faradic waves, while sinusoidal waveforms are termed diadynamic waves, among others [22]. The therapeutic outcomes of ES are significantly influenced by adjustable parameters such as pulse amplitude, pulse duration, pulse frequency, polarity, and temporal patterns [23].

ES devices can be categorized based on several criteria. First, they can be classified by their mode of application: surface stimulators, which use electrodes placed on the skin, and implanted stimulators, where electrodes are embedded within the body [24]. Second, they can be categorized by the type of output waveform, which may be monophasic or biphasic. Biphasic waveforms are often preferred due to their ability to reduce charge accumulation in tissues and delay the onset of muscular fatigue [25]. Third, ES devices can be grouped based on their specific clinical applications. For example, Neuromuscular Electrical Stimulation (NMES) targets motor function, Functional Electrical Stimulation (FES) is frequently used in neurorehabilitation, Transcutaneous Electrical Nerve Stimulation (TENS) is designed for pain relief, and Threshold Electrical Stimulation (TES) is applied at the sensory threshold. Each category of ES device operates within specific parameter ranges—such as duration and frequency —tailored to optimize clinical outcomes [26]. The flexibility to generate diverse waveform patterns across a broad spectrum of durations and frequencies is crucial for ensuring the versatility and adaptability of ES devices in therapeutic applications.

The core components of most ES devices include the user interface (UI), the controller, the pulse generator, and the driving stage or output circuit [1, 3-7, 10, 12, 19, 21, 25]. The UI facilitates user interaction by converting user instructions into parameters for pattern synthesis. The controller manages system operations and communication, while the pulse generator creates voltage waveform patterns based on requests from the UI. The driving stage circuit amplifies these voltage waveforms, converting them into output currents that reach the desired levels, which are then delivered to the target tissues.

One of the key challenges in designing ES devices lies in generating highly nonlinear signals, which often require combinations of various basic waveforms—both continuous and non-continuous, as well as periodic and non-periodic—to achieve diverse stimulation patterns. Early analog pulse generators, though functional, offered

limited flexibility due to fixed parameters and restricted waveform options [1]. The introduction of digital microcontrollers (MCUs) marked a significant advancement by enabling the programmable generation of arbitrary waveforms, providing physiotherapists and clinicians with greater control over the differentiation of ES current patterns and sequences [24]. However, generating precise and diverse signals with MCUs, particularly in multi-channel or multi-functional ES devices, remains a challenge due to memory constraints and real-time processing limitations. In this context, traditional methods relying on Look Up Tables (LUTs) to store pre-programmed patterns have proven inadequate for devices requiring extensive functionality and flexibility [2, 7].

To overcome these limitations, various techniques have been proposed, such as the element-envelope method [1] and the direct digital synthesizer technique [4]. This research explores a real-time synthesizing approach that eliminates the need for LUTs by implementing data transmission and real-time control through the MCU input/output ports. This approach builds upon similar strategies described by [5] but introduces different signal generating algorithms, significantly higher resolution, and faster MCU processing speeds. By doing so, this real-time synthesis technique enables the efficient generation of high-resolution signals with minimal distortion, addressing the key challenges of a typical multi-functional ES device design.

Converting digital signals into analog form is another critical challenge, traditionally addressed using Digital-to-Analog Converters (DACs). DACs are commonly employed alongside any MCU to generate the necessary voltage output signals. Numerous studies have documented the use of DACs, with a preference for integrated circuit DACs (DAC chips) due to their compact packaging and ease of use [1, 4, 5, 10, 12, 21]. However, typical DAC chips have limitations in output range, customization, and speed—factors essential for generating the highly nonlinear signals required by modern ES devices. Additionally, DAC chips are prone to electromagnetic interference (EMI) and availability issues. Previous studies have reported significant signal degradation when using 12-bit DAC chips for ES applications [27, 28]. To overcome these challenges, this study proposes the use of a discrete R-2R ladder DAC circuit, which offers higher slew rates, customizable resolution, and faster operation compared to conventional DAC chips. The proposed circuit achieves a slew rate of approximately 350 V/μs, a substantial improvement over the typical 0.5-50 V/μs offered by most DAC chips. This capability enables the generation of high-frequency signals with minimal

latency, making it suitable for the precise and complex requirements of ES outputs in a broad range of therapeutic applications.

The driving stage circuit is a critical component in typical ES devices, responsible for delivering the desired output currents to target tissues. Among the various design approaches, constant current circuits are often preferred due to their ability to maintain consistent stimulation despite variations in tissue impedance [25]. Numerous designs for driving circuits in ES systems have been proposed: Cheng et al. [2] and Velloso et al. [3] developed constant current circuits using step-up transformers with operational amplifiers (Op-Amp), while Chen et al. [13] proposed a constant voltage circuit utilizing a step-up transformer with a PWM controller and voltage limiter. Wu et al. [1], Yochun et al. [8], Khosravani et al. [9] and Wang et al. [14] focused on constant current circuits based on Wilson current mirrors with Holland structure amplifiers. Additionally, Qu et al. [10] proposed a constant current circuit using an H-bridge with a voltage-controlled current source (VCCS), while Mardar et al. [11] presented a constant current circuit employing symmetric DC sources with Op-Amps. Wang et al. [18] explored a constant current circuit using a high-power field effect transistor (FET) with Op-Amps, and Alam [19] proposed a constant voltage circuit with an H-bridge driver module combined with a DC-DC boost converter.

The H-bridge circuit has gained widespread adoption, not only for its ability to generate biphasic currents but also for its scalability in multi-channel applications. Consequently, the H-bridge configuration has become the preferred method for generating biphasic currents due to its operational efficiency and enhanced flexibility [25]. The proposed design incorporates a constant current driving stage circuit that includes an H-bridge network and VCCS with feedback control. This configuration ensures stable output currents and consistent waveform patterns across various therapeutic applications, even when confronted with the diverse human load conditions.

Recent trends in ES device research emphasize miniaturization, cost-effectiveness, low power consumption, and personalization tailored to specific muscle conditions or intended uses. The increasing use of off-the-shelf components aligns with these trends. For example, Ward et al. [16] developed a compact and low-cost ES device using readily available components, while Das et al. [20] focused on reducing power consumption and area with an MCU less design. Similarly, Alam [19] constructed ES prototypes from ac-cessible components, and Slepyan et al. [21] developed a compact, low power FES device using similar readily available parts. However, these

developments, while beneficial, are not sufficient to address the specific challenges faced in certain regions, such as Thailand.

In many local areas of Thailand, there remains a critical shortage of medical equipment, especially in therapeutic and rehabilitation sectors. Much of the advanced technology must be imported, leading to high costs and limited accessibility, particularly for smaller hospitals and clinics with limited budgets. Additionally, the domestic healthcare sector still heavily relies on imported technology, leading to a scarcity of locally developed and innovative medical devices. Current trends in ES devices, which focus on niche and specialized applications, fail to offer the versatile and comprehensive solutions needed in such settings. There is a clear demand for a device that can address a wide range of operations and treatments while being adaptable to diverse therapeutic needs.

To address these gaps, this research focuses on the design and implementation of a multi-functional ES device capable of delivering various outputs across a broad spectrum of therapeutic applications. Our goal is to develop an adaptable and cost-effective electrical stimulator device using in-house technology, making it more accessible to local healthcare providers and hospitals. By leveraging local expertise and resources, we aim to reduce reliance on costly imported equipment. Furthermore, this development aligns with our objective of securing patents and obtaining Thailand Innovation License certifications, promoting the advancement of local medical technology and contributing to the future of healthcare in the region.

2.2 ELECTRICAL STIMULATION OVERVIEW

Electrical Stimulation (ES) is a broad therapeutic technique that leverages controlled electrical impulses to stimulate nerves or muscles for various medical and rehabilitative purposes. ES is commonly employed in physical therapy, rehabilitation, and pain management. The technique involves multiple physiological mechanisms, depending on the specific system used, the parameters of electrical current, and the therapeutic goals.

The human nervous system uses electrical impulses to communicate between the brain, spinal cord, and muscles. ES replicates these signals using external electrical devices. By applying electrical currents through electrodes, ES can either stimulate motor nerves, causing muscles to contract, or sensory nerves, modulating the sensation of pain. ES relies on key parameters—such as amplitude, frequency, and waveform—to produce specific therapeutic effects [22].

2.2.1 Classification of Electrical Stimulations [22, 26, 29]

ES is widely used in both clinical and therapeutic settings for a variety of purposes, ranging from pain management to muscle rehabilitation. Different modalities of ES target either motor or sensory nerves, each tailored to address specific clinical conditions. These modalities use various types of electrical currents, pulse patterns, and frequencies to achieve distinct therapeutic effects. The effectiveness of ES lies in its ability to enhance natural physiological processes, aid in recovery, and alleviate discomfort.

This section classifies and explains the various types of electrical stimulation commonly used in clinical practice, along with their applications and therapeutic benefits. Each modality plays a unique role in addressing conditions such as chronic pain, muscle atrophy, and impaired motor function, providing targeted solutions for both acute and long-term care.

2.2.1.1 Transcutaneous Electrical Nerve Stimulation (TENS)

TENS delivers low-voltage electrical currents to sensory nerves through the skin to reduce pain. It is based on the Gate Control Theory of Pain, where the stimulation of sensory pathways can block or reduce pain signals. TENS can also increase endorphin production for long-term pain relief. Common applications include chronic back pain, osteoarthritis, and post-surgical pain management.

2.2.1.2 Neuromuscular Electrical Stimulation (NMES)

NMES is designed to target motor nerves and induce muscle contractions. This is especially useful in physical rehabilitation for patients with weakened muscles due to injury, surgery, or immobility. By mimicking natural muscle contractions, NMES helps to maintain muscle strength, prevent atrophy, and enhance blood circulation. It is widely used in post-operative care, sports rehabilitation, and to assist in regaining voluntary muscle control.

2.2.1.3 Functional Electrical Stimulation (FES)

FES aims to restore functional movement in patients with neurological conditions, such as stroke or spinal cord injury. It stimulates motor nerves in a coordinated manner to help patients perform actions like walking or grasping objects. FES is often part of neurorehabilitation programs to retrain neural pathways.

2.2.1.4 Interferential Therapy (IFT)

IFT uses two intersecting medium-frequency currents to produce therapeutic effects deep within the tissues. This technique is primarily used for pain relief, muscle relaxation, and reducing inflammation. Unlike TENS, IFT targets deeper tissues, making it useful for muscle pain and post-surgical recovery.

2.2.1.5 Russian Stimulation

This method involves high-frequency currents delivered in short bursts to induce strong muscle contractions. Initially developed for athletes, it is now used in rehabilitation to increase muscle strength and endurance.

2.2.1.6 Iontophoresis

In this modality, electrical currents are used to drive medication through the skin and into the underlying tissues. Iontophoresis is commonly applied for localized treatment of inflammation, pain, or swelling.

2.2.1.7 High-Voltage Pulsed Current (HVPC)

HVPC is used in tissue healing and wound care. The high-voltage, short-duration pulses help promote tissue repair by enhancing blood flow, stimulating the migration of healing cells, and reducing edema. It is frequently employed in the treatment of chronic wounds, such as diabetic ulcers or pressure sores.

2.2.2 General Electrical Stimulation Applications [22, 26, 29]

Electrical stimulation (ES) has become a versatile therapeutic tool in modern healthcare, with widespread applications across various medical disciplines. It plays a crucial role in both acute and long-term treatment strategies, offering a non-invasive, drug-free alternative for a range of conditions. The therapeutic benefits of ES extend beyond simple muscle stimulation, encompassing pain relief, functional restoration, and wound healing.

This section explores the broad applications of ES in clinical practice, highlighting its effectiveness in physical rehabilitation, pain management, sports medicine, neurological recovery, and wound care. Each application leverages different ES modalities to address specific health challenges, demonstrating the flexibility and impact of ES in promoting recovery and improving patient

2.2.2.1 Physical Rehabilitation

ES is widely applied in physical therapy to aid muscle recovery, particularly in patients recovering from surgery, injury, or neurological conditions. It helps in rebuilding muscle strength, maintaining muscle tone, and restoring voluntary muscle control.

2.2.2.2 Pain Management

TENS and IFT are effective in managing both acute and chronic pain conditions, offering non-invasive alternatives to medications for conditions such as back pain and neuropathic pain.

2.2.2.3 Sports Medicine

NMES and Russian stimulation are frequently used in sports training and rehabilitation to increase muscle strength, endurance, and recovery time.

2.2.2.4 Neurological Rehabilitation

FES plays a role in rehabilitating patients with spinal cord injuries, strokes, or multiple sclerosis, helping restore functional movement and improving quality of life.

2.2.2.5 Wound Care

Electrical stimulation, particularly HVPC, is used in chronic wound care to promote healing and tissue regeneration, making it a valuable tool for treating diabetic ulcers, pressure sores, and other non-healing wounds.

2.2.3 Typical Categories of ES Devices [22, 26, 29]

ES devices come in a variety of forms, each tailored to meet specific medical and therapeutic needs. These devices can be categorized based on several factors, including the mode of application, type of output waveform, and their clinical uses. However, one of the most common ways to classify ES devices is by their design, portability, and the environment in which they are intended to be used.

In both commercial design and medical practice, ES devices are typically divided into three main categories: stationary, portable, and wearable. Each type offers distinct advantages for both clinicians and patients, allowing for flexibility in treatment settings ranging from hospitals to home care. The following sections will provide a detailed exploration of these device categories and their respective roles in therapeutic applications.

2.2.3.1 Stationary ES Devices

Stationary ES devices are typically larger, more powerful units designed for clinical and therapeutic environments. They are capable of delivering multiple modes of electrical stimulation and are often used for more comprehensive treatments that require a higher degree of control and customization. Figure 2.1 show an example of stationary ES device.

Figure 2.1 An example of stationay ES device *[https://www.enraf-nonius.com/]*

- **Characteristics:**
  - Larger, designed for clinical use.
  - Typically feature multiple channels for simultaneous stimulation of different areas.
  - Provide a wide range of adjustable parameters.
  - Often combined with other therapeutic modalities like ultrasound.

- **Examples**:
    - **Chattanooga Intelect® Legend XT**: A multi-modality unit used for pain relief, muscle strengthening, and rehabilitation. It features various therapy modes and is a staple in physiotherapy clinics.
    - **Comprehensive Rehabilitation Systems**: Integrated systems found in hospitals that offer advanced therapeutic functions for neuromuscular reeducation and chronic pain management.
- **Applications**:
    - Used in physiotherapy clinics, hospitals, and rehabilitation centers.
    - Ideal for long-term, in-depth therapy sessions under clinical supervision.

2.2.3.2 Portable ES Devices

Portable ES devices are smaller, battery-powered units that are easy to transport and use in various settings. These devices are designed for home use or by individuals needing therapy outside of clinical environments. While less powerful than stationary devices, they still provide effective pain relief, muscle strengthening, and rehabilitation. Figure 2.2 show an example of portable ES device.

Figure 2.2 An example of portable ES device *[https://www.compex.com/en/]*

- **Characteristics**:
    - Lightweight, compact, and battery-operated.
    - User-friendly interfaces for self-administration of therapy.
    - Lower intensity settings compared to stationary devices but still capable of delivering a range of therapeutic functions.

- **Examples**:
    - **Compex® Sport Elite 3.0**: A portable NMES device used by athletes and patients for muscle strengthening and recovery, particularly after physical activities or injuries.
    -
    - **Empi® Continuum®**: A compact unit offering both TENS and NMES, used for pain relief and muscle rehabilitation in a home setting.
- **Applications**:
    - Designed for home care, sports rehabilitation, and short-term therapy.
    - Suitable for patients recovering from surgery, athletes seeking muscle recovery, or individuals managing chronic pain.

2.2.3.3 Wearable ES Devices

Wearable ES devices represent the latest evolution in electrical stimulation technology. These devices are designed to be worn directly on the body, allowing for continuous stimulation during daily activities. Wearable devices are typically used for specific conditions, such as foot drop or gait training in patients with neurological impairments. Figure 2.3 shows an example of wearable device.

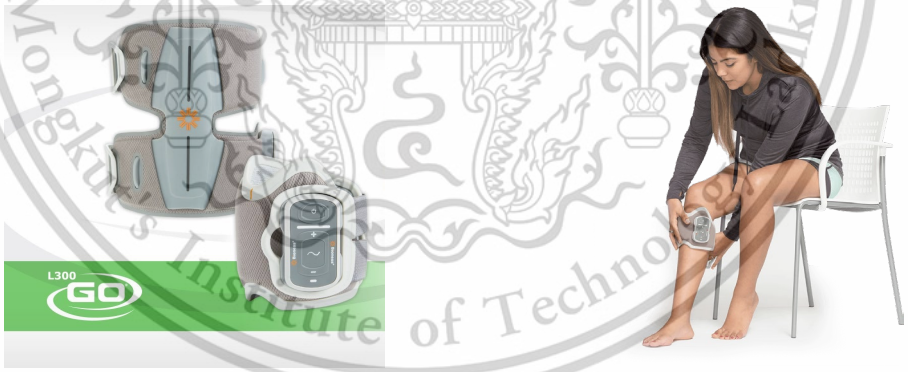


Figure 2.3 An example of wearable ES device *[https://www.l300go.com/]*

- **Characteristics**:
    - Compact, ergonomic design for easy wearing on the body.
    - Wireless operation, often controlled via smartphone apps.
    - Specifically targeted to particular areas of the body for continuous therapy during movement.
    - Adjustable settings for personalized during functional treatment.

- **Examples**:
    - **Bioness® L300 Go**: A wearable FES device designed to improve mobility in patients with foot drop, providing functional stimulation to aid walking.
    - **PowerDot® 2.0**: A wearable NMES device targeting muscle recovery and pain management. It can be worn during workouts or recovery periods and is controlled through a mobile app.
- **Applications**:
    - Ideal for neurorehabilitation, especially for conditions like stroke, multiple sclerosis, or spinal cord injuries.
    - Used in functional therapy to restore natural movements like walking or grasping.
    - Convenient for users requiring therapy during daily activities.

Summary of ES device types is shown in Table 2.1. Each type is suited to specific patient needs and clinical goals. By categorizing devices into stationary, portable, and wearable types, clinicians and patients can select the best device for effective treatment based on the therapy location, mobility requirements, and specific medical condition.

Table 2.1 Summary of ES device types

Type	Typical Use	Environment	Examples
Stationary	Comprehensive clinical treatments	Hospitals, clinics	Chattanooga Intelect® Legend XT
Portable	Home-based therapy, rehabilitation	Home, Sports recovery	Compex® SportElite 3.0, Empi® Continuum®
Wearable	Continuous stimulation during activities	Functional rehabilitation, daily use	Bioness® L300 Go, PowerDot® 2.0

This section provides a clear breakdown of the various types of ES devices and their respective roles in both clinical and at-home settings. The proposed ES device in this work falls under the stationary type category. It is primarily designed for use in hospitals or clinics, where its advanced functionalities can be fully utilized in controlled, professional environments.

2.2.4 Implantable Stimulators vs. Surface Stimulators [22, 26, 29]

In addition to classifying Electrical Stimulation (ES) devices based on their portability (stationary, portable, and wearable), ES systems can also be categorized based on the method of delivering electrical currents to the body: implantable stimulators and surface (transcutaneous) stimulators. Each method offers distinct advantages and is suited to specific clinical applications.

2.2.4.1 Surface Stimulators (Transcutaneous Electrical Stimulators)

Surface stimulators are non-invasive devices that apply electrical current to the body via electrodes placed on the skin. This category includes most commercial ES devices used in clinics and at home for rehabilitation, pain management, and muscle training. Surface stimulators are widely used because of their convenience, ease of use, and non-invasive nature.

- **Characteristics**:
  - **Non-invasive**: Electrical current is delivered through adhesive electrodes applied to the skin's surface, targeting underlying muscles and nerves.
  - **Adjustable**: Surface stimulators allow users or clinicians to adjust parameters such as intensity, frequency, and pulse width to suit the therapeutic goals.
  - **Limited Penetration**: Surface stimulators can effectively target superficial muscles or nerves but may have limited effectiveness in reaching deeper tissues due to skin resistance.
- **Advantages**:
  - **Ease of use**: Surface stimulators are simple to set up and can be used in various settings, including clinics, homes, and sports environments.
  - **Safety**: Being non-invasive, surface stimulators carry fewer risks, making them suitable for a wide range of patients, including those with acute or chronic conditions.
  - **Cost-effective**: Compared to implantable systems, surface stimulators are less expensive and more accessible.
- **Disadvantages**:
  - **Limited depth**: The ability of surface stimulators to reach deep nerves and muscles is constrained by skin and tissue resistance.

- **Electrode placement**: Proper placement of electrodes is critical for the effectiveness of the therapy, and incorrect positioning may lead to suboptimal results.

- **Examples**:
  - **TENS**: Commonly used for pain relief, TENS devices deliver low-voltage electrical currents through electrodes placed on the skin.
  - **NMES**: NMES systems like the **Compex® Sport Elite 3.0** apply electrical impulses to stimulate muscles for rehabilitation and strengthening.
- **Applications**:
  - **Pain management**: TENS devices are widely used for treating chronic pain conditions, such as arthritis, back pain, and post-surgical recovery.
  - **Muscle rehabilitation**: NMES systems are used in physical therapy to promote muscle contraction and prevent atrophy in patients recovering from surgery or injury.

2.2.4.2 Implantable Stimulators

Implantable electrical stimulators involve surgical implantation of electrodes and pulse generators directly into the body to deliver electrical currents to specific nerves or muscles. These systems are used in cases where surface stimulators are insufficient, particularly for deeper muscle or nerve stimulation, or for long-term management of chronic conditions.

- **Characteristics**:
  - **Invasive**: Implantable stimulators require surgical procedures to place electrodes near or on the target nerves or muscles, as well as to implant the pulse generator (often under the skin).
  - **Direct stimulation**: Because the electrodes are implanted close to the nerve or muscle, implantable stimulators bypass the resistance posed by skin and tissues, providing more precise and effective stimulation.
  - **Programmability**: These devices can be fine-tuned remotely by healthcare providers, allowing for ongoing adjustments without the need for additional surgery.
- **Advantages**:
  - **Targeted therapy**: Implantable stimulators are highly effective for targeting specific muscles or nerves, particularly those that are deep within the body and unreachable by surface stimulators.

    - **Long-term solutions**: Implantable systems provide continuous, long-term therapy, making them ideal for chronic conditions.
    - **Lower maintenance**: Once implanted, the devices typically require less frequent maintenance or adjustment compared to surface stimulators, apart from routine check-ups.
- **Disadvantages**:
    - **Surgical risk**: The implantation process carries inherent risks associated with any surgery, such as infection, device migration, or complications during implantation.
    - **Cost**: Implantable stimulators are significantly more expensive due to the surgery and follow-up care involved.
    - **Invasiveness**: Patients must undergo surgery and may face discomfort or complications related to the implanted device.
- **Examples**:
    - **Deep Brain Stimulators (DBS)**: DBS systems are used to treat neurological conditions such as Parkinson's disease by stimulating specific brain regions.
    - **Spinal Cord Stimulators**: These devices are implanted near the spinal cord to manage chronic pain, particularly in cases where other treatments have failed.
    - **Implantable NMES Systems**: These are used for long-term muscle stimulation in patients with spinal cord injuries or other conditions that result in severe muscle weakness.
- **Applications**:
    - **Neurological Disorders**: Implantable devices, such as **Deep Brain Stimulators**, are used to manage tremors and motor dysfunction in conditions like Parkinson's disease and dystonia.
    - **Chronic Pain**: **Spinal Cord Stimulators** are used to reduce chronic pain by disrupting pain signals before they reach the brain.
    - **Functional Neuromuscular Stimulation (FNS)**: Implantable NMES devices are employed in individuals with spinal cord injuries to restore functional movements, such as walking or gripping.

2.2.4.3 Comparison of Implantable and Surface Stimulators

Table 2.2 summarizes the comparison of Implantable and surface stimulators. The choice depends largely on the therapeutic needs of the patient. Surface stimulators are non-invasive, easily accessible, and effective for a wide range of conditions, particularly for pain management and muscle rehabilitation. However, for patients requiring deep tissue stimulation or continuous, long-term therapy, implantable stimulators offer a more targeted and durable solution, though at the cost of greater invasiveness and higher expense. This distinction is crucial in clinical decision-making, as it allows healthcare providers to match the most appropriate device type with the specific needs and conditions of the patient.

Table 2.2 Comparison of implantable and surface stimulators

Aspect	Surface Stimulators	Implantable Stimulators
Invasiveness	Non-invasive	Invasive (requires surgery)
Target	Superficial nerves and muscles	Deeper nerves, muscles, or brain regions
Ease of Use	Simple, user-friendly	Requires surgical implantation and follow-up
Cost	Generally affordable	High due to surgery and long-term care
Adjustability	Easily adjustable by the user or clinician	Programmable by healthcare provider
Risks	Low risk	Surgical risks, such as infection or migration
Therapeutic Scope	Effective for many conditions, but limited for deep targets	High precision for chronic conditions or deep tissue

This section compares the two approaches to electrical stimulation—surface and implantable—highlighting their respective applications, advantages, and limitations. The proposed ES device in this work is a surface stimulator, designed for non-invasive treatment, making it suitable for a wide range of therapeutic applications in clinical settings.

2.2.5 Examples of Commercial ES Devices

To better understand how electrical stimulation device's function, it is useful to look at some commercially available ES systems that are widely used in clinical, rehabilitative, and personal therapy settings. These devices vary in their design and application but are built around similar principles of delivering controlled electrical currents for therapeutic purposes.

1. **Chattanooga Intelect® Legend XT**:
    - **Type**: This multi-modality therapy system combines TENS, NMES, and IFT, making it suitable for both pain relief and muscle rehabilitation.
    - **Features**: The device allows for customized waveform selection, adjustable parameters, and multiple channels for simultaneous stimulation. It is used widely in physiotherapy clinics for treating musculoskeletal pain, improving muscle function, and promoting recovery from injury.
    - **Applications**: Pain management, muscle re-education, and post-injury recovery.
2. **Compex® Sport Elite 3.0**:
    - **Type**: A portable NMES device designed for athletes to improve muscle strength and recovery.
    - **Features**: It offers multiple stimulation programs, including strength, endurance, and recovery modes, targeting specific muscle groups. The device is favored for its portability, making it convenient for at-home or on-the-go rehabilitation.
    - **Applications**: Muscle strengthening, recovery from training, injury prevention, and rehabilitation.
3. **Empi® Continuum®**:
    - **Type**: A combined NMES and TENS device used for both pain management and muscle stimulation.
    - **Features**: Empi Continuum offers pre-set programs that cater to various therapeutic needs, such as muscle rehabilitation and pain relief, making it versatile for both clinical and at-home use. The user-friendly interface and compact design have made it a popular choice in the home care market.
    - **Applications**: Pain management for chronic conditions, post-surgical muscle stimulation, and muscle strengthening.

4. **Zynex NexWave®**:
    - **Type**: A three-in-one electrotherapy device offering TENS, NMES, and IFC (Interferential Current) functionalities.
    - **Features**: NexWave is designed for pain relief, muscle stimulation, and recovery, particularly for chronic pain sufferers. Its flexibility allows for the adjustment of intensity, frequency, and waveform depending on the specific therapy needed.
    - **Applications**: Chronic pain management, muscle atrophy prevention, and post-injury rehabilitation.
5. **Bioness® L300 Go**:
    - **Type**: A Functional Electrical Stimulation (FES) system designed to improve mobility for individuals with foot drop resulting from neurological conditions.
    - **Features**: The L300 Go system uses wireless FES technology to stimulate the muscles in the lower leg, helping patients walk more naturally. The device is often used in neurorehabilitation for patients recovering from stroke, multiple sclerosis, or spinal cord injury.
    - **Applications**: Neurological rehabilitation, functional movement recovery, and gait training.

These devices are designed to meet the varying needs of patients, from general pain relief to specialized neuromuscular rehabilitation. Each device demonstrates the versatility and widespread application of ES technology in both clinical and home environments. Understanding the capabilities of these commercial systems provides context for the technical and therapeutic discussions that follow.

2.2.6 Waveform Characteristics and Applications in ES Devices [22, 29-31]

The effectiveness of ES devices depends largely on the waveform characteristics of the electrical current or voltage applied to human tissues. Different waveforms elicit distinct physiological responses from muscles and nerves, and are selected based on specific therapeutic objectives such as pain management, muscle stimulation, or rehabilitation. The following sections explore various waveform types, highlighting their characteristics and applications in clinical settings.

2.2.6.1 Monophasic Waveforms

Monophasic waveforms involve a single phase of current that flows in one direction, either positive or negative, throughout the pulse duration. These waveforms are commonly used in applications such as tissue healing, regeneration, and pain management due to their effectiveness in stimulating specific physiological responses. Monophasic currents typically consist of short-duration pulses, which reduce the risk of tissue irritation, especially when used at low frequencies. The example waveform shape can be seen in Figure 2.4.

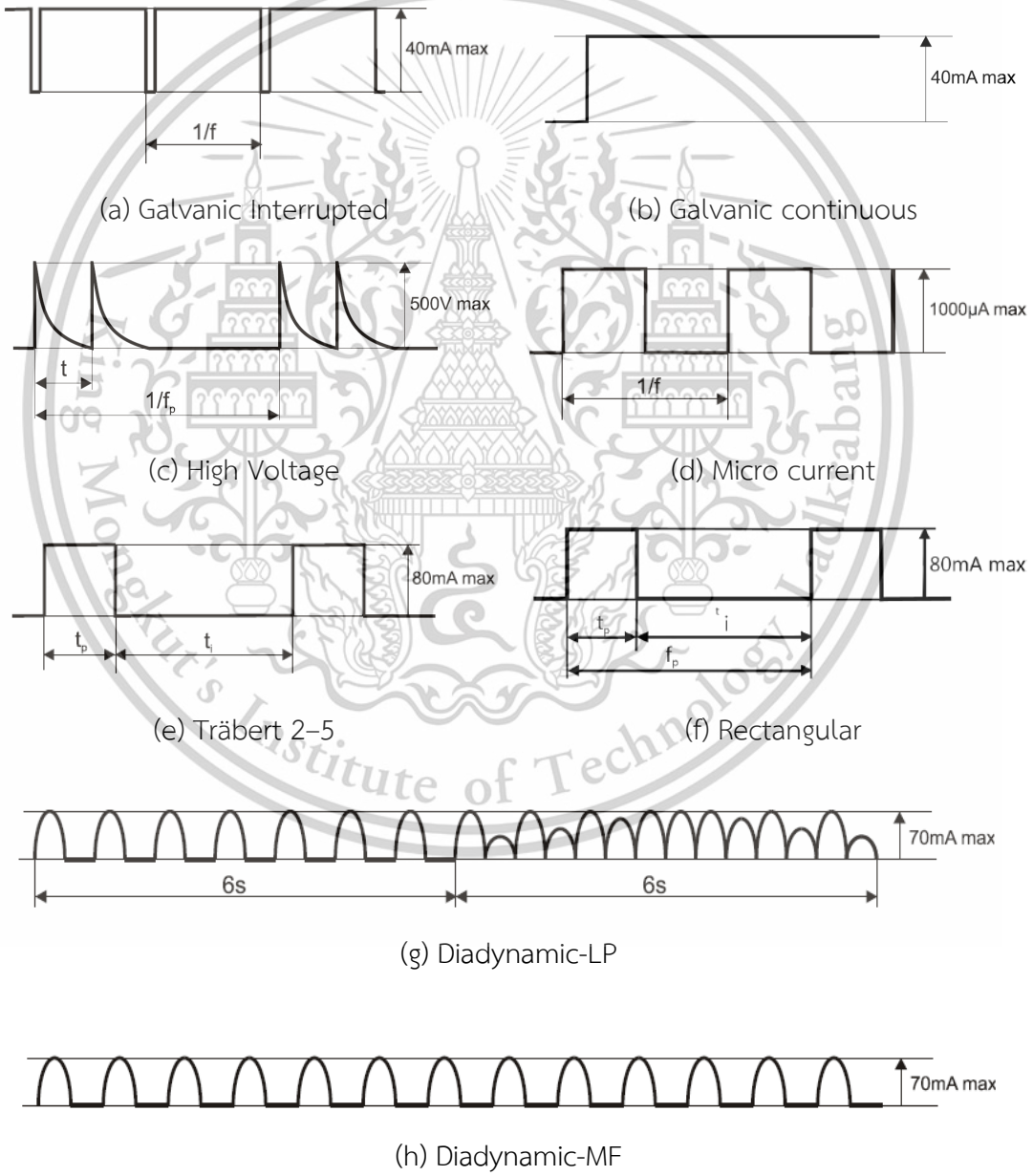


Figure 2.4 Examples of monophasic waveform [31]

2.2.6.2 Biphasic Waveforms

Biphasic waveforms consist of two phases—positive and negative—where the current flows in one direction and then reverses during each pulse. These waveforms are versatile and widely used in muscle stimulation and pain relief therapies. By alternating the current between phases, biphasic waveforms reduce the buildup of charge, minimizing the risk of skin irritation. Depending on the therapeutic goal, the waveform can be symmetrical, with equal amplitude and duration for both phases, or asymmetrical, where the two phases differ. The example waveform shape is illustrated in Figure 2.5.

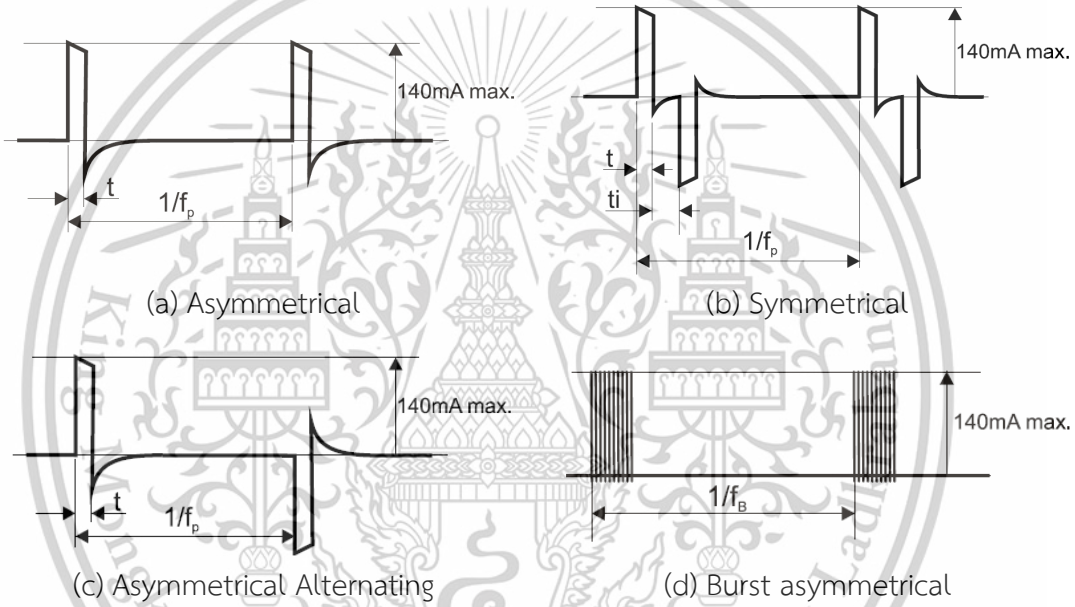
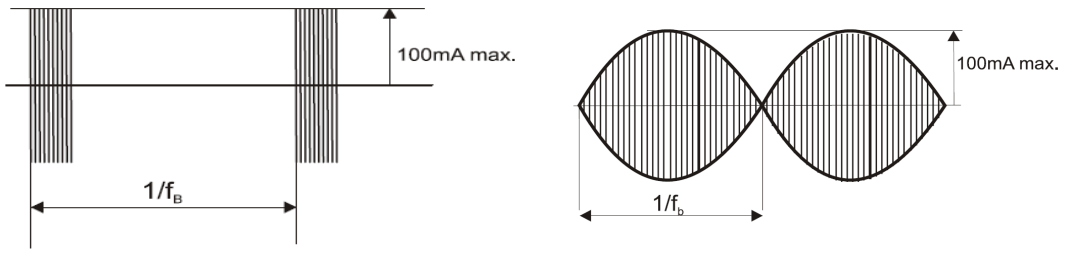


Figure 2.5 Examples of biphasic waveform [31]

2.2.6.3 Polyphasic Waveforms

Polyphasic waveforms contain multiple phases within a single pulse, offering a more complex structure that is typically used in advanced therapies requiring precise control over stimulation. These waveforms can deliver bursts of high-frequency pulses, making them especially effective for deep tissue stimulation. Their ability to target large muscle groups or areas needing intense stimulation makes polyphasic waveforms highly suitable for therapeutic applications demanding deeper penetration and higher efficacy. The example waveform shape is shown in Figure 2.6.

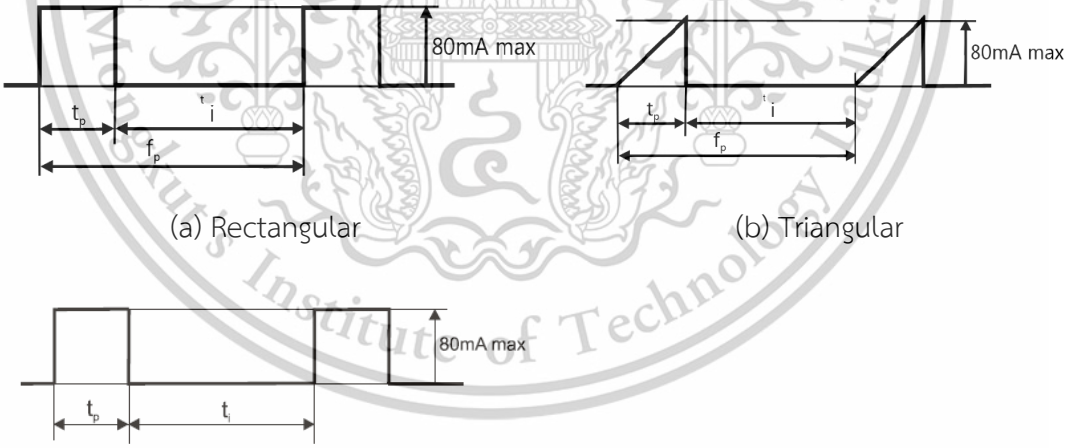


(a) Russian (b) Premodulated

Figure 2.6 Examples of polyphasic waveform [31]

2.2.6.4 Pulsed Waveforms

Pulsed waveforms are made up of discrete pulses that are separated by intervals with no current, allowing for periods of rest between stimulations. This type of waveform is particularly beneficial in longer therapy sessions, as it helps prevent muscle fatigue. Pulsed waveforms can be either monophasic or biphasic and are frequently used in neuromuscular rehabilitation and pain management. The intermittent nature of the pulses makes them suitable for both short-term and long-term therapy, reducing the risk of fatigue compared to continuous waveforms. The example waveform shape is illustrated in Figure 2.7.



(a) Rectangular (b) Triangular

(c) Träbert 2–5

Figure 2.7 Examples of pulsed waveform [31]

2.2.6.5 Burst Waveforms

Burst waveforms consist of a series of pulses delivered rapidly in succession, followed by a pause. These waveforms are particularly effective in generating strong muscle contractions while minimizing discomfort, making them ideal for both

rehabilitation and performance training. The short bursts of high-frequency pulses allow for intense stimulation, while the pauses reduce the strain on muscles. Burst waveforms are often combined with other waveforms to enhance therapeutic results. The example waveform shape is shown in Figure 2.8.

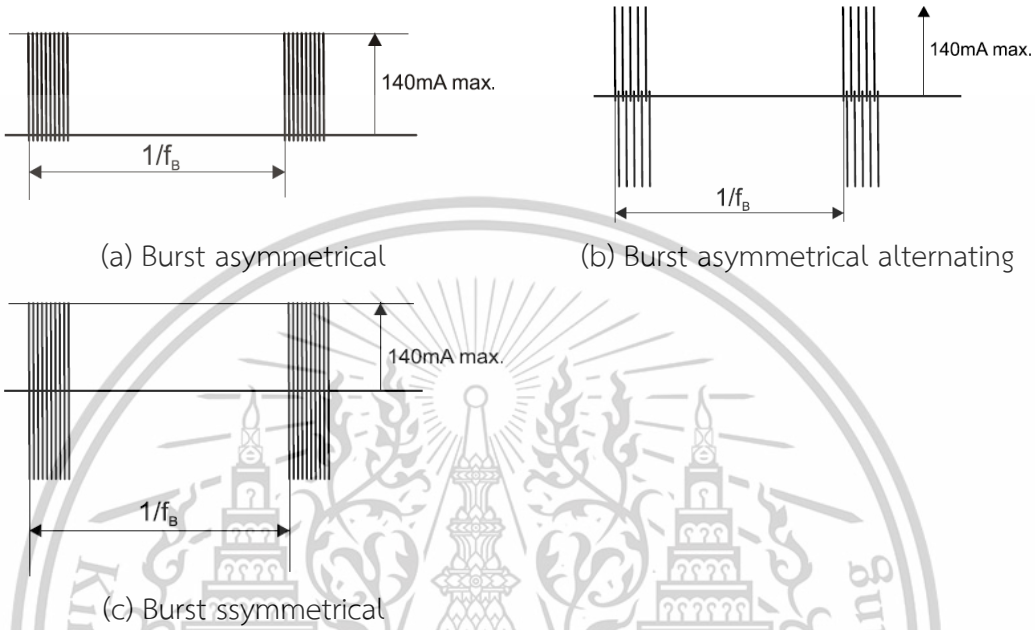


Figure 2.8 Examples of burst waveform [31]

2.2.7 Technical ES Parameters [22, 29-32]

The effectiveness of Electrical Stimulation (ES) devices is influenced by both the waveform and a range of technical parameters. Key factors such as amplitude, frequency, pulse duration, and duty cycle play crucial roles in determining the physiological response and the overall therapeutic outcome. A deep understanding of these parameters is essential for optimizing treatments in various clinical applications.

While waveform selection is vital, the precise adjustment of technical parameters—amplitude, frequency, pulse duration, and duty cycle—is equally important in achieving the desired therapeutic effect. By fine-tuning these elements alongside the waveform, ES devices can deliver highly targeted and effective therapies.

2.2.7.1 Amplitude

Amplitude, often measured in milliamps (mA), defines the strength or intensity of the electrical current applied during stimulation. It directly influences how deeply the current penetrates tissue and the magnitude of the physiological response elicited. For a visual reference of amplitude variations, see Figure 2.9.

- **Higher Amplitude**: Utilized for deeper tissue stimulation or to induce stronger muscle contractions. This setting is essential in NMES where effective muscle contractions are necessary for rehabilitation.
- **Lower Amplitude**: Suitable for targeting superficial tissues, often used in TENS for pain relief, minimizing discomfort to the patient.

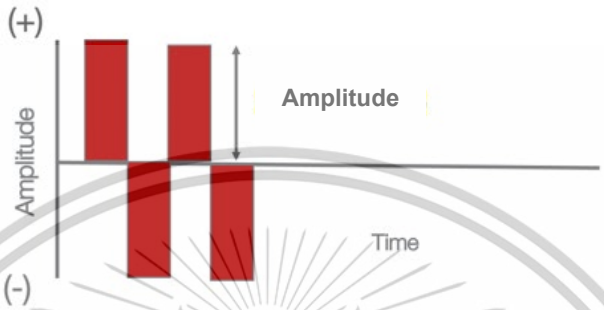


Figure 2.9 Illustration of amplitude in an ES Device [32]

Impact on Therapeutic Outcomes:

- **Higher amplitudes** are critical in therapies requiring strong muscle engagements, such as rehabilitation from severe muscle atrophy or injury, where profound and effective contractions are needed.
- **Lower amplitudes** are beneficial for managing pain without causing undue stress or discomfort to the patient, making them ideal for prolonged use in chronic pain management.

The selection of amplitude is a crucial consideration in electrical stimulation therapy, directly affecting the comfort level and effectiveness of treatment. By adjusting the amplitude, therapists can fine-tune the therapy to achieve desired therapeutic goals ensuring treatments are both beneficial and tolerable for the patient.

2.2.7.2 Pulse Repetitive Frequency

Pulse Repetitive Frequency (PRF), commonly referred to as Frequency or Pulse Rate, is measured in Hertz (Hz) or pulses per second (pps). It specifies the number of electrical pulses delivered per second and is a crucial parameter in designing therapeutic protocols. Different frequencies are known to elicit varying physiological responses, thus playing a pivotal role in the effectiveness of electrical stimulation therapy. For an illustrative example of how frequency affects electrical pulses in an ES device, refer to Figure 2.10.

- **Low Frequency (1-10 Hz)**: This range is typically used for managing chronic pain and enhancing endorphin release, making it ideal for long-term pain control applications.
- **Medium Frequency (20-50 Hz)**: Frequencies in this range are commonly used to stimulate muscle contractions without inducing rapid fatigue. This is particularly beneficial in physical rehabilitation settings where gradual muscle strengthening is required.
- **High Frequency (80-120 Hz)**: High frequencies are frequently employed in acute pain relief applications, such as with Transcutaneous Electrical Nerve Stimulation (TENS). Rapid pulse rates in this range help in reducing the perception of pain.

Figure 2.10 Illustration of frequency in an ES Device [32]

Impact on Therapeutic Outcomes:

- **Low frequencies** are preferred for continuous pain management over extended periods due to their ability to stimulate endorphin release and manage persistent pain symptoms.
- **Medium frequencies** effectively support muscle recovery and strengthening as they balance between inducing muscle contractions and preventing fatigue.
- **High frequencies** are optimal for immediate pain relief scenarios, leveraging fast pulse rates to block pain signals effectively.

By understanding and applying the correct PRF, therapists can tailor treatments to meet specific patient needs, enhancing both the efficiency and comfort of electrical stimulation therapies. This strategic application of varied frequencies ensures that treatments are not only effective but also aligned with the specific recovery or pain management goals of each patient.

2.2.7.3 Pulse Duration

Pulse Duration, or pulse width, determines the duration of each electrical pulse delivered during therapy, typically measured in microseconds (μs) or milliseconds (ms). It is a critical parameter because it affects how much of the muscle mass is activated during the stimulation. A visual reference of pulse duration variations, see Figure 2.11.

- **Short Pulse (50-200 μs)**: Primarily used for sensory nerve stimulation in TENS therapies aimed at pain relief. These shorter pulses focus on modulating pain signals without significant muscle contraction.
- **Long Pulse (200-400 μs or more)**: Employed in NMES settings to achieve deeper and more forceful muscle contractions. This range is optimal for engaging more motor units, which is crucial for muscle re-education and recovery in physical rehabilitation.

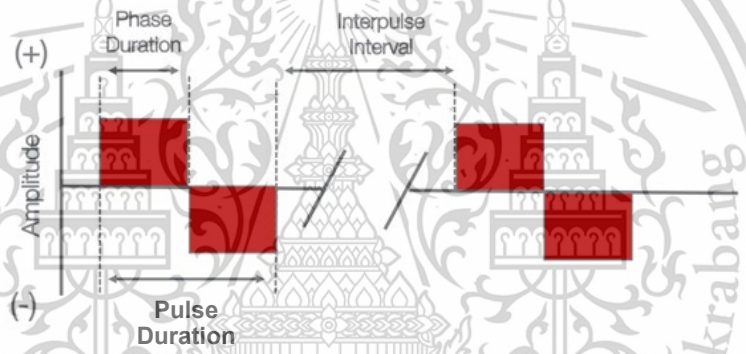


Figure 2.11 Illustration of pulse duration in an ES Device [32]

Impact on Therapeutic Outcomes:

- **Longer pulse durations** are indispensable for therapies targeting muscle strengthening and recovery, as they ensure effective engagement of targeted muscle groups.
- **Shorter pulse durations** are preferred for pain management therapies where prolonged sessions are common, as they minimize muscle fatigue and discomfort.

Adjusting pulse duration allows practitioners to tailor the therapy according to specific clinical goals, enhancing the efficacy of treatments for muscle rehabilitation or pain management. By effectively choosing between short and long pulse durations, therapists can optimize the stimulation to achieve desired responses, whether it's alleviating pain or reinforcing muscle strength.

2.2.7.4 Duty Cycle

The Duty Cycle represents the proportion of time the current is active ("on-time") relative to the total cycle duration, which includes both active and inactive ("off-time") phases. This parameter is crucial for balancing therapeutic effectiveness and managing muscle fatigue, especially in prolonged sessions. For visual representation, refer to Figure 2.12.

- **Long Duty Cycles (Continuous Stimulation)**: Typically employed for consistent nerve stimulation necessary in pain management therapies. Continuous stimulation ensures that pain signals are effectively moderated over extended periods.
- **Short Duty Cycles (Intermittent Stimulation)**: Preferable in rehabilitation settings for muscle strengthening. These cycles incorporate rest periods between contractions, crucial for preventing muscle fatigue during intensive therapy sessions.

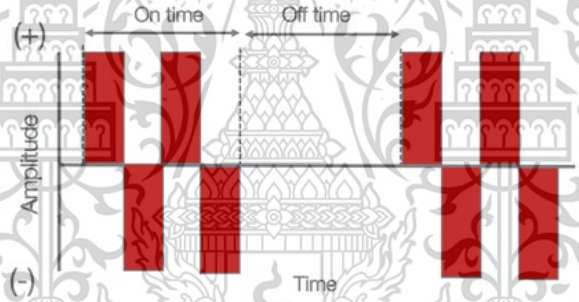


Figure 2.12 Illustration of duty cycle in an ES Device [32]

Impact on Therapeutic Outcomes:

- **Longer duty cycles** are essential for therapies requiring sustained stimulation to achieve analgesic effects.
- **Shorter duty cycles** optimize the recovery time between muscle contractions, crucial for enhancing muscle endurance and strength without overstraining the muscle tissue.

Effective management of the duty cycle allows therapists to customize treatments to meet individual patient needs, ensuring that each session provides the maximum therapeutic benefit without compromising muscle health. This is particularly important in protocols where the balance of stimulation and rest can dictate the success of the therapy.

2.2.8 Relevant Medical Device Standards [33-35]

The development, certification, and deployment of Electrical Stimulation (ES) devices are stringently regulated through a series of international and national medical device standards. These standards are pivotal in ensuring the safety, efficacy, and overall performance of ES devices within clinical environments. Compliance with these standards is crucial for manufacturers to not only achieve regulatory approval but also to ensure their devices are safe for patient use and capable of delivering the intended therapeutic benefits. These regulations encompass a broad spectrum of criteria including electrical safety, electromagnetic compatibility (EMC), device-specific functionalities, and clinical efficacy. By adhering to such standards, manufacturers can address potential risks associated with the use of ES devices, such as electrical shocks, unintentional stimulation, and interference with other medical equipment.

Internationally, standards such as those from the International Electrotechnical Commission (IEC) provide frameworks that guide the design, testing, and validation processes of ES devices. Locally, regulations such as those enforced by Thailand's FDA, ensure that devices meet specific national requirements that may include additional safety protocols or efficacy benchmarks. Together, these standards facilitate the integration of ES devices into the healthcare system, supporting their use in a safe and regulated manner while fostering innovation and trust in emerging medical technologies.

2.2.8.1 IEC 60601-1: General Requirements for Basic Safety and Essential Performance

The IEC 60601-1 standard [34] is a widely recognized framework that outlines the general requirements for the basic safety and essential performance of medical electrical equipment, including Electrical Stimulation (ES) devices. It ensures that these devices operate safely under both normal and fault conditions. The standard covers a range of safety aspects, such as electrical safety, protection against electric shock, mechanical safety, and environmental risks. Its scope applies to all types of medical electrical equipment, including stationary, portable, and wearable ES devices, ensuring comprehensive protection for patients and users alike.

2.2.8.2 IEC 60601-2-10: Particular Requirements for the Safety of Nerve and Muscle Stimulators

The IEC 60601-2-10 standard [33] specifically addresses the safety and performance requirements for nerve and muscle stimulators, including most Electrical Stimulation (ES) devices. Building upon the general framework of IEC 60601-1, this standard focuses on the unique characteristics of electrical stimulation equipment. It outlines requirements related to key output parameters, such as amplitude, frequency, and pulse width, as well as patient control mechanisms. Additionally, it provides guidelines for preventing adverse physiological effects, such as burns or muscle overstimulation. The standard also establishes protocols for testing devices to ensure they meet clinical safety standards.

2.2.8.3 IEC 60601-1-2: Electromagnetic Compatibility (EMC) Requirements

The IEC 60601-1-2 standard [35] focuses on the electromagnetic compatibility (EMC) of medical electrical devices, ensuring that ES devices do not interfere with other electronic equipment in healthcare environments, and that they are also immune to interference from external sources. The standard sets limits for emissions and immunity to electromagnetic disturbances that could affect the operation of medical devices. It also provides testing procedures to verify compliance with these EMC requirements, ensuring that devices function safely and reliably in clinical settings.

2.2.8.4 Thailand's FDA Regulations

In Thailand, the Food and Drug Administration (FDA) sets regulations for the approval, marketing, and clinical use of Electrical Stimulation (ES) devices. These standards ensure that both locally manufactured and imported ES devices meet strict safety, efficacy, and quality requirements. The Thai FDA reviews technical documentation, clinical efficacy, and safety data before devices are approved for use.

Compliance with these regulations is mandatory for manufacturers entering the Thai market, and the framework aligns with international standards such as those from the International Electrotechnical Commission (IEC). Additionally, the Thai FDA requires post-market surveillance to monitor device performance and safety, ensuring continuous compliance throughout the product's lifecycle. This regulatory oversight protects patients and strengthens the medical device industry's credibility in Thailand.

CHAPTER 3

RESEARCH METHODOLOGY

This chapter outlines the design and implementation of the proposed electrical stimulation (ES) device. This chapter provides a comprehensive breakdown of the system's conceptual framework and its key components, including the controller and user interface, pulse generator, driving stage, and protection unit. Each section details the functionality and interaction of these components, focusing on signal generation, electrical safety, and system integration. By presenting the methodology behind the design, this chapter ensures the ES device meets clinical and regulatory standards, offering both reliability and versatility in its therapeutic applications.

3.1 DESIGN OVERVIEW

This section provides an overview of the proposed 2-channel, multi-functional therapeutic ES device, as shown in Figure 3.1, with a more detailed diagram available in Figure 3.2. The system consists of four main units: (A) the user interface (UI) and controller unit, (B) the pulse generator unit, (C) the driving stage unit, and (D) the protection unit. Each of these units plays a vital role in ensuring the device's functionality, reliability, and safety in a variety of therapeutic applications. Further details for each unit will be explained in the subsequent sections.

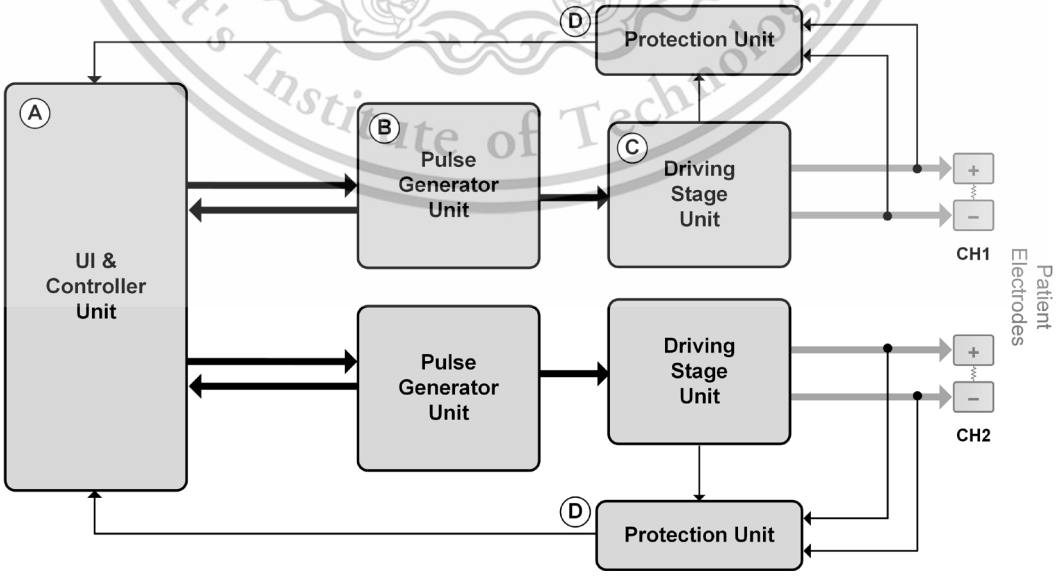


Figure 3.1 Design Overview of the proposed ES device

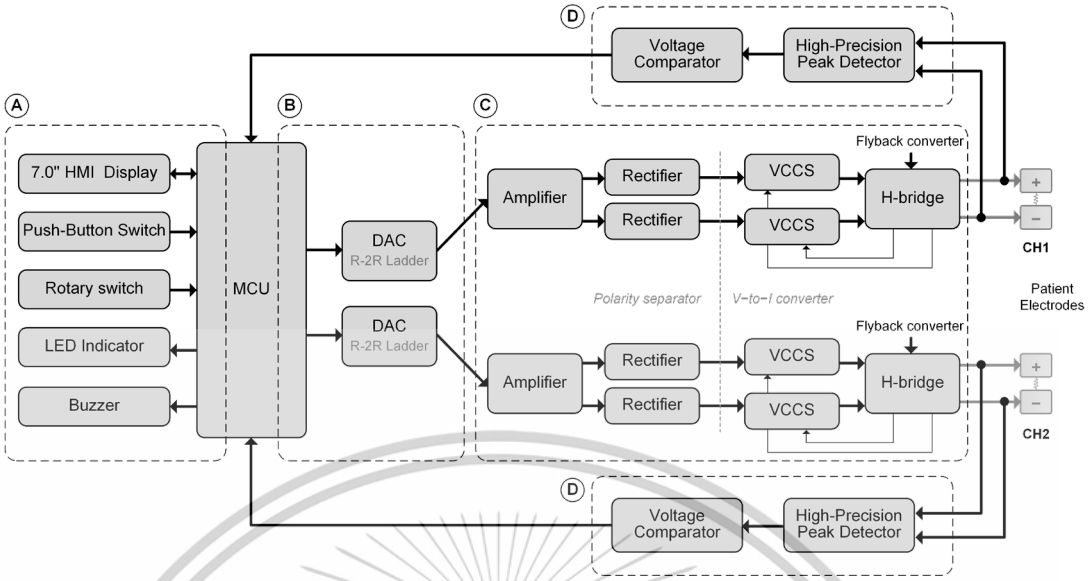


Figure 3.2 Detailed diagram of the main system overview

(A) UI and Controller Unit: This unit manages user interaction and controls system operations. It integrates input peripherals, such as a touchscreen and switches, along with LED indicators and a buzzer for system notifications. The controller coordinates the communication between the UI, pulse generator, and driving stage units.

(B) Pulse Generator Unit: This unit is responsible for generating the electrical pulses used in therapy. It allows for flexible adjustments in pulse amplitude, duration, and frequency. The design incorporates twelve essential waveforms used in physiotherapy, with additional special functions for further waveform modulation.

(C) Driving Stage Unit: The driving stage amplifies voltage signals from the pulse generator and converts them into current signals for delivery to patient electrodes. It ensures stable and precise current output, critical for effective therapy.

(D) Protection Unit: This unit monitors the real-time condition of the system. It prevents unsafe conditions, such as electrode detachment or circuit malfunctions, by shutting down the system if faults are detected, ensuring patient safety.

3.2 USER INTERFACE (UI) AND CONTROLLER DESIGN

3.2.1 User Interface (UI)

The user interface (UI) is designed to serve as an input system, display, and notification system. It comprises five main components: a multipoint touchscreen display, push-button switches, a rotary switch, LED status indicators, and a buzzer for audible alerts, as illustrated in Figure 3.3.

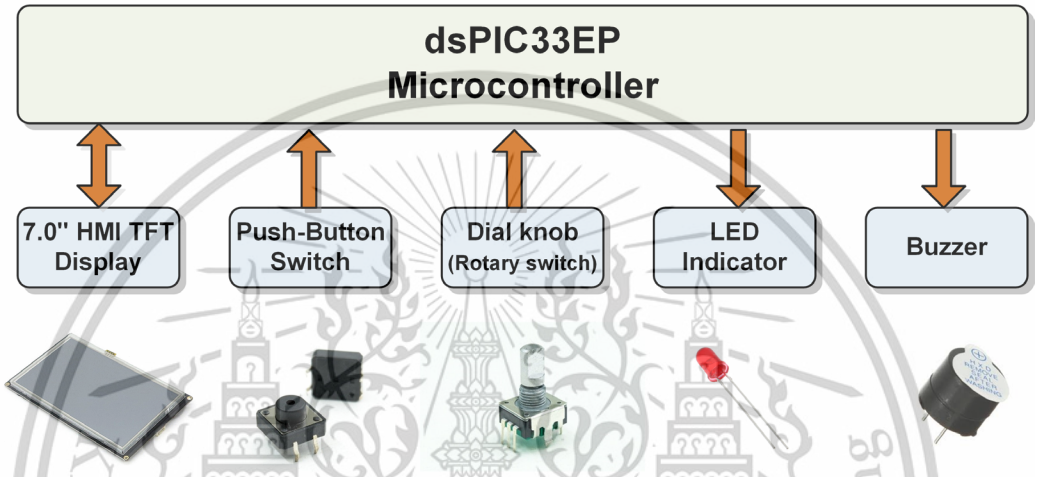


Figure 3.3 User interface design

3.2.1.1 Input

The input system is designed for parallel operation, enabling the rotary switch, push-button switch, and touchscreen to function either independently or in combination. This flexibility ensures effective system usability, even if one component fails or if the user prefers a specific input method. For instance, if the user opts not to use the touchscreen, they can adjust values through the rotary and push-button switches. Alternatively, the user can rely entirely on the touchscreen if preferred.

- **Push-Button Switch Design**

The push-button switches used in this thesis are of the "push-on, release-off" type, as shown in Figure 3.4. There are four switches, each with a specific function:

Switch 1: "Home" – Returns the display to the main screen.

Switch 2: "Start-Stop" – Starts or stops the therapy.

Switch 3: "Reset" – Resets all treatment parameters to their default values.

Switch 4: "Back" – Navigates the display back to the previous screen.

Figure 3.4 An example of a push button used in this design

Figure 3.5 illustrates the circuit connection between the control switches and the microcontroller. The switches are configured in an Active Low arrangement, where pressing a button sends a signal with a logic level of "0" (Logic "0") and releasing it sends a logic level of "1" (Logic "1"). These signals are processed by the microcontroller through the Interrupt Port (INT), which activates the corresponding function of each switch according to its assigned role.

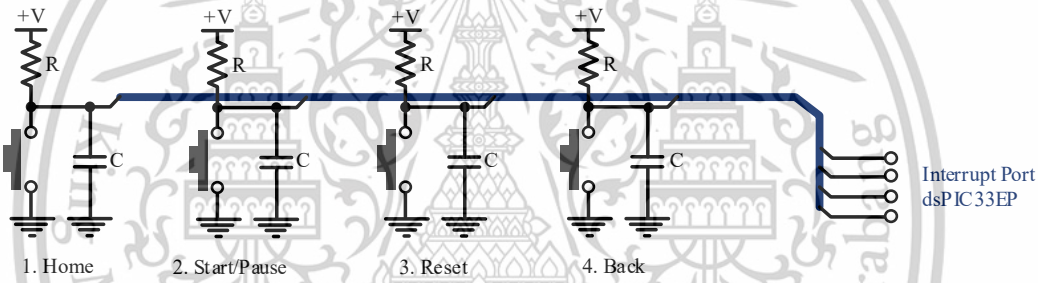


Figure 3.5 The circuit of push button in this design

- **Rotary Switch Design**

This design incorporates a rotary switch for adjusting parameters and selecting other settings. The rotary switch enhances ease of use for the operator by providing precise control. The selected switch is an Encoder Rotary Switch, as shown in Figure 3.6, which allows for accurate adjustments. Additionally, it includes a built-in push-button function, offering further flexibility in operation.

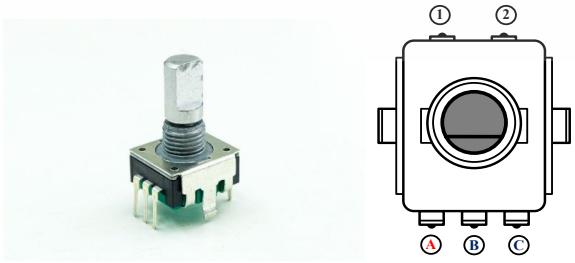


Figure 3.6 Rotary switch used in this design

The rotary switch sends both rotational and push-button commands to the microcontroller. Communication is established by connecting the rotary switch to the microcontroller's Interrupt Port, as shown in Figure 3.7. Resistors and capacitors are incorporated into the circuit to filter noise and prevent erroneous processing. The push-button signal is transmitted through terminal “1,” while rotational signals—indicating clockwise or counterclockwise movement—are sent through terminals “A” and “B”.

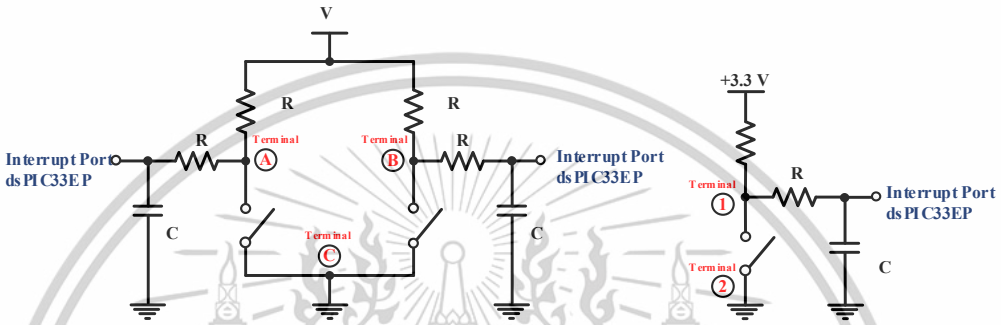


Figure 3.7 The circuit of rotary switch in this design

Figure 3.8 depicts the signal pattern for clockwise and counterclockwise rotation, which appears as a square-wave pulse with a time-shifted overlap. When the switch is rotated clockwise, the signal from terminal A precedes that of terminal B, whereas for counterclockwise rotation, terminal B leads terminal A. These signals are transmitted to the microcontroller, enabling it to detect the rotation direction and adjust the corresponding parameters accordingly.

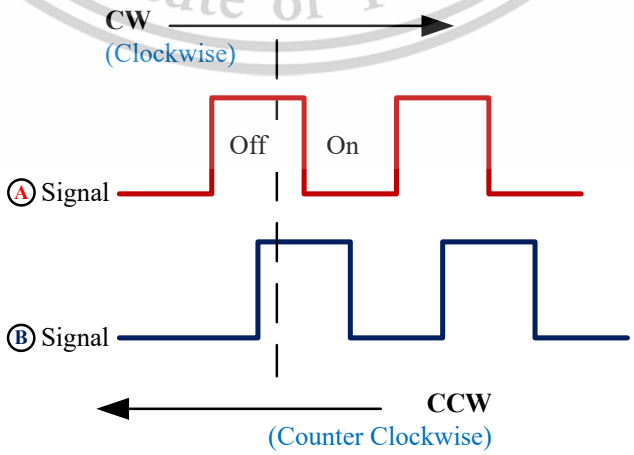


Figure 3.8 Signal pattern diagram of an encoder rotary switch

3.2.1.2 Display

The display component is designed to present critical information to the user, utilizing the same touchscreen interface that is used for input. It provides essential details such as general usage information, parameter settings, treatment data, operational status, alerts, and the remaining treatment time. This ensures that the user is continuously informed about the system's current state, enabling efficient monitoring and control of the device during operation.

- **Design of the Touchscreen Display**

The display utilizes a 7.0-inch TFT capacitive touchscreen with a resolution of 800x480 pixels, as shown in Figure 3.9. This display provides flexible design options and customization capabilities. Communication between the display and the microcontroller is bidirectional through the Universal Asynchronous Receiver Transmitter (UART) module, allowing the display to function both as an input device and an output screen. The connection diagram is illustrated in Figure 3.10.

Figure 3.9 The touch-screen display in this design

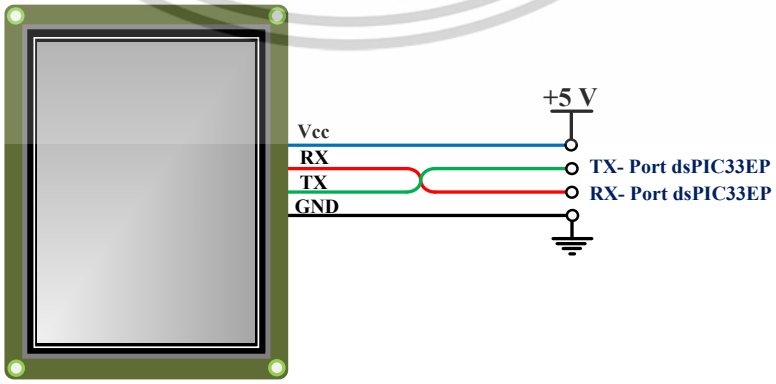


Figure 3.10 The circuit of a touch-screen display

The on-screen symbols and elements can be fully customized using the editor tool, a powerful software provided by the manufacturer. This tool enables developers to design a user interface specifically tailored to the application's needs. With the editor, users can easily create interactive elements such as buttons, sliders, and data displays, arranging them on the touchscreen to suit the desired layout. Its intuitive drag-and-drop functionality allows for easy customization of graphic components. Figure 3.11 displays the main interface of the editor, while Figure 3.12 illustrates an example of the graphical user interface created with this tool. This flexibility ensures that the user interface is optimized for both functionality and user experience.

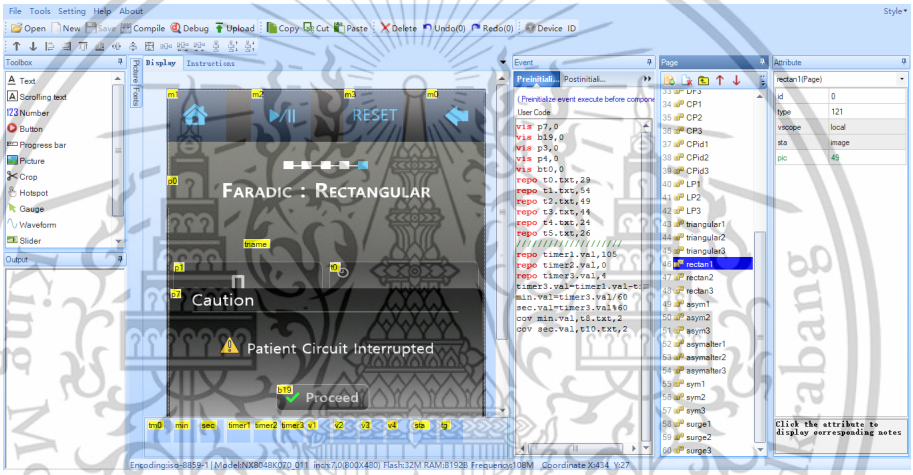


Figure 3.11 A multi touch-screen editing software

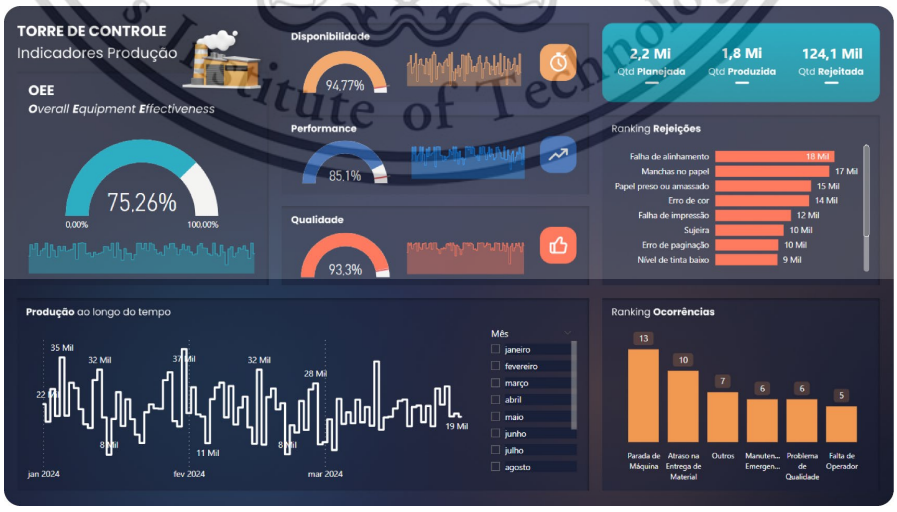


Figure 3.12 Example of GUI

3.2.1.3 Notification

The notification system is designed to provide alerts through three distinct methods, ensuring that users are consistently informed of the device's operational status and any potential issues. These methods include LED status indicators, which provide visual cues by using different colors and blinking patterns to signify various operational states or warnings. The system also employs an audio buzzer that delivers audible alerts, varying in tone and duration to communicate different conditions such as errors, completion of treatment, or emergency stops. Additionally, pop-up messages on the display screen offer real-time textual information, giving the user clear, detailed explanations about the current status, errors, or necessary actions. This multi-channel notification system enhances user awareness and safety by providing redundant and accessible forms of communication for all types of alerts.

- **LED Status and Indicators**

Important operational statuses are communicated to the user via LED lights, as shown in Figure 3.13, with the control circuit for the LEDs illustrated in Figure 3.14. The LEDs are controlled by the microcontroller, which sends a logic "0" or "1" signal to either turn the lights on or off, respectively. Two LED colors are utilized: blue and red, each of which has five distinct lighting patterns to represent different operational statuses. These patterns and their corresponding meanings are outlined in Table 3.1.

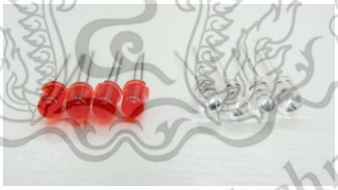


Figure 3.13 LED in this design

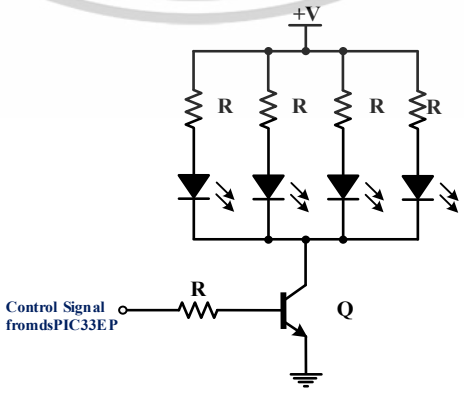


Figure 3.14 The control circuit of LEDs in this design

Table 3.1 LED patterns and status meaning

LED Pattern	Blue LED	Red LED	Meaning
1	Off	Off	No abnormal conditions, normal operation.
2	On	Off	Rotary switch ready for parameter adjustments.
3	Off	On	Error: Electrode not in contact with patient or circuit malfunction.
4	Gradual on (1 sec), then off	Off	Device is ready for use after startup or exiting power-saving mode.
5	Gradual off	Off	Device entering power-saving mode.

- **Buzzer Design for Audible Notifications**

For audio notifications, a self-drive buzzer is employed, as shown in Figure 3.15. This buzzer emits a single-tone sound, and its control circuit is illustrated in Figure 3.16. The microcontroller sends control signals to activate the buzzer, triggering different audio alerts. There are four distinct sound patterns, each conveying a specific message, as detailed in Table 3.2.

Figure 3.15 Self-drive buzzer in this design

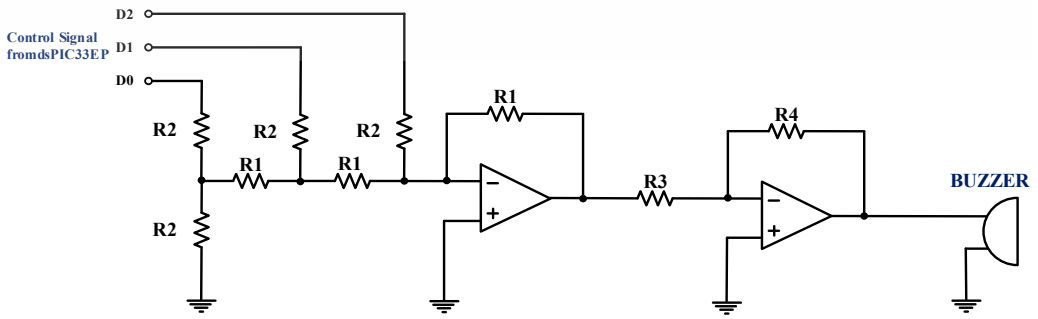


Figure 3.16 The control circuit of a buzzer in this design

Table 3.2 Buzzer sound patterns and status meaning

Sound Pattern	Meaning
No sound	Normal operation.
Continuous (2 sec)	End of treatment, parameter reset, or emergency stop.
Two short beeps	Parameter adjustment not allowed during treatment.
One short beep	Stimulation resuming after a programmed break.

The buzzer volume can be adjusted across eight levels, ranging from 0 (no sound) to 7 (maximum volume). The microcontroller controls the volume by sending out logic signals to the buzzer, with the volume level determined by the state of three control pins: D0, D1, and D2. The specific logic combinations for each volume level are shown in Table 3.3. This allows for precise adjustment of the audio alerts, ensuring that they are appropriately audible for different environments and user preferences.

Table 3.3 Buzzer volume control by microcontroller logic signals

Volume Level	Port D0	Port D1	Port D2
0 (No sound)	0	0	0
1	0	0	1
2	0	1	0
3	0	1	1
4	1	0	0
5	1	0	1
6	1	1	0
7 (Max volume)	1	1	1

This notification system ensures that users are consistently informed of the device's status through a combination of visual, audio, and on-screen alerts. By providing multiple methods of communication, the system guarantees that users receive clear and immediate notifications, whether through LED indicators, audible buzzers, or detailed messages displayed on the screen. This redundancy enhances user safety and ensures that important information is conveyed effectively, regardless of the situation.

3.2.2 Controller

The controller is the central processing unit of the Electrical Stimulation (ES) device, responsible for managing all core system functions and coordinating communication between key components, including the user interface, pulse generator, and driving stage. For this design, the **dsPIC33EP512MU810** microcontroller, core with integrated DSP and enhanced on-chip peripherals, from Microchip Technology Inc was selected due to its advanced digital signal processing capabilities and efficient real-time control features.

Key Specifications [36]:

- **CPU Speed**: 70 MIPS (Million Instructions Per Second), ensuring high-speed processing for real-time waveform generation and control.
- **Memory**: 512 KB of Flash Program Memory and 48 KB of SRAM, providing sufficient storage for waveform generation algorithms and system settings.
- **I/O Ports**: 85 digital I/O pins, allowing for efficient communication with peripheral devices such as the touchscreen, buttons, sensors, and pulse generator circuits.
- **Analog-to-Digital Converters (ADC)**: 12-bit ADC for accurate reading of sensor inputs and feedback from the electrodes.
- **Digital-to-Analog Converter (DAC)**: Supports high-resolution output signals, essential for generating precise stimulation waveforms.
- **PWM (Pulse Width Modulation)**: Multiple PWM channels for generating the required pulse patterns for therapeutic stimulation.
- **Safety Features**: Includes watchdog timers, fault detection, and built-in error correction mechanisms to ensure the safety of the device during operation.

The **dsPIC33EP512MU810** microcontroller facilitates the real-time processing of control algorithms and coordinates input/output functions. It manages communication between subsystems, ensuring that the correct waveforms are generated and that user inputs are processed efficiently. This centralized controller architecture ensures the precise execution of therapeutic waveforms and functions, supporting both performance and safety in clinical applications.

3.2.3 User Interface (UI) and Controller Integration

The connection between the **controller** and the **user interface (UI)** is fundamental for the operation of the Electrical Stimulation (ES) device, as the controller processes inputs from the UI and translates them into actions that manage the entire system. Figure 3.16 provides a visual representation of this interaction, highlighting how the microcontroller processes inputs from various UI components and ensures accurate control of the device.

The user interface consists of multiple input/output devices such as the touchscreen, push-button switches, rotary switch, LED indicators, and buzzer. These elements allow the user to interact with the system by selecting waveforms, adjusting parameters, and receiving feedback.

1. **Touchscreen**: The controller communicates with the touchscreen, processing input commands such as selecting waveforms, modifying stimulation parameters, and navigating through various menu options. The controller translates these actions into specific output signals that adjust the pulse generator accordingly.
2. **Push-button Switches and Rotary Switch**: The controller receives input from the push-button switches and rotary switch to further adjust parameters, initiate treatments, or reset the system. These inputs are processed in real-time, allowing users to change the intensity, frequency, and duration of the stimulation. The rotary switch offers fine-tuning of parameters for greater precision.
3. **LED Indicators and Buzzer**: These components are controlled directly by the microcontroller to provide immediate feedback to the user. The controller monitors the system's operational status and uses the LED indicators to signal different modes or alerts, while the buzzer provides audible notifications for events such as treatment completion or system errors.

By serving as the central processing unit, the controller coordinates all aspects of the user interface. It ensures that the inputs from the user are accurately processed and executed, and that the device provides real-time feedback. The successful communication between the controller and UI components, as shown in Figure 3.17, validates the seamless integration of hardware and software, ensuring smooth and reliable operation of the ES device.

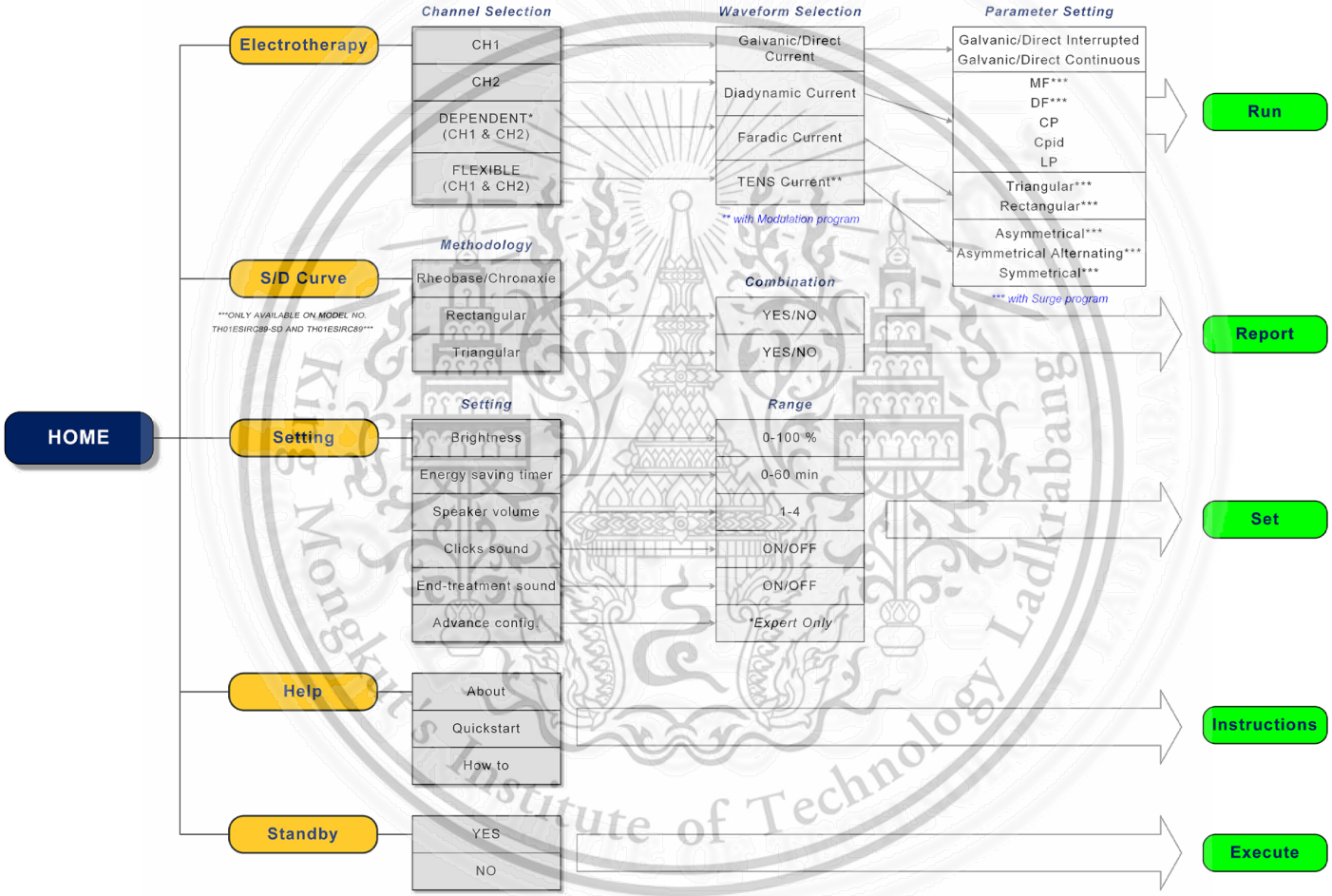


Figure 3.17 Interaction between the controller and the User Interface (UI)

3.3 PULSE GENERATOR UNIT DESIGN

This section details the design considerations, hardware selection, and implementation of the pulse generator unit. The pulse generator design in this research consists of two key components: the **microcontroller (MCU)** and the **digital-to-analog converter (DAC)**.

3.3.1 MCU

The MCU plays a crucial role in generating the desired waveforms by executing control algorithms that precisely manage the timing, frequency, and amplitude of the stimulation pulses. It processes input parameters, such as pulse width and frequency, to create the appropriate digital signals. These signals are then sent to the DAC. This research utilizes the dsPIC33EP512MU810, a 16-bit DSP microcontroller known for its high-speed processing capabilities.

This research utilizes a real-time technique with proprietary in-house algorithms to generate the required waveforms. These algorithms are designed to create four fundamental signal types: direct current (DC), sinusoidal, square, and triangular waves. By combining these algorithms, the system is capable of producing all twelve essential waveforms required for our multi-functional ES design, as well as the two additional special functions. This method offers notable advantages over the traditional Look-Up Table (LUT) approach [1, 2, 4, 7]. It is computationally more efficient, faster, and uses fewer resources, significantly improving the system's overall speed and performance.

The algorithms for generating current waveforms are programmed in C language, utilizing the microcontroller's capabilities to produce precise electrical signals for muscle and nerve stimulation. The key parameters involved in waveform generation include pulse amplitude, pulse frequency, and pulse duration. The range of these parameters in the design is provided in Table 3.4, offering flexibility to adapt to various therapeutic needs.

Table 3.4 Parameters for generating electrical signals

Parameters	Minimum	Maximum	Resolution
Intensity/ Amplitude	0 mA	140 mA	0.2 mA
Pulse Frequency	0.2 Hz	1,000 Hz	0.1/1 Hz
Pulse duration	20 μs	1,000,000 μs	10/100 μs

The process of generating waveforms can be broken down into two main stages: parameter conversion and pulse generation. In the first stage, the input parameters—such as the desired current amplitude, frequency, and pulse width—are converted into values that the microcontroller can process. This conversion involves translating the physical parameters (e.g., mA, Hz, and μs) into digital values that correspond to voltage levels and timer counts required for the microcontroller's operation.

Once the parameters are converted, the process moves to the pulse generation stage. Here, the microcontroller uses the converted values to control the timing and shape of the electrical pulses. Each type of waveform, whether it's a sine wave, square wave, or triangle wave, has a specific algorithm for how the pulse is generated and output to the electrodes. By precisely controlling the timing and amplitude of the pulses, the system ensures accurate and effective stimulation tailored to the patient's needs. This two-stage process—conversion followed by pulse generation—enables the device to deliver customized electrical stimulation with a high degree of precision.

3.3.1.1 Parameter Conversion

In the design of the ES device, the input parameters—such as amplitude, frequency, and pulse duration—must be converted into a digital format that can be processed by the MCU for real-time waveform generation. This section explains how these user-defined values are translated into corresponding digital signals.

- **Amplitude conversion**

When the amplitude is set or adjusted, the program calculates and converts the input value into a corresponding voltage ranging from 0 to 3.3 V, as well as a 16-bit digital value between 0 and 65535. This digital value is calculated using Equation (3.1), with example calculations shown in Table 3.5. Once calculated, the value is transmitted as a binary code via a 16-bit parallel communication channel to the microcontroller's 16 output pins, which are connected to an R-2R Ladder DAC.

$$Vm = \frac{I(mA) \times R(\Omega)}{3.3(V)} \times 65535 \tag{3.1}$$

Where: Vm is 16-bit digital value

I is Current amplitude (mA)

R is Resistor value in ohms
(in this design, a resistor value of 15Ω is selected)

Table 3.5 Examples of converting values of current intensity or amplitude

Input Current (0-150 mA)	Voltage (0-3.3 V)	Digital Value (0-65535)	Binary code (0000 0000 0000 0000 – 1111 1111 1111 1111)
1	0.015	298	0000 0001 0010 1010
5	0.075	1489	0000 0101 1101 0001
10	0.15	2979	0000 1011 1010 0011
20	0.3	5958	0001 0111 0100 0110
30	0.45	8937	0010 0010 1110 1001
40	0.6	11915	0010 1110 1000 1011
50	0.75	14894	0011 1010 0010 1110
80	1.2	23831	0101 1101 0001 0111
100	1.5	29789	0111 0100 0101 1101
120	1.8	35746	1000 1011 1010 0010
140	2.1	41704	1000 1011 1010 0010
150	2.25	44683	1010 1110 1000 1011

- **Pulse Frequency and Pulse Duration**

The adjustment of frequency (f) and pulse duration (Ton) involves modifying the time period, and these two parameters are interrelated, as shown in Figure 3.18. When one parameter is changed, the other adjusts accordingly. However, in actual operation, when the pulse duration is adjusted, the frequency remains fixed, and similarly, when the frequency is modified, the pulse duration stays constant.

This timing relationship is managed using the microcontroller's timer module, which defines the signal generation timing based on the set values. The input values are converted into machine cycles or timer counts for the microcontroller to process and use accordingly.

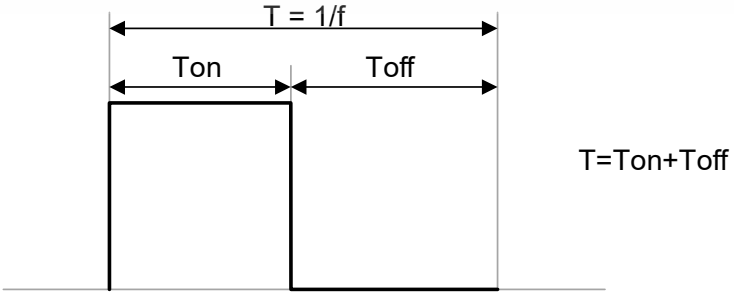


Figure 3.18 A relationship between pulse frequency (f) and pulse duration (Ton)

The timer in the microcontroller counts every 1 machine cycle, which corresponds to the clock signal period generated by the crystal oscillator, operating at a frequency of 60 MHz. Therefore, 1 machine cycle is equal to 1/60 MHz. The timer continues counting until it exceeds its maximum value and then resets to begin a new counting cycle. In this thesis, the microcontroller's timer, with a 16-bit resolution, can count up to 65535. The time period for the desired signal can be calculated using Equation (3.2). Table 3.6 provides examples of how pulse frequency and pulse duration values are converted into timer counts.

$$T = Tosc \times Prescaler\ Value \times TMR1 \tag{3.2}$$

Where: T is Time period of the signal,

$Tosc$ is Time period of 1 machine cycle (or timer count), (In this design, a machine cycle = 1/60 MHz),

$Prescaler\ Value$ is The ratio for prescaling, (In this design, a ratio of 1:1 is used),

$TMR1$ is Number of machine cycles required to generate the signal.

Table 3.6 Examples of frequency and pulse duration conversion to timer counts

Pulse Frequency Conversion			Pulse Duration Conversion	
f (Hz)	T (ms)	TMR1	Ton (ms)	TMR1
0.2	5000	300000000	0.1	6000
0.5	2000	120000000	0.5	30000
1	1000	60000000	1	60000
5	200	12000000	10	600000
10	100	6000000	50	3000000
50	20	1200000	100	6000000
100	10	600000	200	12000000
150	6.67	400200	500	30000000
200	5	300000	1000	60000000

This table illustrates how frequency and pulse duration values are converted into timer counts, which the microcontroller uses to generate the corresponding signal for electrical stimulation.

3.3.1.2 Waveform Synthesis

Once the input parameters—amplitude, frequency, and duration—are converted into digital values, the next crucial step is generating the required electrical waveforms. The system can produce various waveform shapes, including DC signals, sinusoidal waves, square waves, and triangular waves, depending on the intended therapy. The microcontroller selects the appropriate algorithm to generate these waveforms based on the user's input, ensuring that the output aligns with the specific therapeutic requirements.

3.3.1.2.1 Direct Current (DC) Signal

The DC signal is the simplest waveform type, as it does not involve frequency modulation. The only adjustable parameter for this signal is the amplitude. Since the DC signal lacks a frequency component, there is no need to configure timer counts for its generation. The process for generating this signal is outlined in the flowchart presented in Figure 3.19.

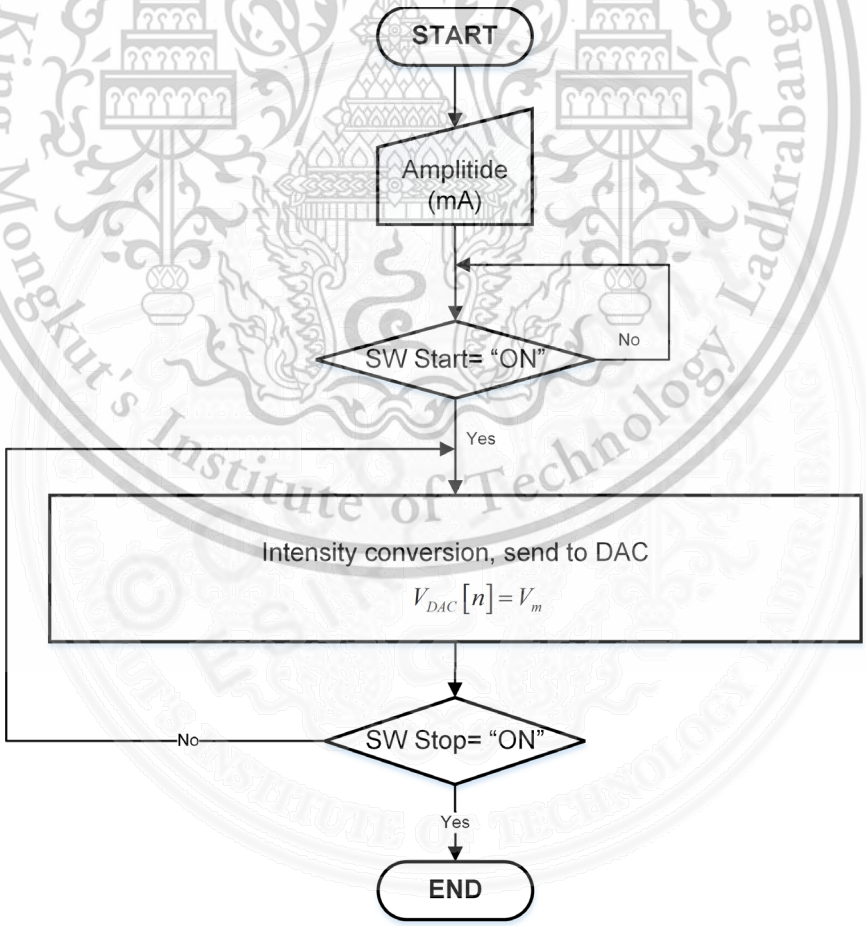


Figure 3.19 Process of generating a direct current (DC) signal

3.3.1.2.2 Sinusoidal Wave

The sinusoidal wave signal involves both amplitude and frequency. To generate this waveform, timer values must be configured. In this thesis, the sinusoidal wave is set to a fixed frequency of 50 Hz. The process for generating the sinusoidal signal is illustrated in the flowchart in Figure 3.20.

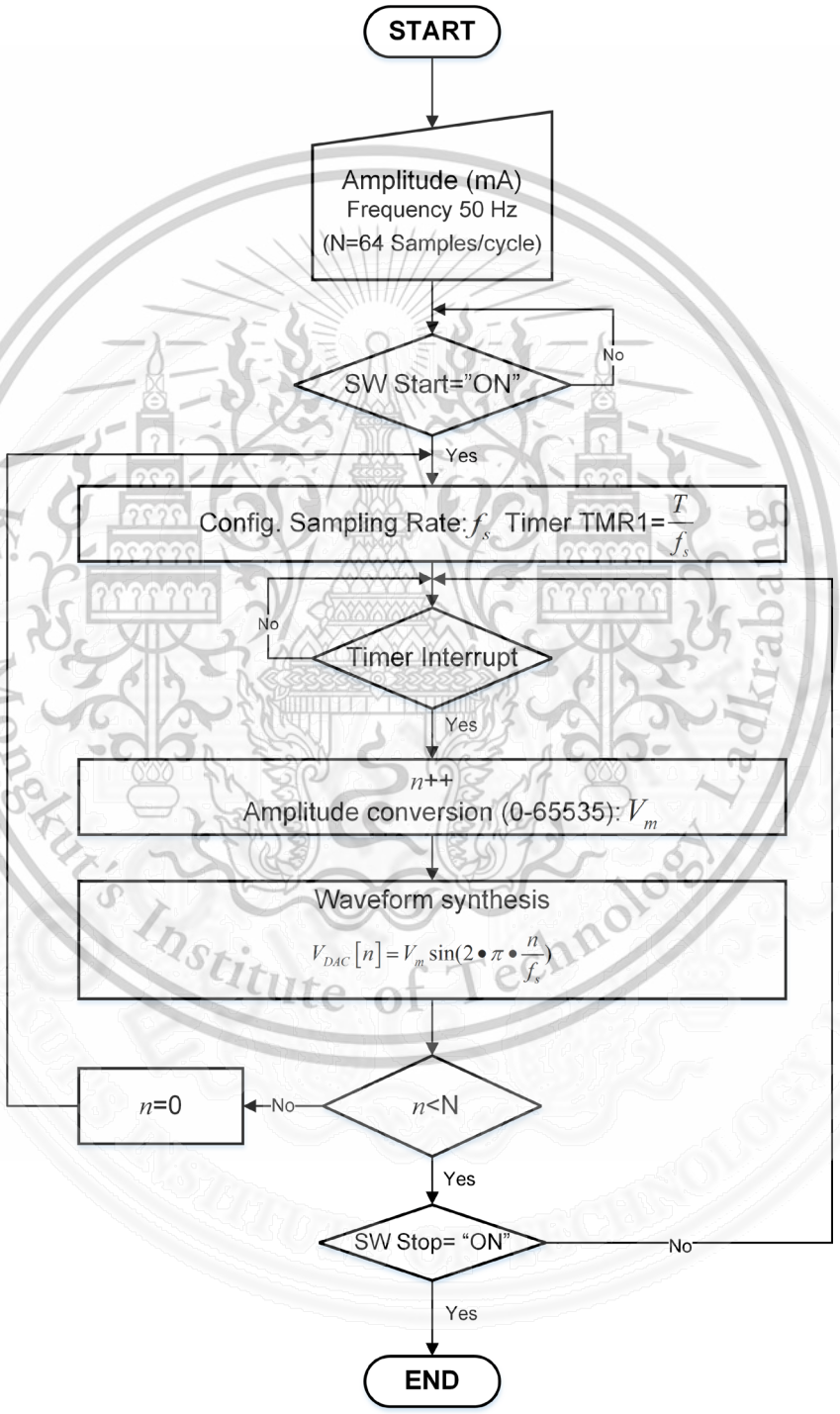


Figure 3.20 Process of generating a sinusoidal wave signal

3.3.1.2.3 Square Wave

The process of generating a square wave signal is detailed in the flowchart in Figure 3.22. Unlike the sinusoidal wave signal, which can be produced using a fixed sampling rate, square wave signals with very short pulse durations (Ton) require a different approach. If the pulse duration is too brief, the number of sampling points may be insufficient, leading to signal distortion and a loss of the square wave shape. Therefore, the square wave is generated by toggling the logic of the port connected to the DAC based on the timer's configuration.

An example of generating a 200 Hz square wave with a 1 ms pulse duration and a current intensity of 50 mA is shown in Figure 3.21. Using Equation 3.1, the amplitude in a 16-bit digital value (Vm) is calculated as 14,894. A square wave signal with a 200 Hz frequency has a period of 5 ms, corresponding to 300,000 machine cycles (calculated from Equation 3.2). The 1 ms pulse duration equals 60,000 machine cycles, while the rest period amounts to 240,000 machine cycles.

To generate the signal, the microcontroller sends a logic "1" to the DAC circuit (VDAC = Vm) and initiates counting with the timer. When the timer reaches 60,000 (TMR1), it triggers an interrupt, sending a logic "0" to the DAC (VDAC = 0). The logic remains at "0" until the timer counts up to 300,000, after which the logic toggles back to "1" to begin the next cycle. Since the timer register has a 16-bit resolution, with a maximum count of 65,535, the counting process is divided into intervals, and the timer interrupt is reconfigured accordingly.

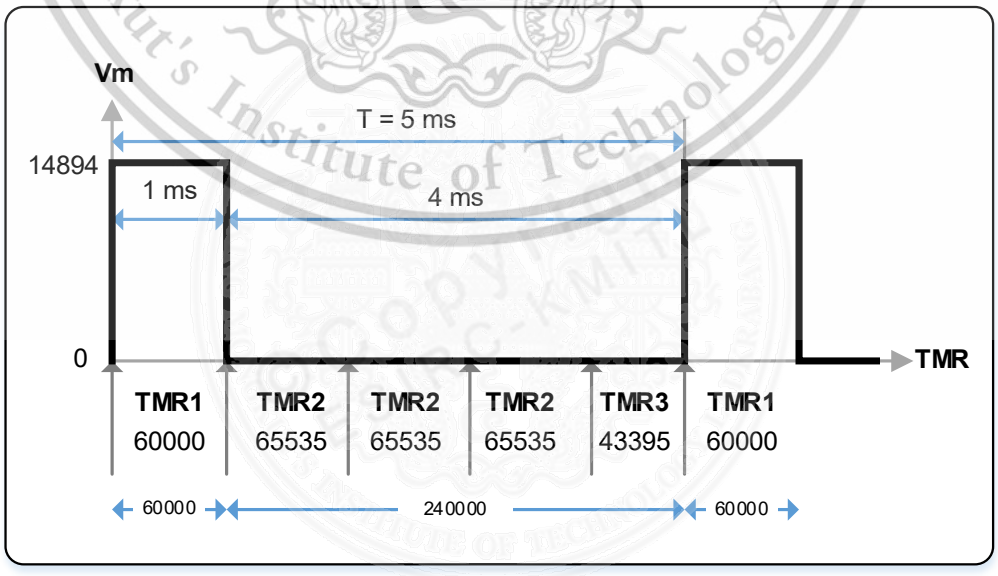


Figure 3.21 An example of generating square wave signal

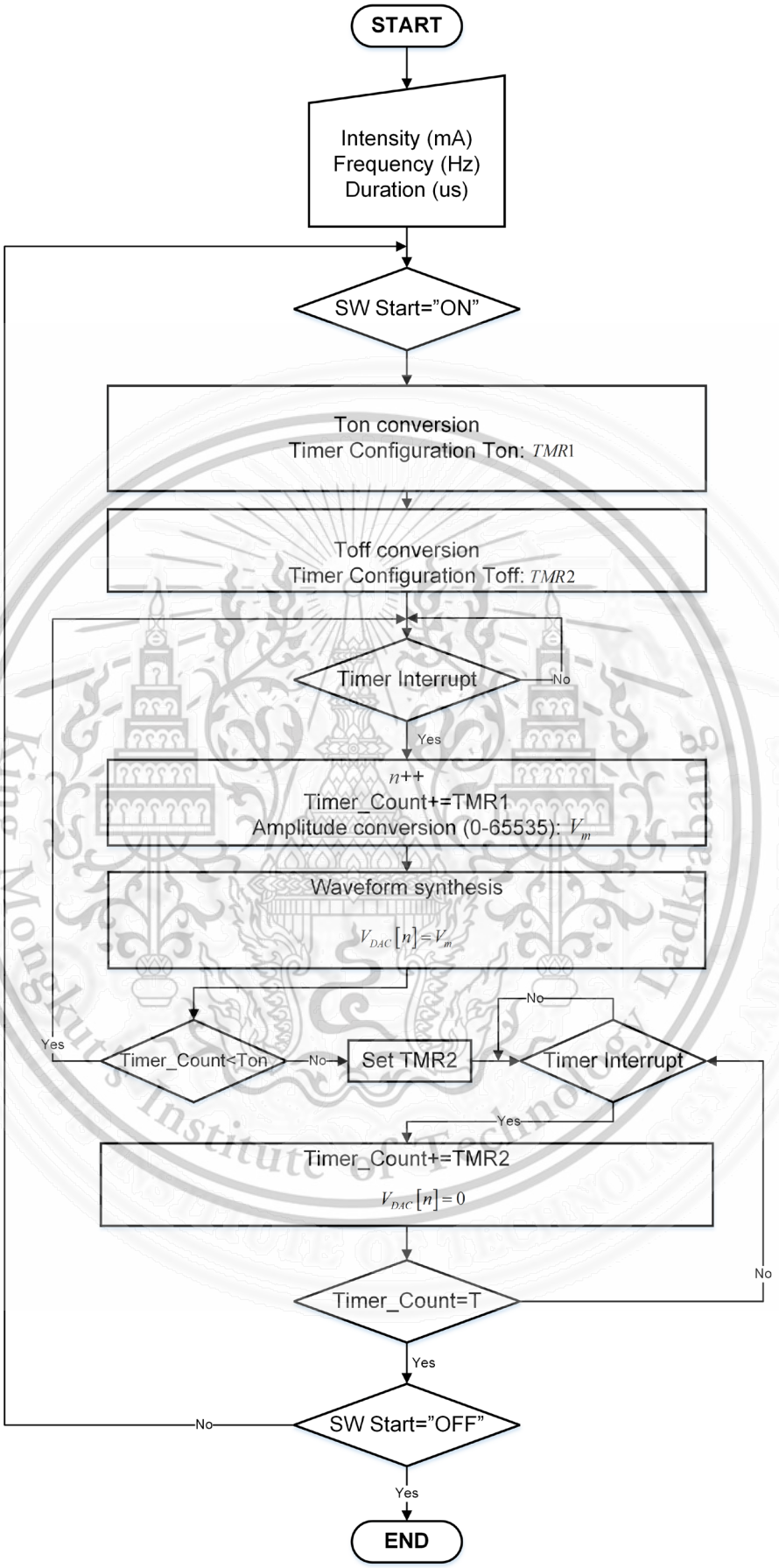


Figure 3.22 Process of generating a square wave signal

3.3.1.2.4 Triangle Wave

The process for generating a triangle wave signal is illustrated in the flowchart in Figure 3.24. Similar to square wave generation, creating a triangle wave signal cannot rely on a fixed sampling rate, as used in sine wave generation. When the pulse duration (Ton) is narrow, there can be too few points generated within the pulse, resulting in a step-like slope rather than a smooth triangle. Therefore, the generation of the triangle wave combines the principles used for sine wave generation during Ton and square wave generation during the Toff period.

An example of generating a 100 Hz triangle wave with a 5 ms Ton and a current intensity of 50 mA is illustrated in Figure 3.23. Using Equation 3.1, the amplitude of the signal in a 16-bit digital value (Vm) is calculated as 14,894. A 100 Hz triangle wave has a period of 10 ms, corresponding to 600,000 machine cycles (calculated from Equation 3.2). During Ton, 10 points are used to create the signal, resulting in an interval of 0.5 ms between each point (Ts), which corresponds to 30,000 timer counts (TMR1). The amplitude value sent to the DAC is calculated using Equation 3.3.

$$V_{DAC}[n] = \frac{V_m}{N} \times n \tag{3.3}$$

After the Ton phase is complete, the timer triggers an interrupt and sends a 0 amplitude to the DAC (VDAC = 0) until it counts to 300,000, at which point the logic toggles to initiate the next cycle.

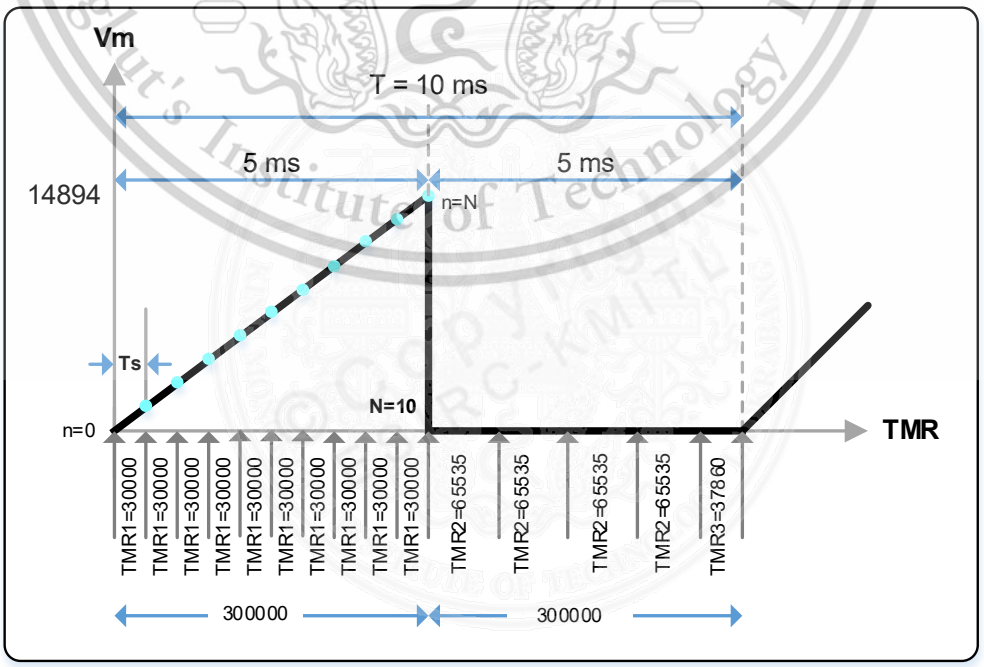


Figure 3.23 An example of generating triangular wave signal

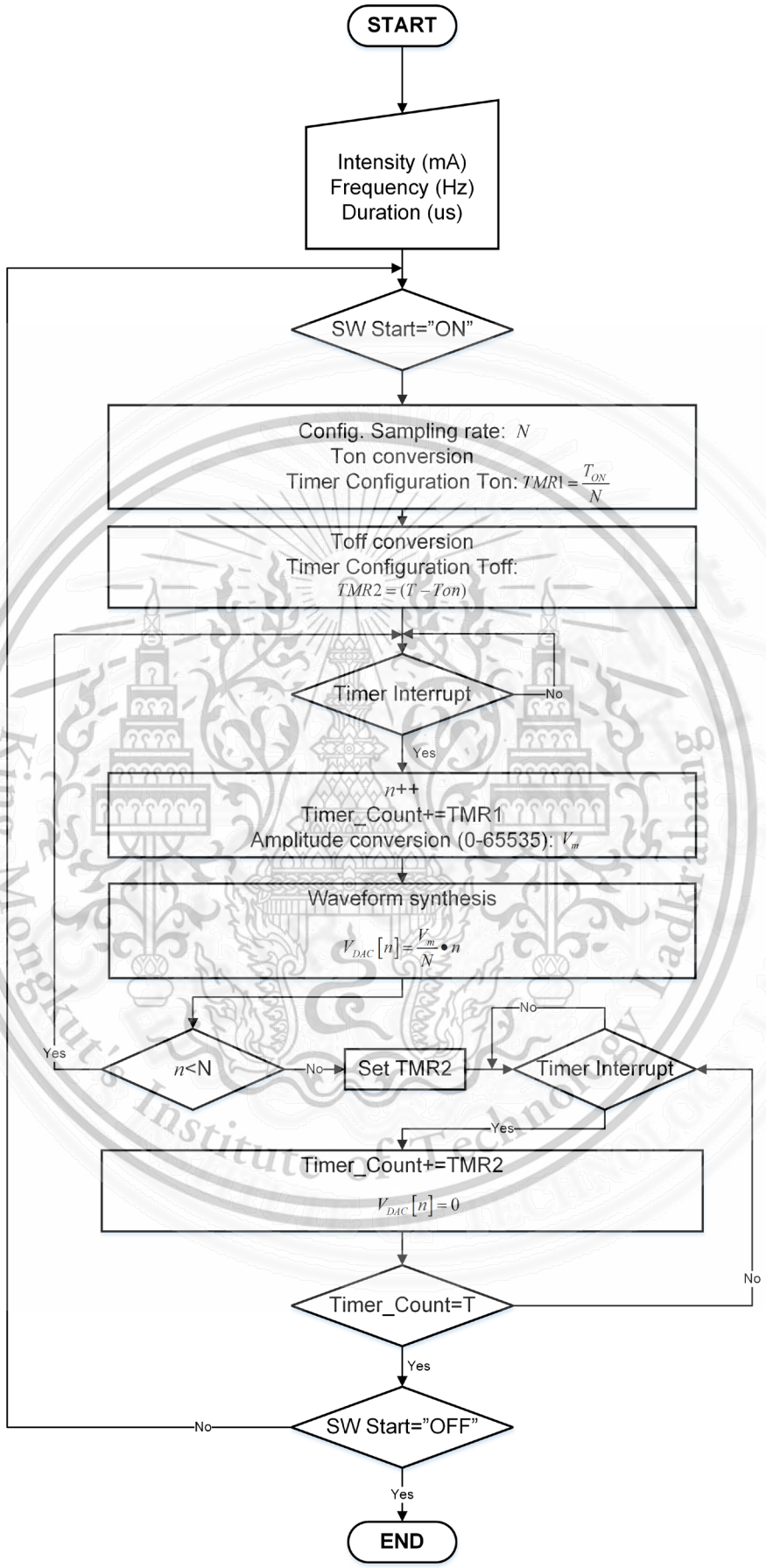


Figure 3.24 Process of generating a triangular wave signal

3.3.2 DAC

The DAC converts the digital signals generated by the MCU into analog electrical pulses. This conversion is essential because the therapeutic waveforms applied to the patient must be smooth and continuous to provide effective stimulation. By using a high-resolution DAC, the system ensures the accuracy of the generated waveforms, which directly impacts the therapeutic outcomes.

In this work, an R-2R ladder circuit, consisting of resistors with values of either R or 2R, was selected as the DAC. This choice meets the design requirements for resolution, speed, continuity, and notably higher slew rates compared to conventional DAC chips [37]. The proposed R-2R ladder DAC is paired with a high-speed operational amplifier (Op-Amp) to generate analog output signals, $V_{Ra}(t)$.

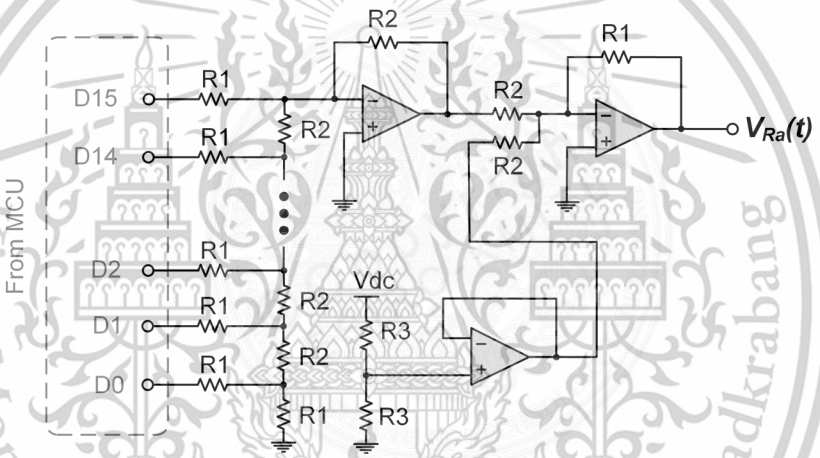


Figure 3.25 The proposed R-2R ladder DAC circuit

This design achieves a very high slew rate of 350 V/μs, and a bandwidth of 50 MHz, [38] which is sufficient for generating highly nonlinear signals with minimal distortion. Figure 3.25 illustrates the proposed R-2R ladder DAC developed in this work. Another advantage of employing an R-2R ladder circuit is its ability to interface with the MCU using a parallel peripheral interface (PPI) via the MCU's input/output ports. This interface offers significantly faster communication speeds compared to the Serial Peripheral Interface (SPI) typically used in most of the DAC chips [39]. The enhanced speed provided by the PPI used in this work ensures more efficient data transmission, which is crucial for high-speed applications and complex waveform generation in therapeutic ES devices.

The actual schematic of the proposed pulse generator unit implementation is depicted in Figure 3.26.

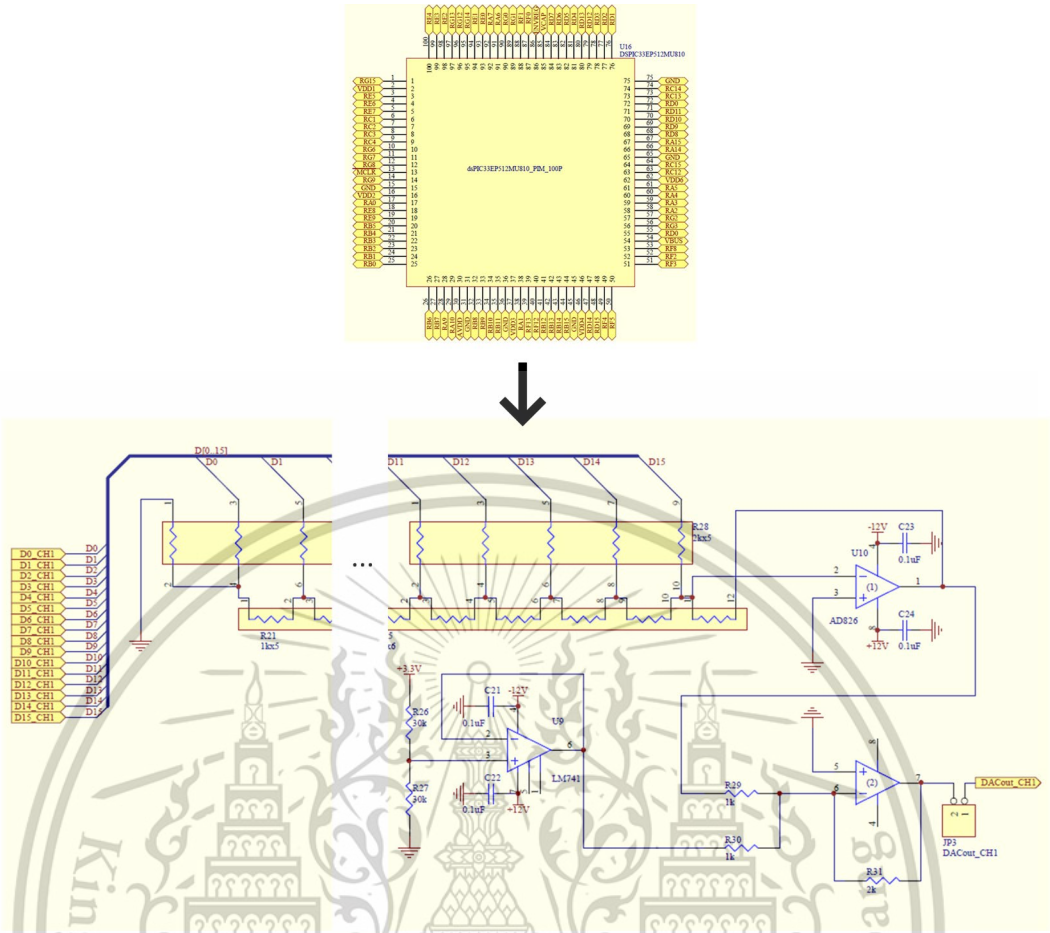


Figure 3.26 The actual schematic of the proposed pulse generator unit

3.4 DRIVING STAGE UNIT DESIGN

The driving stage unit, commonly referred to as the ES power or ES output circuit, is primarily responsible for delivering the appropriately transformed current pulses to the targeted patient tissues, ensuring the intensity settings prescribed by the physiotherapist are met. This unit comprises two essential components: (1) the polarity separator and (2) the voltage-to-current (V-to-I) converter.

3.4.1 Polarity Separator

The polarity separator generates control signals for the Voltage-Controlled Current Source (VCCS) and H-bridge circuit within the V-to-I converter. This separator utilizes an inverting amplifier and two half-wave rectifier circuits, as depicted in Figure 3.27, to decompose any analog input voltage, $V_{Ra}(t)$, from the previous DAC into its positive and negative components, $V_{Ra+}(t)$ and $V_{Ra-}(t)$. These decomposed signals are then sent to the V-to-I converter for further processing.

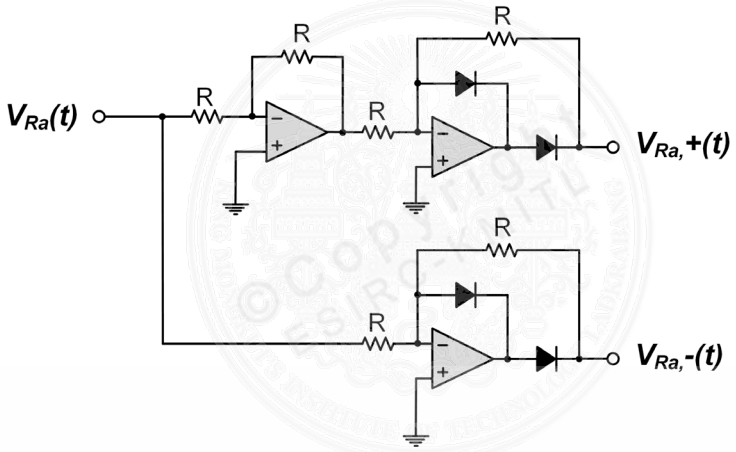


Figure 3.27 The signal polarity separator circuit in this design

3.4.2 Voltage-to-Current Conversion

The V-to-I converter in this study is designed using two VCCS circuits in conjunction with an H-bridge circuit, as illustrated in Figure 3.28. The VCCS circuits are essential for controlling the pulse shapes, amplitudes, and polarities of the desired output currents. The H-bridge circuit, which contains four transistors (Q1, Q2, Q3, and Q4), operates in pairs and is controlled by the two VCCS circuits. The right-hand VCCS circuit, consisting of U1 and Q5, controls transistors Q1 and Q2 to produce a positive directional current flow. Conversely, the left-hand VCCS circuit, consisting of U2 and Q6, controls transistors Q3 and Q4 to produce a negative directional current flow.

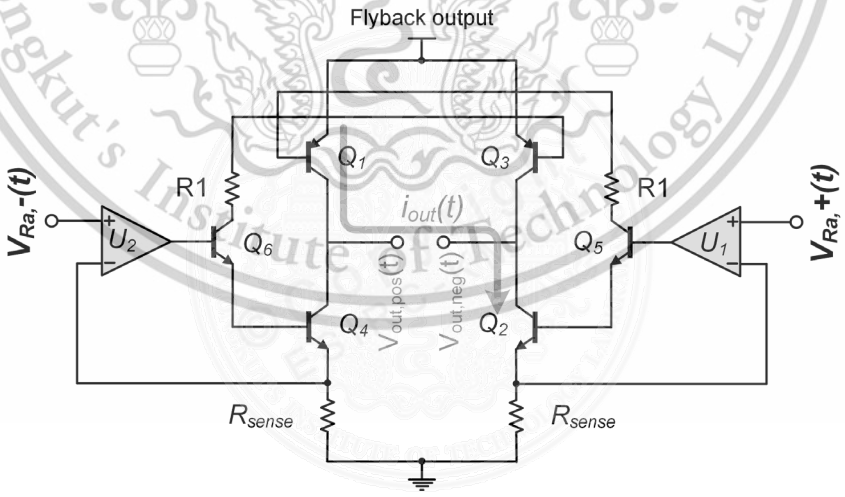


Figure 3.28 V-to-I converter in this work

The H-bridge circuit outputs for each channel are directly connected to two electrodes, which attach to the patient's skin or targeted tissues. Two feedback signals from R-sense resistors in the H-bridge outputs, along with the two polarized output

signals from the DAC, are simultaneously compared and adjusted to maintain a constant current out-put as set by the users. This ensures accurate and consistent delivery of therapeutic output currents [25]. The proposed driving stage unit, as in Figure 3.28, is designed to generate a maximum output current of 150 mA on both the negative and positive sides. The output characteristics of this driving stage unit can be derived by the following equation:

$$i_{out}(t) = \frac{V_{out,pos}(t)}{R_{sense}} + \frac{V_{out,neg}(t)}{R_{sense}} \tag{3.4}$$

The flyback converter in Figure 3.28 is integrated as the power supply for the H-bridge circuit. Given the direct interface of the H-bridge with human skin, ensuring safety is paramount. To this end, an isolated flyback converter, depicted in Figure 3.29, has been utilized for its robust safety features. This converter produces an output voltage of 150 volts and can deliver a maximum current of 200 mA. Safety is ensured through the use of a transformer with a 13:115 turns ratio. The flyback circuit is regulated by the TL494 IC, operating at a switching frequency of 50 kHz, and employs a constant voltage with pulse width modulation (PWM) controller. This configuration ensures stable and reliable power delivery while maintaining stringent safety standards [40].

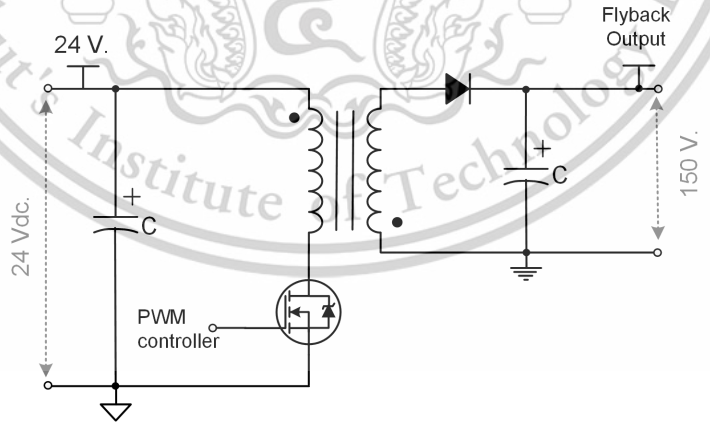


Figure 3.29 The flyback converter circuit

The actual schematic of the proposed driving stage unit implementation is depicted in Figure 3.30. This figure provides a detailed illustration of the circuitry and components involved in achieving the desired voltage-to-current conversion.

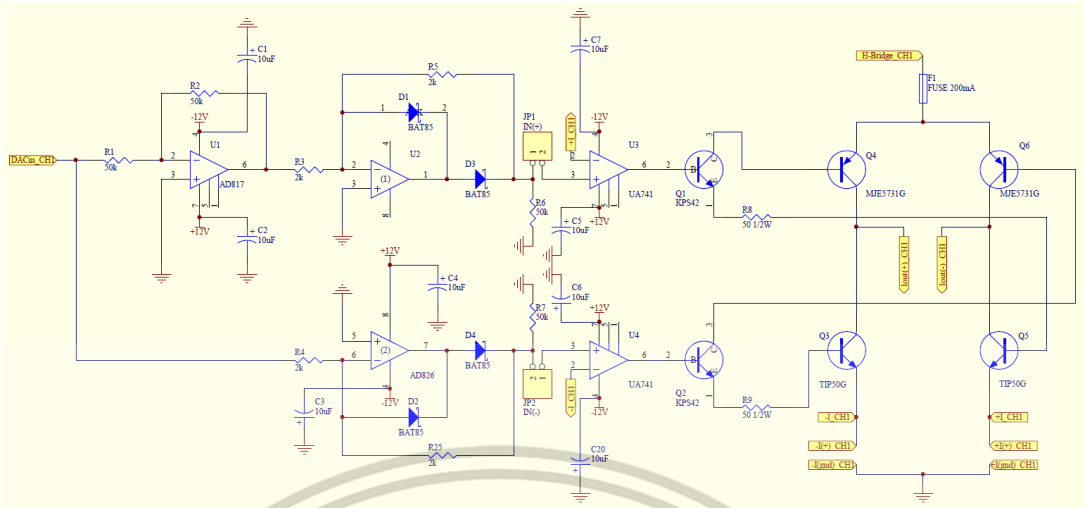


Figure 3.30 The actual schematic of the proposed driving stage unit

3.5 PROTECTION AND SAFETY CONSIDERATIONS

The unit is responsible for ensuring the safety and well-being of patients or users. It monitors real-time input signals from the patient electrodes and sends to (A) for real-time analysis and appropriate actions. It is designed to prevent potentially unsafe conditions during ES operation, which could occur due to various causes; for example, the detachment of electrodes during use, inadequate contact between electrodes and human skin, or other electrical circuit malfunctions/faults. This unit was designed such that if either overvoltage/overcurrent problems or electrical faults occur, the unit will transmit logic 0 to (A), resulting in stopping operation of the entire ES device to assure the patient safety.

As shown in Figure 3.31, a voltage divider is connected to a voltage follower circuit, which serves to stabilize the signal and prevent any loading effects from the subsequent stages. The stabilized signal is then sent to a differential amplifier, which accurately calculates the difference in voltage between the two inputs. This differential voltage represents the potential difference across the electrodes, which is crucial for detecting any abnormalities. Once the differential voltage is obtained, it is converted into a direct current (DC) signal by a peak detector circuit, as illustrated in Figure 3.32. The peak detector captures the maximum voltage level, ensuring that any sudden spikes or abnormalities are recorded. Finally, the processed signal is sent to the microcontroller for further analysis. The microcontroller then evaluates this signal to verify whether the device is operating correctly, ensuring that the electrodes maintain proper contact and that no unsafe conditions are present during treatment.

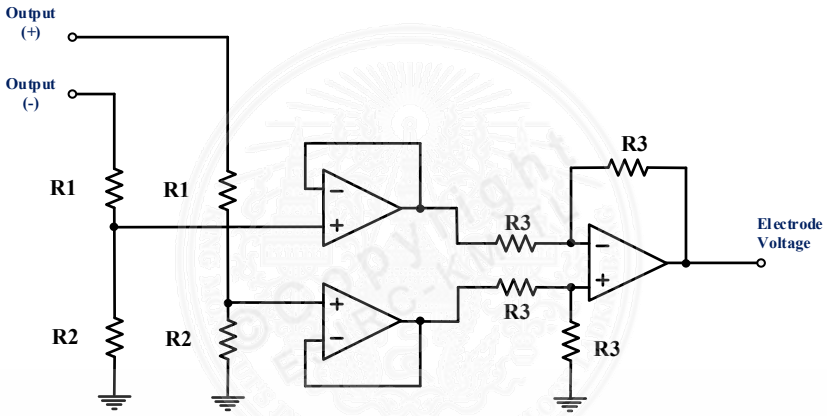


Figure 3.31 Differential voltage detector in this design

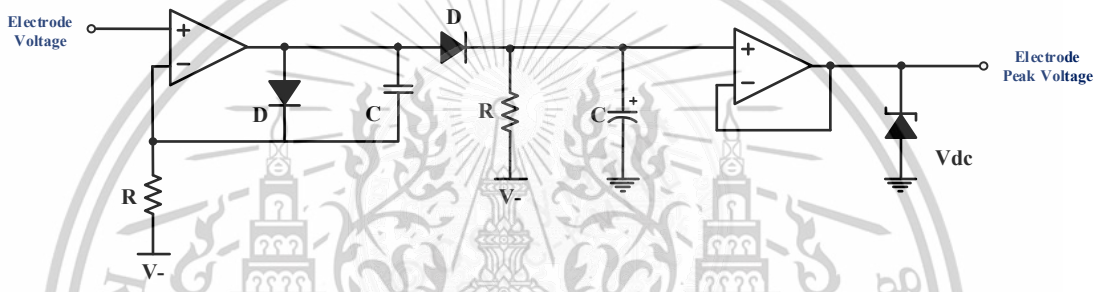


Figure 3.32 Peak detector circuit in this design

3.6 PROPOSED TARGET OUTPUTS

In this section, we provide a brief definition and description of the essential waveforms and special functions that form the foundation of the proposed ES device. These target outputs were carefully selected based on the recommendations and requests gathered from a preliminary survey of a large group of local physiotherapists and rehabilitation doctors. Their input has shaped the design to ensure that the device meets the practical needs of therapeutic applications. Specifically, the twelve essential waveforms identified in the survey will serve as mandatory output options for this device.

A key advantage of our design, which leverages in-house technology, proprietary algorithms, and a versatile hardware configuration, is its flexibility for future expansion. Should additional therapeutic waveforms or specialized output current requirements arise, the system can be easily modified to accommodate more than the initial twelve waveforms. Furthermore, the adjustability of both existing and future waveforms can be expanded as needed, ensuring that the design remains adaptable to evolving clinical demands.

3.6.1 Twelves Essential Waveforms [22, 27, 28, 30, 41]

3.6.1.1 Interrupted Galvanic (IG) Waveform

The IG waveform is a direct current (DC) that is periodically interrupted, producing a series of short pulses. This waveform is particularly beneficial for deep tissue stimulation and is effective in inducing muscle contractions. It is commonly used for rehabilitating paralyzed muscles and improving blood circulation, making it ideal for patients with muscle atrophy or peripheral nerve injuries. The IG waveform promotes better muscle tone and enhances tissue oxygenation, which aids in recovery and rehabilitation. The waveform shapes are illustrated in Figure 3.33.

Figure 3.33 The waveform shapes of GC

3.6.1.2 Continuous Galvanic (CG) Waveform

The CG waveform consists of a continuous, unmodulated direct current (DC). It is primarily used for pain relief in chronic conditions such as arthritis and inflammatory diseases. The continuous nature of the CG waveform helps reduce inflammation, and it is also utilized in iontophoresis treatments, where it facilitates the delivery of medications into tissues. This targeted approach provides localized therapeutic effects, making CG an effective solution for patients requiring pain management and anti-inflammatory therapy. The waveform shapes are illustrated in Figure 3.34.

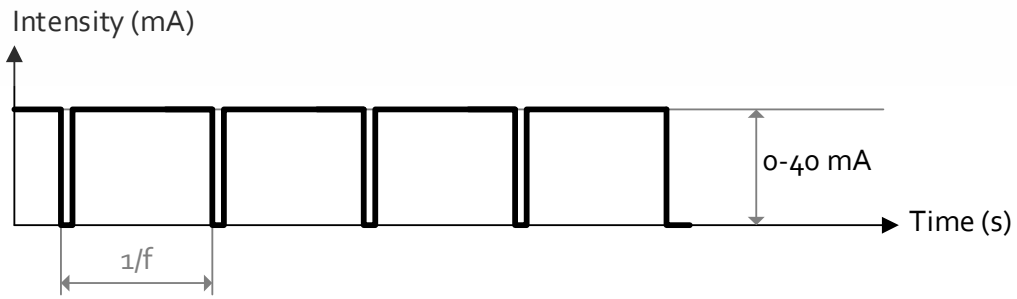


Figure 3.34 The waveform shapes of GI

3.6.1.3 Monophase Fixed (MF) Waveform

The MF waveform is a single-phase, rectified sinusoidal current with a frequency of 50 Hz. Its consistent, unidirectional current reduces skin resistance, allowing deeper tissue penetration. This makes the MF waveform especially useful for pain relief in deep muscles and muscle strengthening. It is frequently employed in the treatment of patients with muscle weakness or those recovering from injury, as it delivers targeted stimulation to the affected muscle groups. The waveform shapes are illustrated in Figure 3.35.

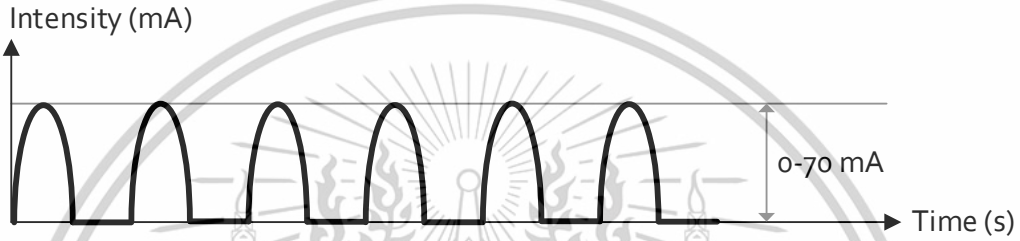


Figure 3.35 The waveform shapes of MF

3.6.1.4 Diphase Fixed (DF) Waveform

The DF waveform features a dual-phase, rectified sinusoidal current with a frequency of 100 Hz. By alternating between positive and negative phases, the DF waveform ensures balanced muscle stimulation. It is highly effective for pain relief, improving circulation, and treating muscle spasms. This waveform is particularly useful in post-operative recovery, as it reduces pain while promoting faster muscle recovery and rehabilitation. The waveform shapes are illustrated in Figure 3.36.

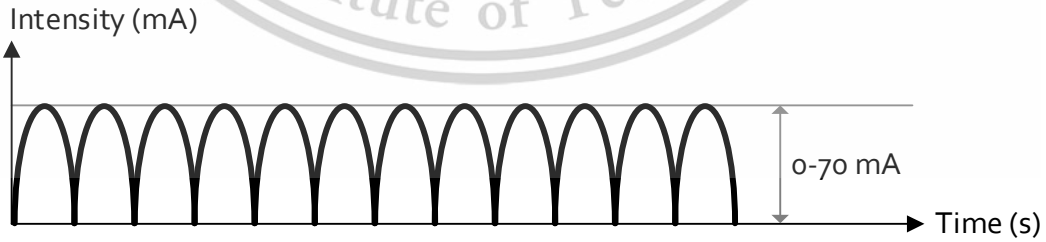


Figure 3.36 The waveform shapes of DF

3.6.1.5 Courted Period (CP) Waveform

The CP waveform alternates rapidly between one second of Monophase Fixed (MF) current and one second of Diphase Fixed (DF) current. This alternating current is highly effective for muscle re-education and strengthening, as it generates consistent muscle contractions without causing discomfort. The CP waveform is particularly beneficial for patients recovering from stroke or neurological injuries, as it supports muscle recovery without excessive fatigue. The waveform shapes are illustrated in Figure 3.37.

Figure 3.37 The waveform shapes of CP

3.6.1.6 Courted Period Iso-Dynamic (CPid) Waveform

Similar to the CP waveform, the CPid waveform alternates between MF and DF cur-rents, but with the MF phase having 12.5% lower amplitude than the DF phase. This con-figuration helps to prevent muscle fatigue while providing intermittent muscle contrac-tions, making the CPid waveform ideal for muscle strengthening and functional rehabili-tation. It is commonly used in neuromuscular training, where controlled and alternating stimulation is required for effective recovery. The waveform shapes are illustrated in Figure 3.38.

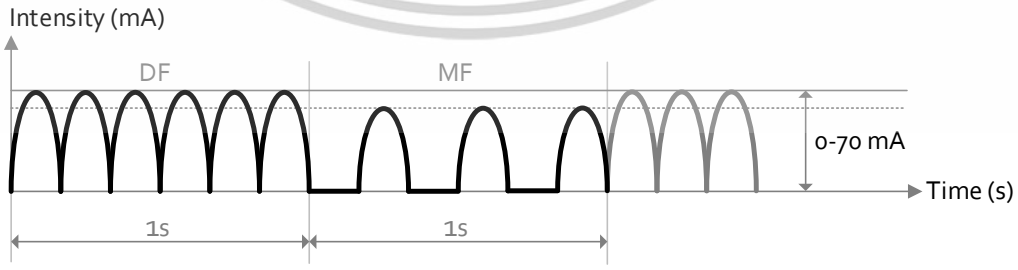


Figure 3.38 The waveform shapes of CPid

3.6.1.7 Long Period (LP) Waveform

The LP waveform alternates between six seconds of Monophase Fixed (MF) current and six seconds of Diphase Fixed (DF) current. During the DF phase, additional pulses with gradually increasing and decreasing amplitude are introduced. This gradual modulation makes the LP waveform particularly useful for activating larger muscle groups, such as those in the legs and back. It is highly beneficial for lower limb rehabilitation, posture correction, and spinal cord injury recovery, as it provides deeper and more sustained stimulation. The waveform shapes are illustrated in Figure 3.39.

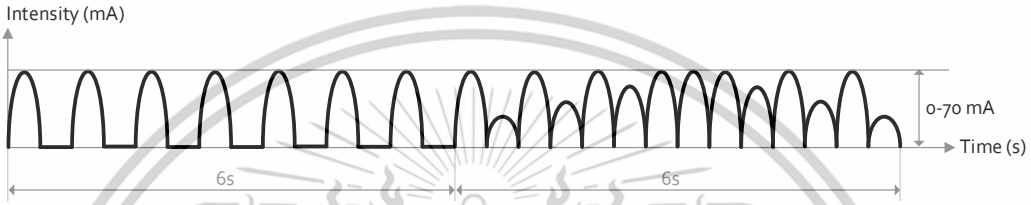


Figure 3.39 The waveform shapes of LP

3.6.1.8 Triangular Faradic (TF) Waveform:

The TF waveform is a saw-tooth shaped current with adjustable parameters for amplitude, duration, and frequency. Its gradual rise and fall pattern provide a smooth stim-ulation, which is particularly effective for muscle re-education and tissue healing. This waveform is ideal for patients recovering from injury or surgery, where muscle strength needs to be regained gradually and progressively. The waveform shapes are illustrated in Figure 3.40.

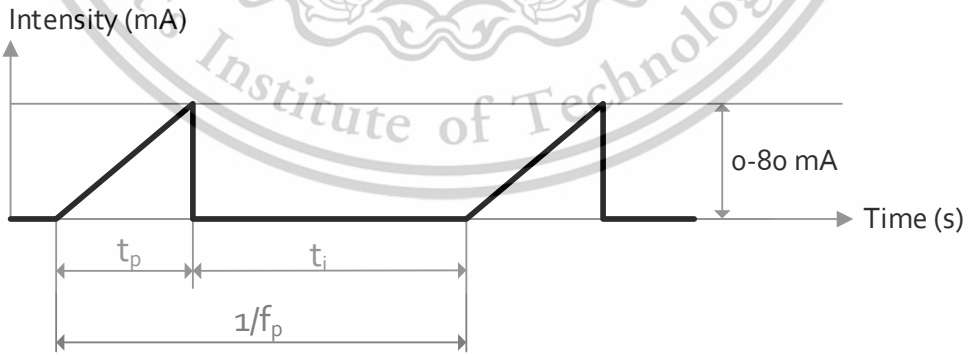


Figure 3.40 The waveform shapes of TG

3.6.1.9 Rectangular Faradic (RF) Waveform

The RF waveform is a rectangular-shaped pulsed current with adjustable settings for amplitude, duration, and frequency. It is commonly used for targeted muscle stimulation and nerve activation, particularly in Functional Electrical Stimulation (FES). The RF waveform helps restore movement in patients with neurological disorders such as stroke or multiple sclerosis by delivering precise, controlled stimulation to specific muscle groups. The waveform shapes are illustrated in Figure 3.41.

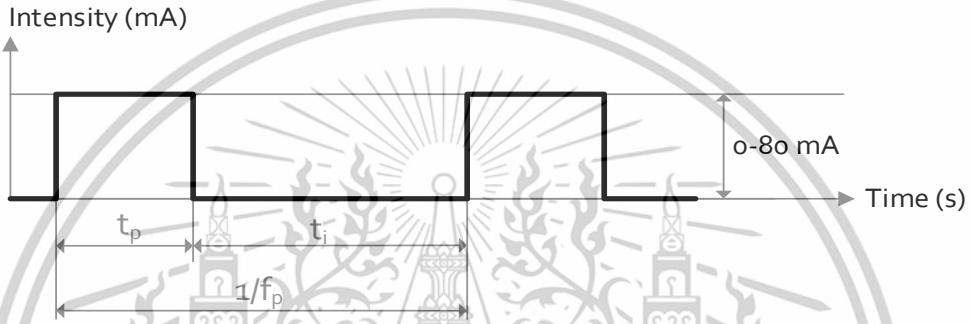


Figure 3.41 The waveform shapes of RT

3.6.1.10 Asymmetrical (ASYM) Waveform

The ASYM waveform is particularly effective for preventing muscle fatigue and improving endurance during long-term therapy. The asymmetrical pulse reduces skin irritation, making it suitable for patients who require chronic pain management or muscle rehabilitation over extended periods. Its gentle, continuous stimulation helps sustain therapy without causing discomfort. The waveform shapes are illustrated in Figure 3.42.

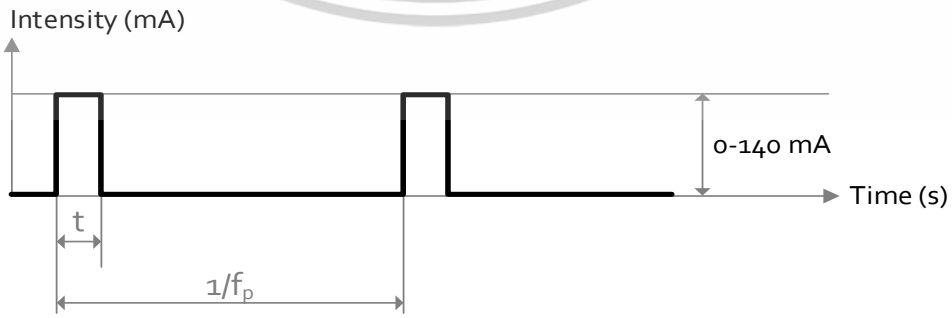


Figure 3.42 The waveform shapes of ASYM

3.6.1.11 Asymmetrical Alternating (ASYM-A) Waveform

The ASYM-A waveform is a biphasic, asymmetrical pulsed current that provides greater control over the intensity of stimulation. This waveform is beneficial for gradual muscle strengthening and preventing muscle atrophy. It is particularly effective in progressive rehabilitation programs, as clinicians can adjust the intensity and balance of the pulses as the patient's muscle strength improves over time. The waveform shapes are illustrated in Figure 3.43.

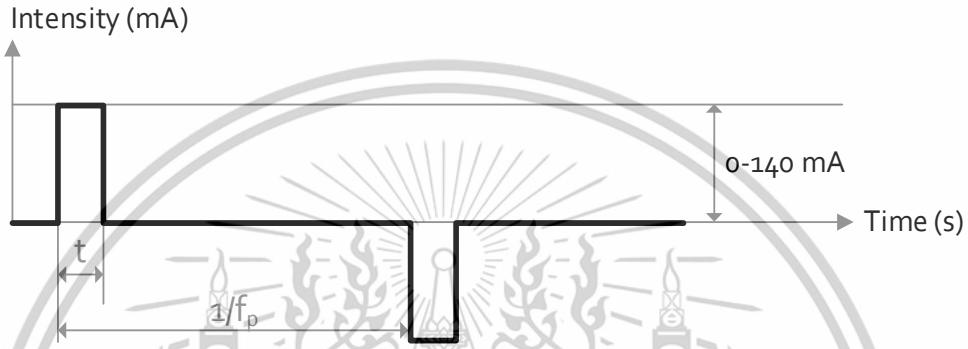


Figure 3.43 The waveform shapes of ASYM-A

3.6.1.12 Symmetrical (SYM) Waveform

The SYM waveform is a biphasic, symmetrical pulsed current that ensures equal stimulation across muscle groups. This balanced stimulation reduces the risk of muscle fatigue and tissue irritation, making it ideal for muscle reconditioning. The SYM waveform is commonly used in bilateral limb rehabilitation, where balanced muscle development on both sides of the body is crucial for recovery and overall functionality. The waveform shapes are illustrated in Figure 3.44.

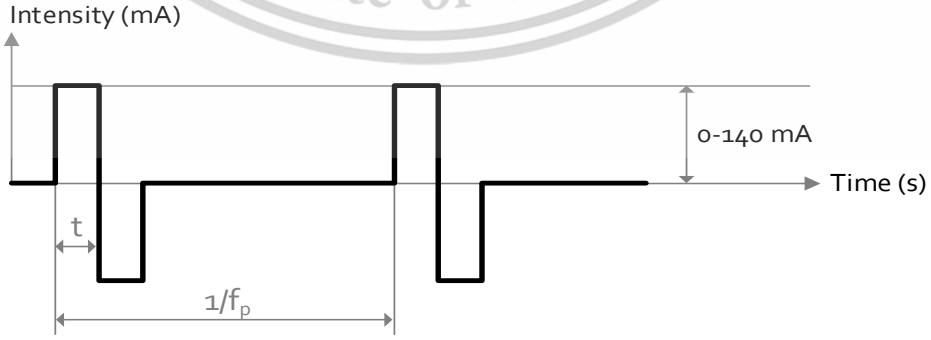


Figure 3.44 The waveform shapes of SYM

3.6.2 Two Special Functions

This section introduces the two special functions, Surge and Modulation, highlighting their importance and the added value they bring to standard therapeutic protocols. These functions are designed to enhance conventional therapy by providing more controlled and dynamic stimulation options, which in turn improve the flexibility and effectiveness of treatment.

Compared to standard therapy, the inclusion of Surge and Modulation significantly increases adaptability and patient comfort, potentially leading to improved therapeutic outcomes. These functions are particularly beneficial in personalized treatments, where static waveforms may not be as effective. While electrical stimulation devices without these features can still offer effective therapy, they often fall short in terms of comfort, adaptability, and long-term efficacy.

3.6.2.1 Surge Program [30, 41, 42]

The Surge program offers a gradual increase and decrease in intensity, allowing for more effective targeting of deeper tissues while minimizing abrupt changes in stimulation. This function is particularly advantageous for pain management and muscle stimulation, providing patients with a smoother and more comfortable therapeutic experience.

The program controls the timing of muscle contraction and relaxation by gradually adjusting the current intensity (amplitude) in a controlled pattern. This is achieved by defining specific time intervals: the Ramp-up time (t_r) for gradually increasing the current, the Hold time (t_h) for maintaining the current at a constant level, the Ramp-down time (t_f) for gradually decreasing the current back to zero, and the Interval time (t_i) for the rest period between current pulses. These characteristics are illustrated in Figure 3.45.

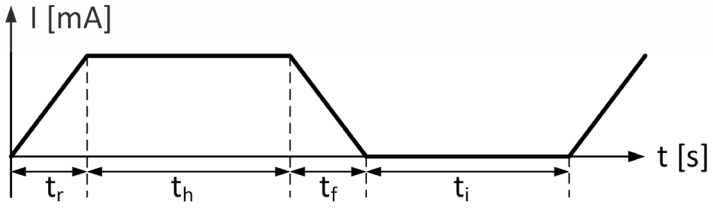


Figure 3.45 Surge program characteristic

3.6.2.2 Modulation Program [30, 41, 42]

The Modulation program introduces variations in the frequency or intensity of the current, preventing the body from adapting or habituating to the therapy. By maintaining the body's response to stimulation over extended periods, Modulation enhances the effectiveness of long-term treatments.

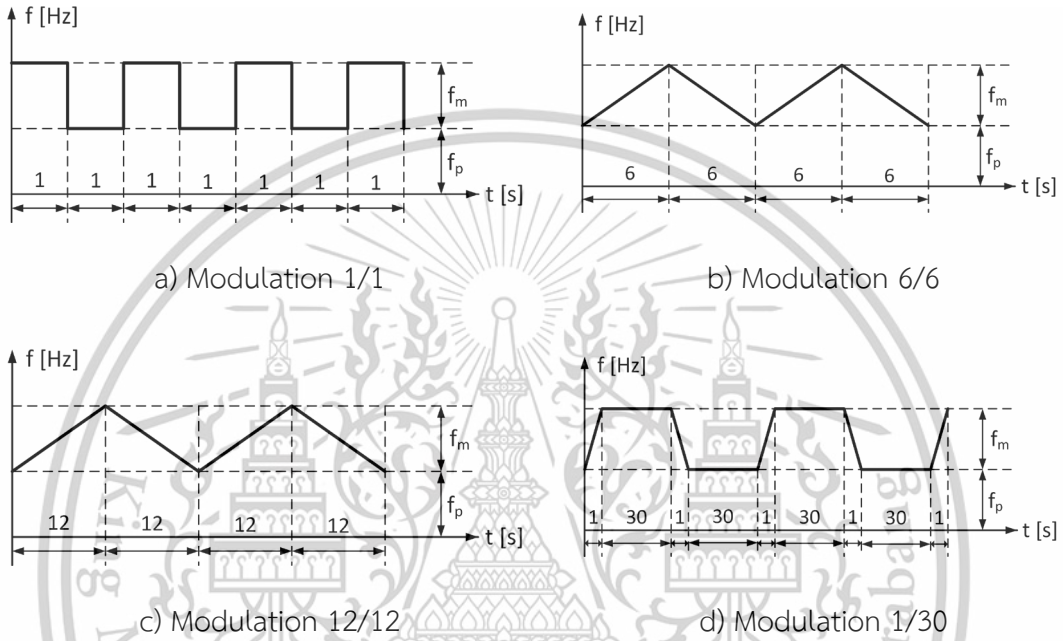


Figure 3.46 Modulation program characteristic

This program is commonly used to prevent nerve adaptation or to increase the patient's tolerance to the current by varying the waveform frequency over a defined period. The modulation frequency (Frequency Modulation: fm) alternates the current's frequency between the pulse frequency (fp) and the sum of the pulse frequency and modulation frequency (fm + fp) based on a predefined time pattern. Four modulation patterns are designed:

1. **1/1 Modulation**: The frequency starts at fm + fp for 1 second, then switches to fm for another 1 second, alternating throughout the treatment period. The characteristics are shown in Figure 3.46 (a).
2. **6/6 Modulation**: The frequency gradually transitions from fp to fm + fp over 6 seconds, then gradually returns to fp over the next 6 seconds, alternating back and forth during the treatment. The characteristics are shown in Figure 3.46 (b).

3. **12/12 Modulation**: The frequency gradually shifts from fp to fm + fp over 12 seconds, then gradually returns to fp over the next 12 seconds, repeating throughout the treatment. The characteristics are illustrated in Figure 3.46 (c).
4. **1/30 Modulation**: The frequency gradually changes from fp to fm + fp in 1 second and holds at fm + fp for 30 seconds. It then gradually returns to fp in 1 second and holds at fp for 30 seconds, alternating throughout the treatment period. The characteristics are depicted in Figure 3.46 (d).

These modulation patterns dynamically vary the frequency to prevent patient desensitization, thereby enhancing the overall effectiveness of the treatment.

The combination of essential waveforms and special programs results in more complex and diverse current patterns, providing greater flexibility in treatment. An example of the resulting current patterns is shown in Figure 3.47.

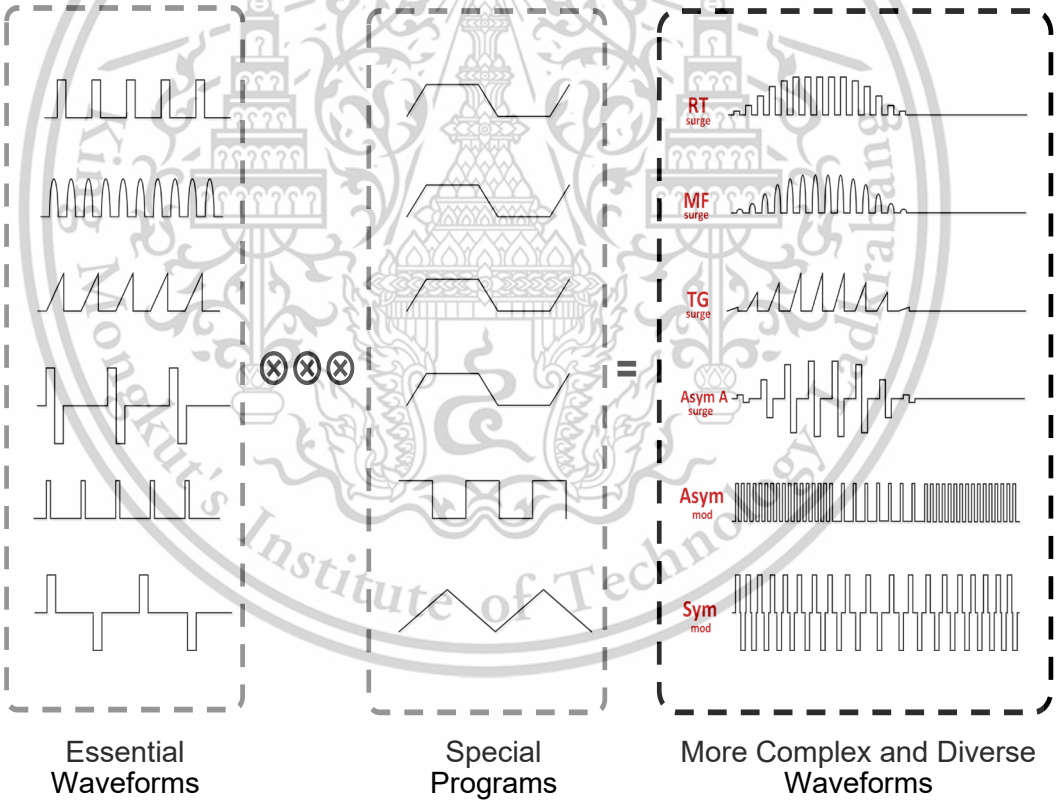


Figure 3.47 Examples of essential waveforms operation with special programs

3.7 DESIGN SPECIFICATIONS AND OPERATIONAL RANGES

Table 3.7 below presents the design specifications of the proposed ES device, offering a comprehensive overview of its capabilities. It highlights the intricate relationship between the device's adjustable parameters and their respective operational ranges. Given the device's twelve essential output current patterns, understanding these interactions is crucial for optimizing its performance. The table is structured to clarify how each parameter can be tuned within its specific limits, offering a detailed matrix that captures the nuanced relationships between the various output patterns and their respective adjustable ranges. This organized approach shown in Table 3.7 will help readers navigate the complexities of the proposed ES device's specifications and its operational ranges with greater ease and precision.

Table 3.7 Design specifications and operational ranges of the proposed es device

Output current patterns		Group	Operational ranges and its adjustability			Special functions availability	
			Pulse amplitude (mA)	Pulse duration (μs)	Pulse repetitive frequency (Hz)	Surge	Modulation
1	IG	Galvanic	0-40	-	-	-	-
2	CG		0-40	-	-	-	-
3	MF	Diadynamic	0-70	-	-	Yes	-
4	DF		0-70	-	-	Yes	-
5	CP		0-70	-	-	-	-
6	CPid		0-70	-	-	-	-
7	LP		0-70	-	-	-	-
8	TF	Faradic	0-80	20-1,000,000	0.2-1,000	Yes	Yes
9	RF		0-80	20-1,000,000	0.2-1,000	Yes	Yes
10	ASYM	TENS	0-140	20-400	1-200	Yes	Yes
11	ASYM-A		0-140	20-400	1-200	Yes	Yes
12	SYM		0-140	20-400	1-200	Yes	Yes

3.8 IMPLEMENTATION

The implementation of the proposed Electrical Stimulation (ES) system focuses on the integration and assembly of key components, leading to a fully functional device. This section describes the development process, from the design and testing of individual circuit components to the final assembly of the ES device.

3.8.1 Circuit Board Design and Integration

The integrated circuit board was designed to ensure the reliable functioning of each system component, including the pulse generator unit, user interface (UI), and driving stage unit. Each component was extensively tested for functionality, and the printed circuit board (PCB) layout was optimized for performance across different waveform settings. The boards were fabricated and assembled, followed by thorough testing to verify signal integrity and system reliability. Figure 3.48 illustrates the integrated circuit board.

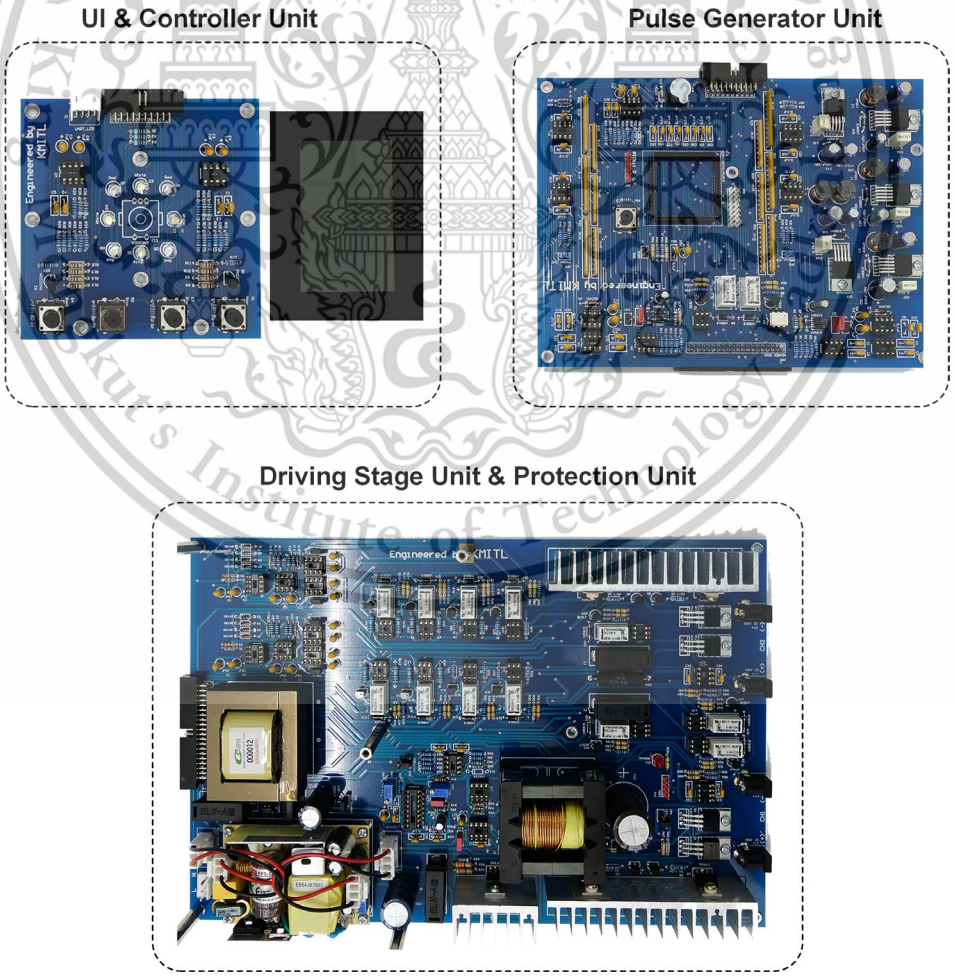


Figure 3.48 Integrated circuit board in this design

3.8.2 Graphical User Interface (GUI)

The GUI of the proposed ES device was designed with ease of use and intuitive interaction in mind. The interface allows users to seamlessly select waveforms, adjust stimulation parameters such as intensity and frequency, and start or stop the therapy session. Key feedback indicators are integrated into the display, providing real-time updates on therapy progress, safety notifications, and system status.

The GUI features large, clearly labeled buttons to enhance usability, making it accessible for clinicians and patients alike. The interface is optimized for touch interactions, ensuring that all critical controls are easy to navigate. Figure 3.49 shows an example of the GUI interface as displayed on the device, demonstrating options for waveform selection, parameter adjustment, and real-time feedback.

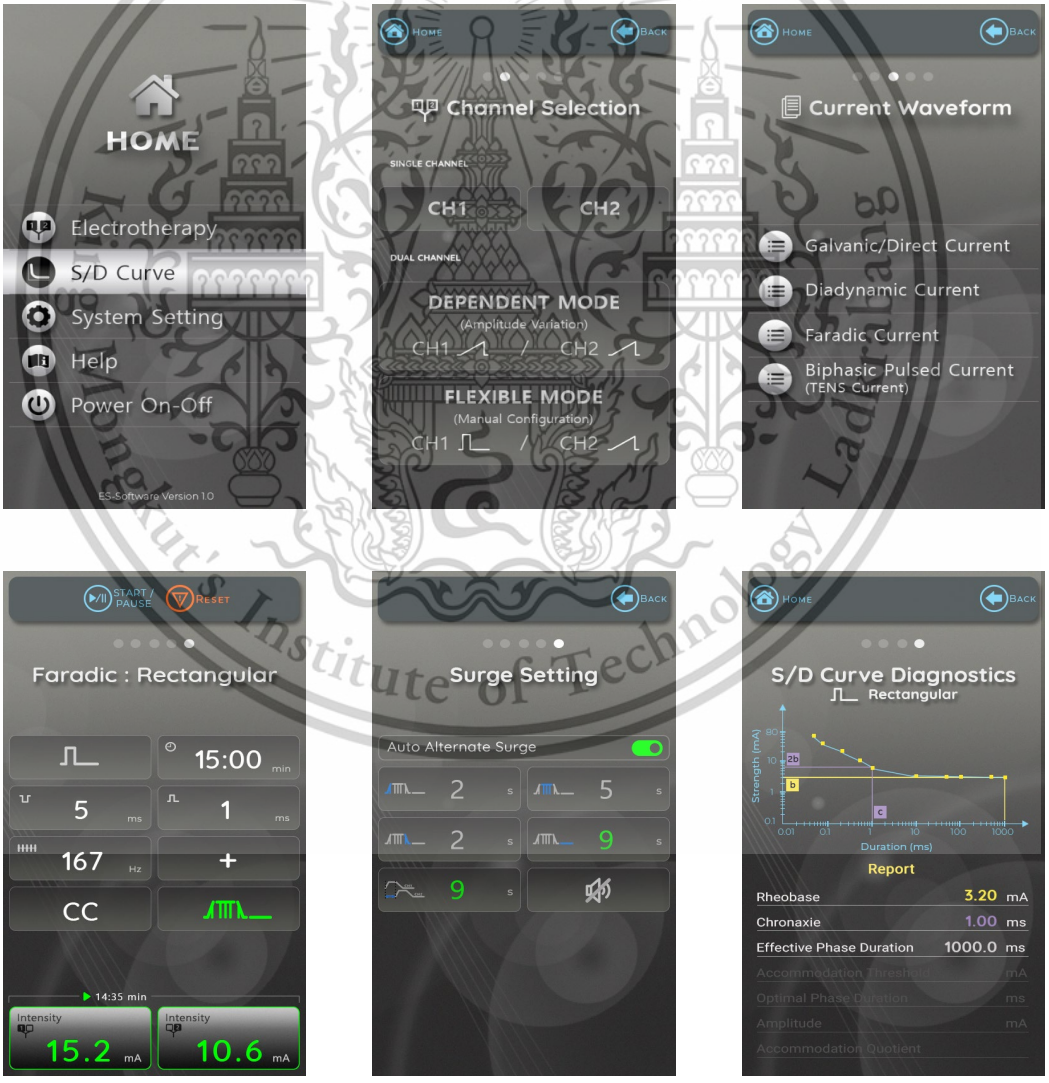


Figure 3.49 Examples of the GUI interface in this work

3.8.3 Industrial Product Design

3.8.3.1 Prototype Development

The prototype development phase involved transforming the electronic components and circuits of the ES device into a functional physical product. During this stage, the design focused on creating a 3D-printed casing to house the internal components, providing an initial model that could be tested for both functionality and user ergonomics. Special attention was given to the placement of the user interface elements, such as the touchscreen display, switches, and indicators, ensuring ease of use for clinicians. Figure 3.50 shows the 3D design of the prototype used in this work.

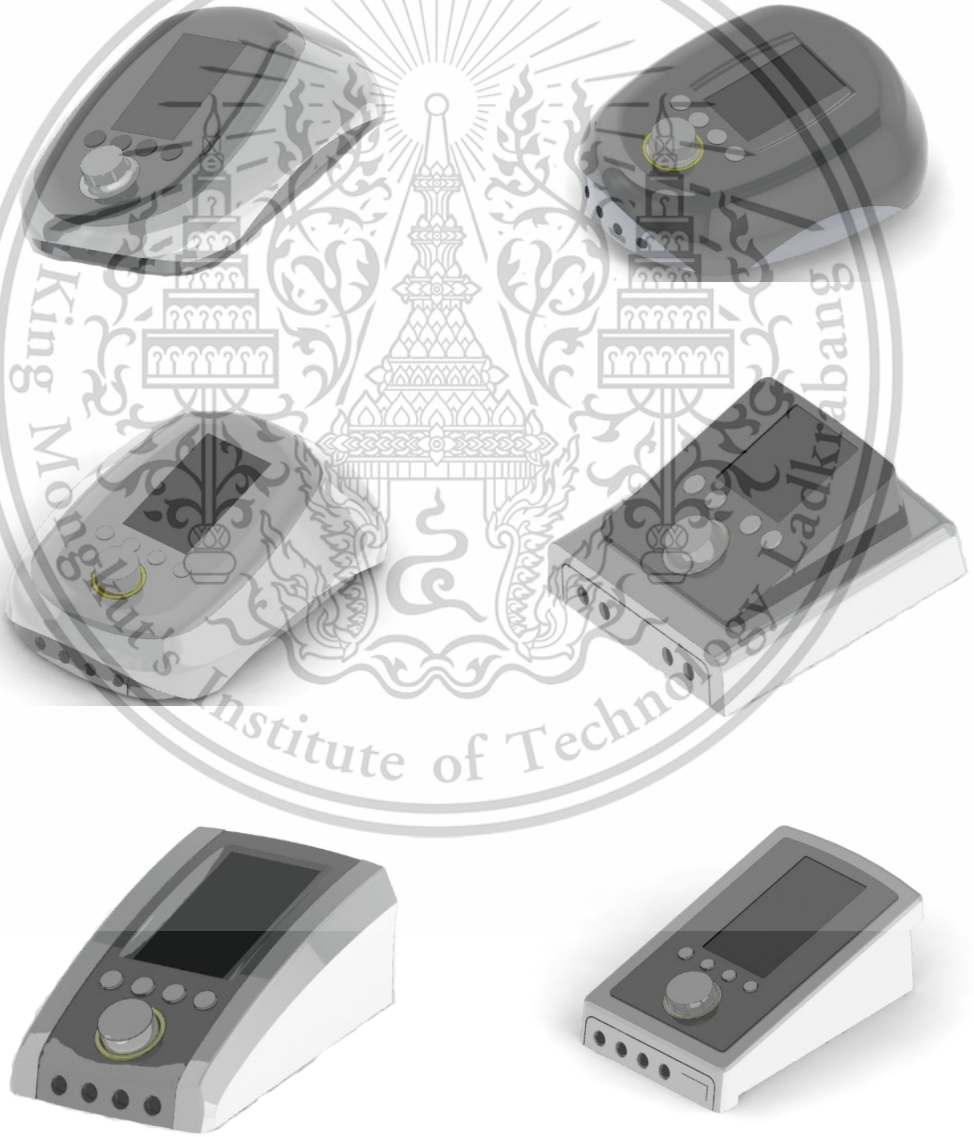


Figure 3.50 The 3D designs of the prototype developed in this work

3.8.3.2 Final Design

After refining the prototype based on testing and feedback, the final design phase aimed to produce a more polished, durable product ready for clinical use. The final version maintained the ergonomic and user-friendly features of the prototype but incorporated enhancements in material quality and structural integrity, ensuring the device could withstand long-term usage in medical environments. Figure 3.51 illustrates the final 3D design of the ES device in this work. These sections emphasize the transition from concept to a fully functional, ready-for-use medical device.

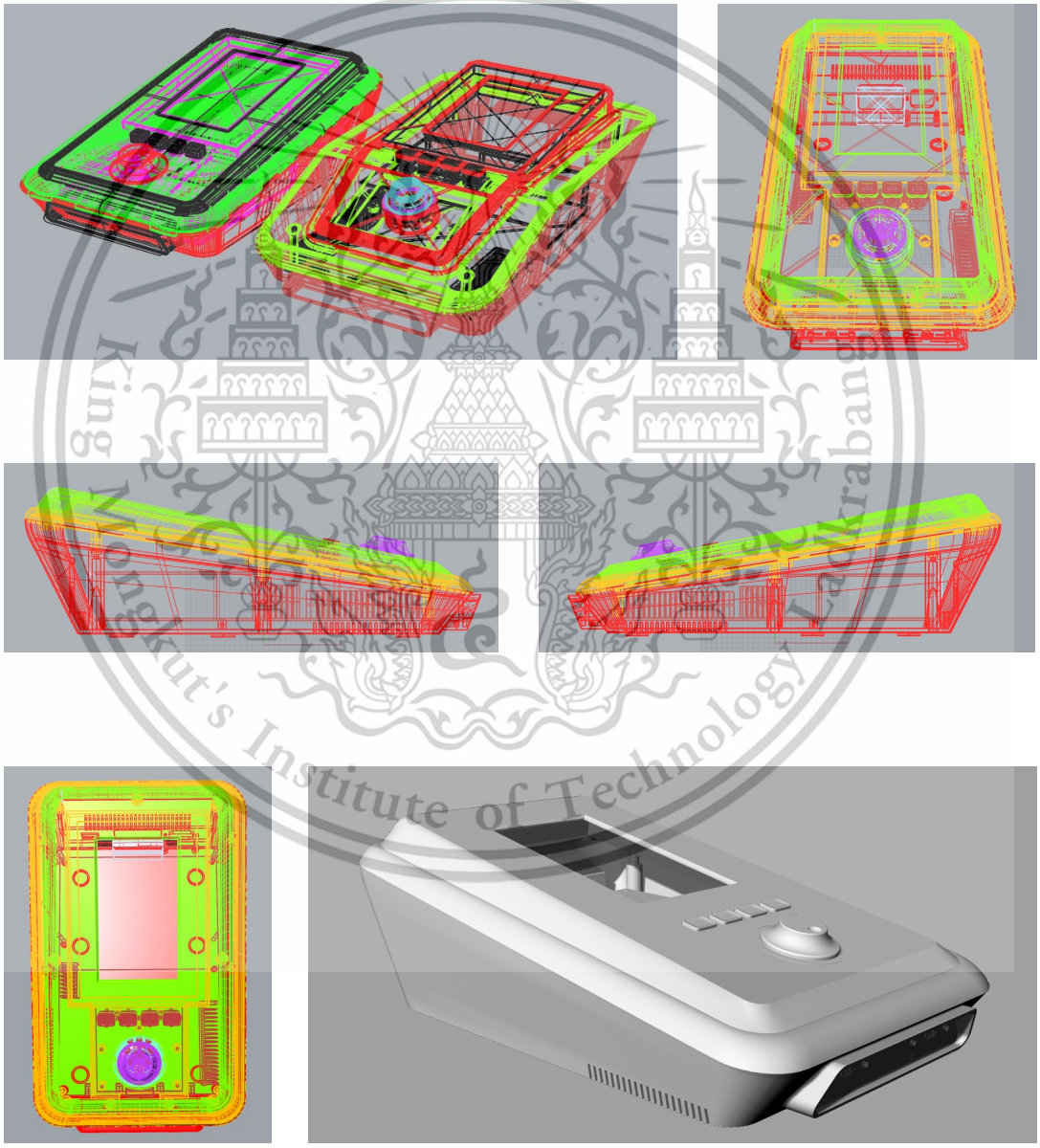


Figure 3.51 The final 3D design of the ES device in this work

3.8.4 Assemblying the Device

The final assembly process involved the integration of the circuit boards, power supply, and casing into a single operational unit. After assembly, the device was subjected to a series of operational tests to verify its functionality and performance under various conditions. This phase confirmed that the system met the design specifications, output accuracy, and user interface usability. Figure 3.52 shows the fully assembled ES device, ready for further testing and clinical validation.

Figure 3.52 Final assemblied ES device in this work

CHAPTER 4

EXPERIMENTS AND RESULTS

This section presents the experimental evaluation of the proposed ES device. The experiments had been designed to assess the device's performance across various critical dimensions, including its ability to generate diverse therapeutic waveforms, maintain precise and stable output currents, and adhere to stringent international standards for medical electrical equipment. The experimental setup was carefully configured to imitate several clinical conditions, ensuring that the experimental results obtained are meaningful and applicable to practical therapeutic treatment scenarios [6, 26]. The following sections provide a comprehensive assessment of the device's performance and reliability covering test configurations, output demonstration and accuracy, stability under variable load conditions, user interface testing, and compliance with the relevant IEC standards.

4.1 EXPERIMENTAL SETUP

The experimental setup, as illustrated in Figure 4.1, was meticulously configured to evaluate the performance of the proposed ES device across various tests. Figure 4.2 illustrates the actual experimental setup including all equipment used. The process begins with the pulse generator unit, which receives input configuration settings from the UI and controller unit. These settings are processed to generate voltage pulse signals, denoted as V_{Ra}, which are subsequently fed into the driving stage unit. The driving stage unit converts these voltage pulse signals into output currents I_{Out}, which are then delivered directly to a resistive load R, simulating the impedance of human tissue [1].

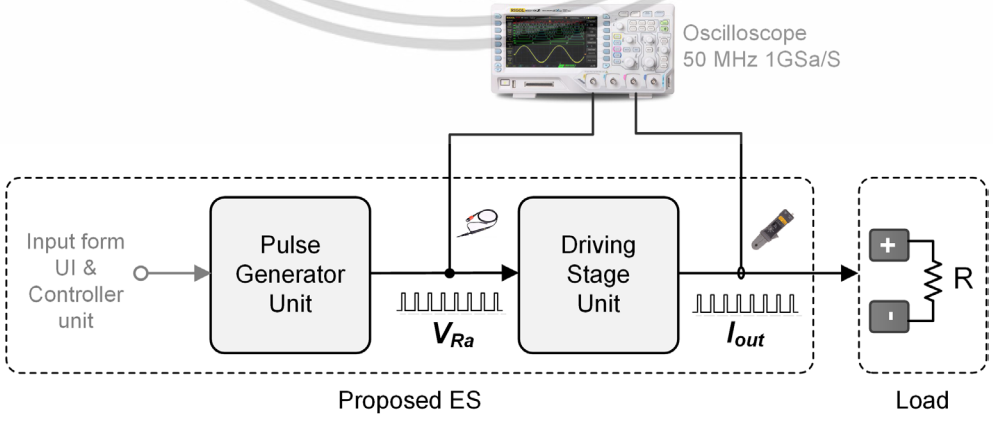


Figure 4.1 The experimental configuration diagram

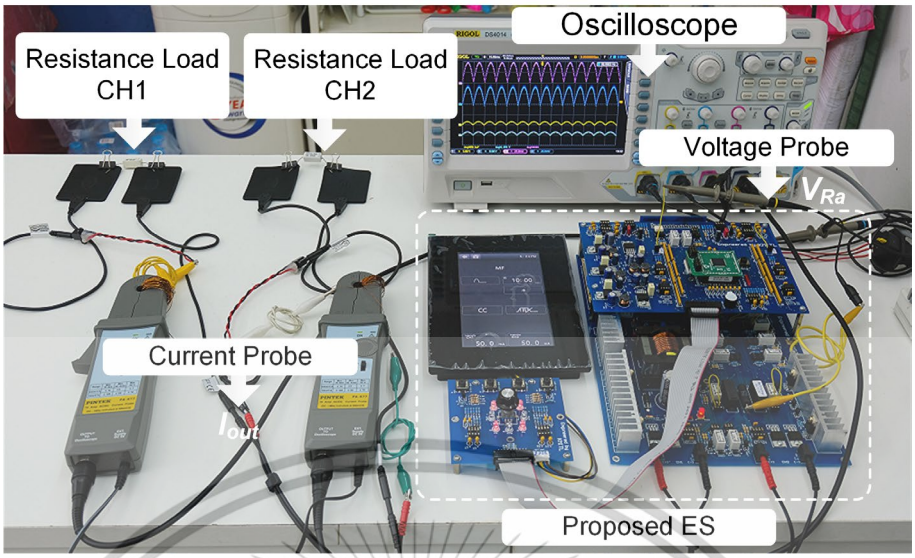


Figure 4.2 The actual experimental setup

4.2 DEMONSTRATION OF PROPOSED ES OUTPUT CURRENTS

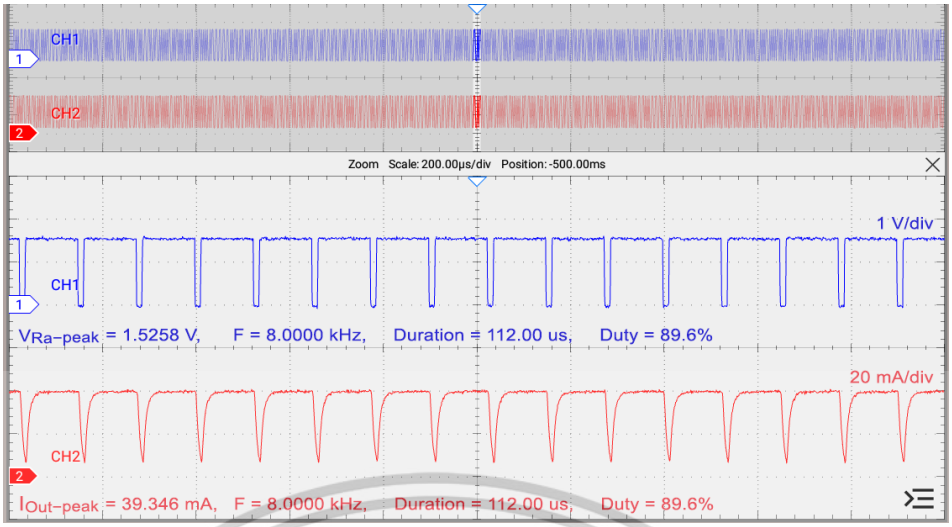
The main objective for this test is to demonstrate and evaluate capabilities of the proposed ES device in generating all twelve essential therapeutic output currents, including its adjustability and also two special functions (Surge and Modulation).

4.2.1 Essential Waveforms Demonstration

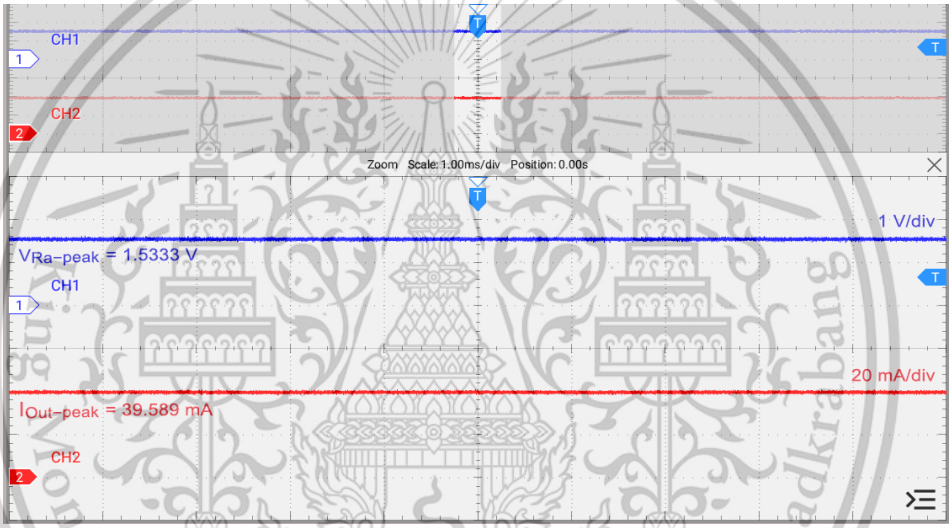
Figure 4.3 presents the experimental results where the proposed ES device was configured to deliver a constant 40 mA across each of the twelve essential current outputs (IG, CG, MF, DF, CP, CPid, LP, TF, RF, ASYM, ASYM-A, and SYM). The voltage signal, V_{Ra}, generated by the pulse generator unit, and the corresponding output currents, I_{Out}, produced by the driving stage unit, were captured via Channel 1 (blue) and Channel 2 (red) of the oscilloscope, respectively.

The results across all twelve sub-figures confirm the close alignment between V_{Ra} and I_{Out} waveforms, with consistent similarities in shape, pulse duration, and pulse repetitive frequency. Additionally, the current output amplitudes are precisely aligned with the gain as can be derived from Equation (3.4).

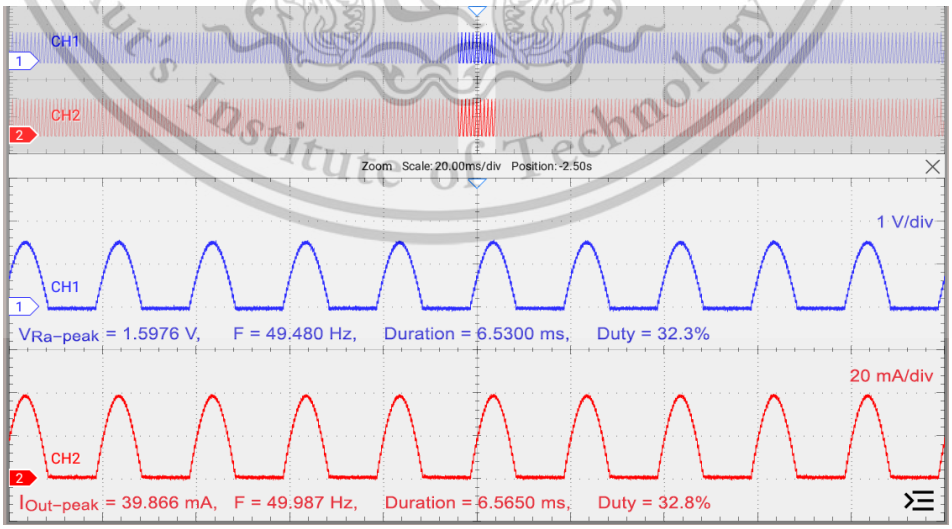
It is important to note that Figure 4.3 provides examples of each essential current output waveform. Given the wide range and variability of output adjustability, it is not feasible to display every possible variation of the twelve waveforms.



(a) IG

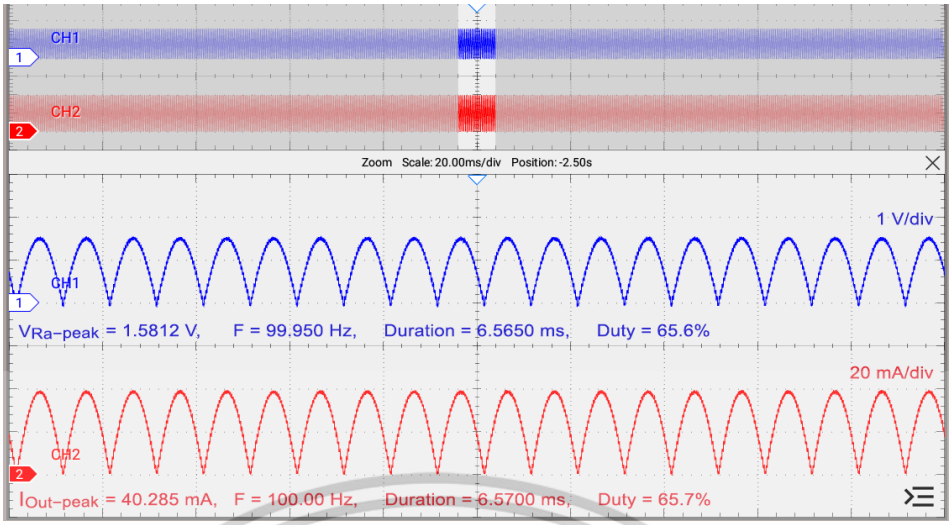


(b) CG

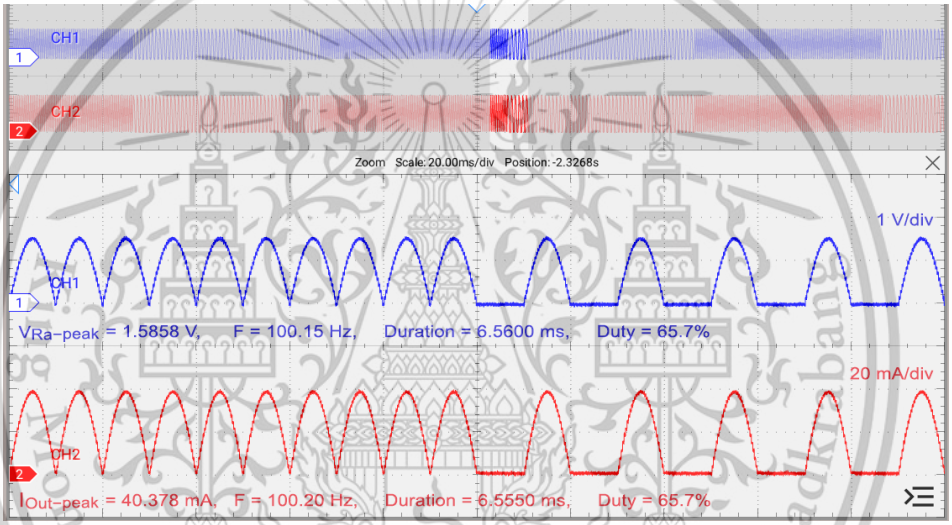


(c) MF

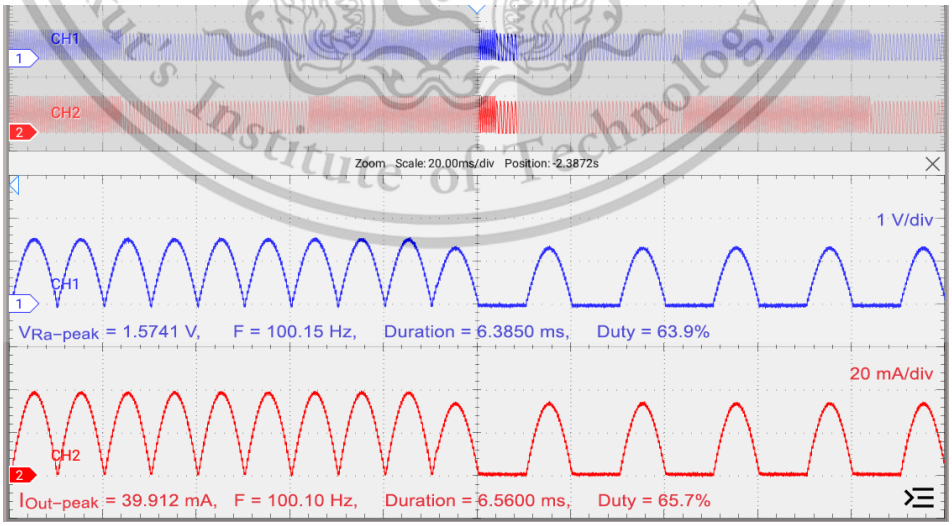
Figure 4.3 Demonstration of twelve essential output currents (IOut) compared to controlled voltage (VRa) of the proposed ES device



(d) DF

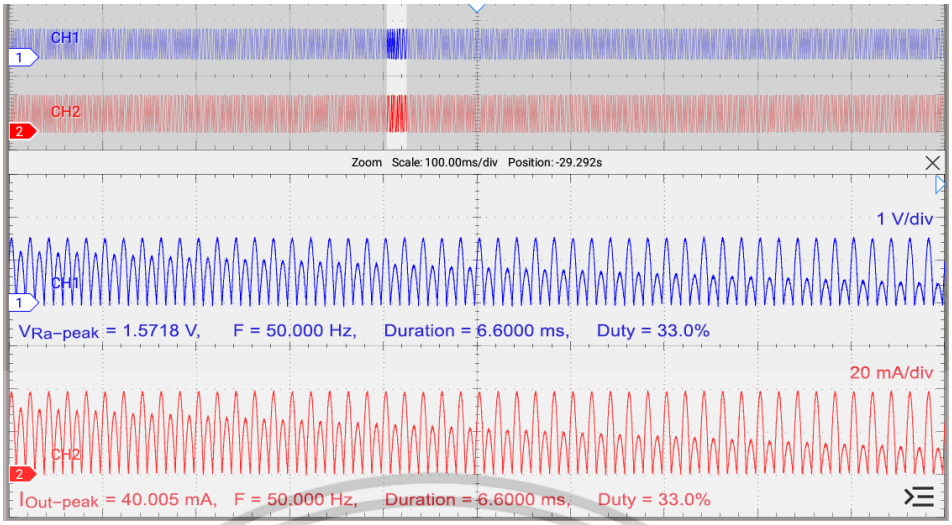


(e) CP

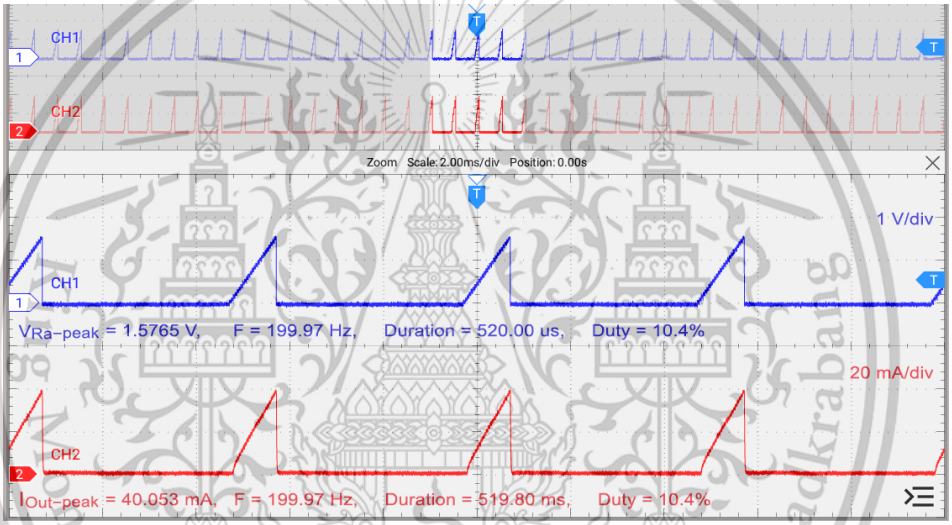


(f) CPid

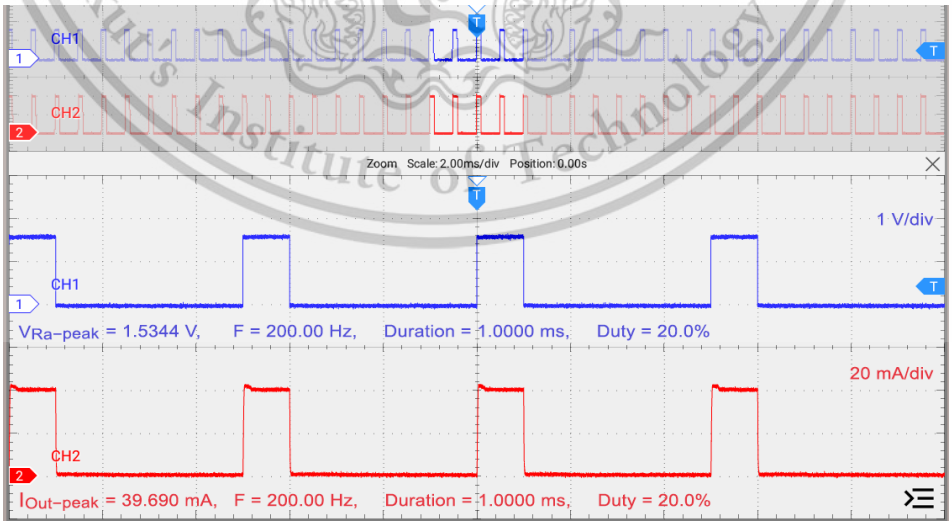
Figure 4.3 Demonstration of twelve essential output currents (IOut) compared to controlled voltage (VRa) of the proposed ES device (Cont.)



(g) LP

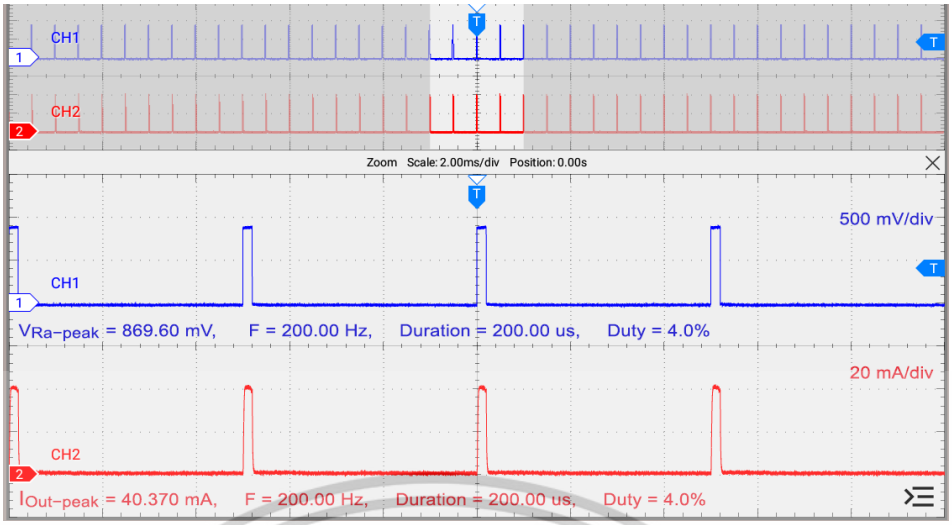


(h) TF

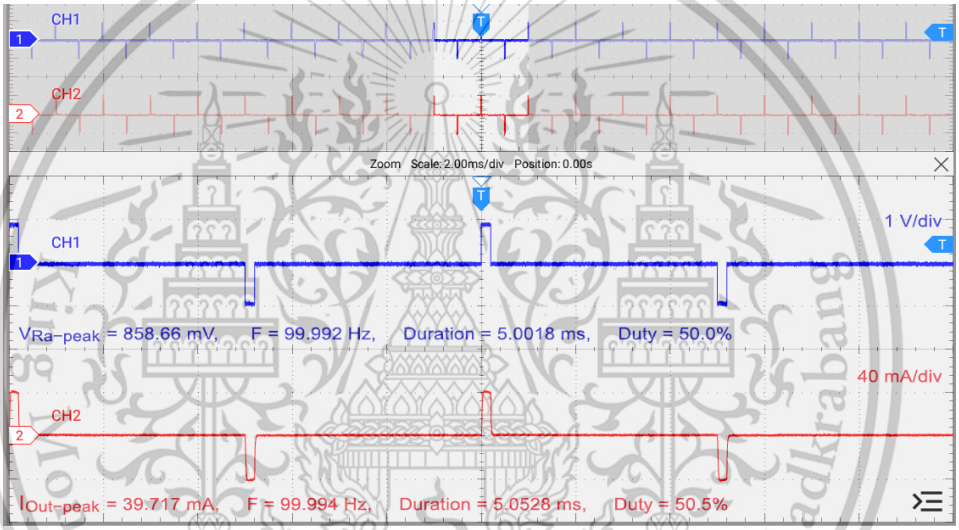


(i) RF

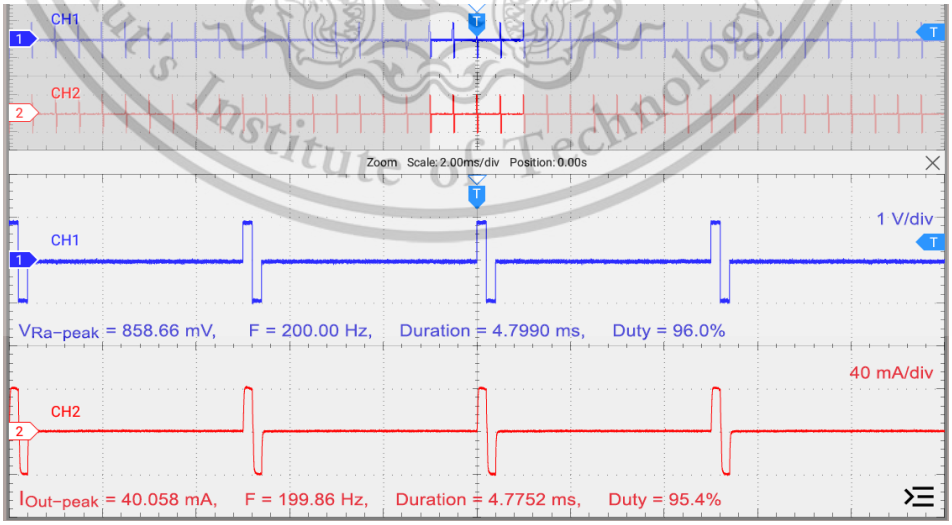
Figure 4.3 Demonstration of twelve essential output currents (IOut) compared to controlled voltage (VRa) of the proposed ES device (Cont.)



(j) ASYM



(k) ASYM-A



(l) SYM

Figure 4.3 Demonstration of twelve essential output currents (IOut) compared to controlled voltage (VRa) of the proposed ES device (Cont.)

4.2.2 Adjustability Demonstration

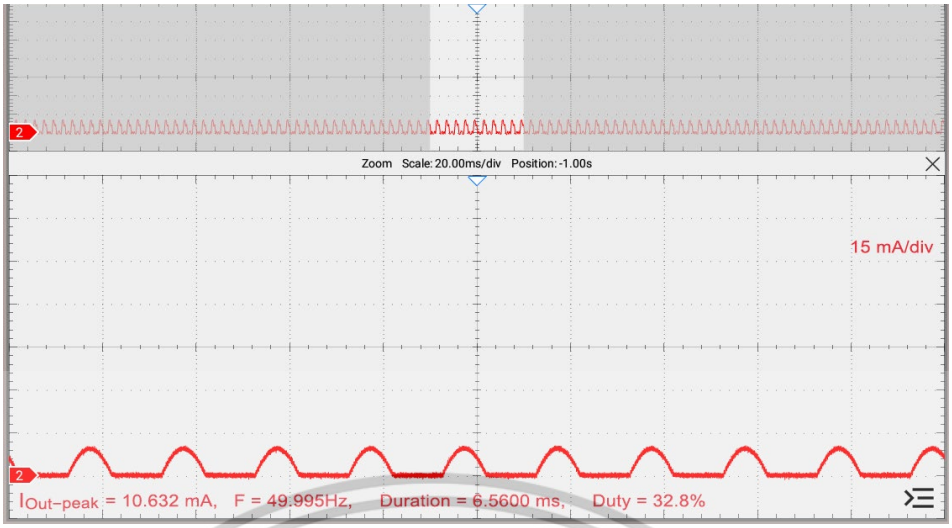
The experimental results presented in Figures 4.4 to Figure 4.6 highlight the performance of the proposed ES device across three main adjustable parameters, including pulse amplitude, pulse duration, and pulse repetitive frequency. These figures demonstrate the proposed ES device's ability to be precisely configured to achieve the target outputs for each parameter.

In Figure 4.4, the MF current pattern was selected as a representative of sinusoidal-based current signals, while the ASYM current pattern was chosen as a representative of pulse-based current signals to illustrate the pulse amplitude adjustability of the proposed ES device.

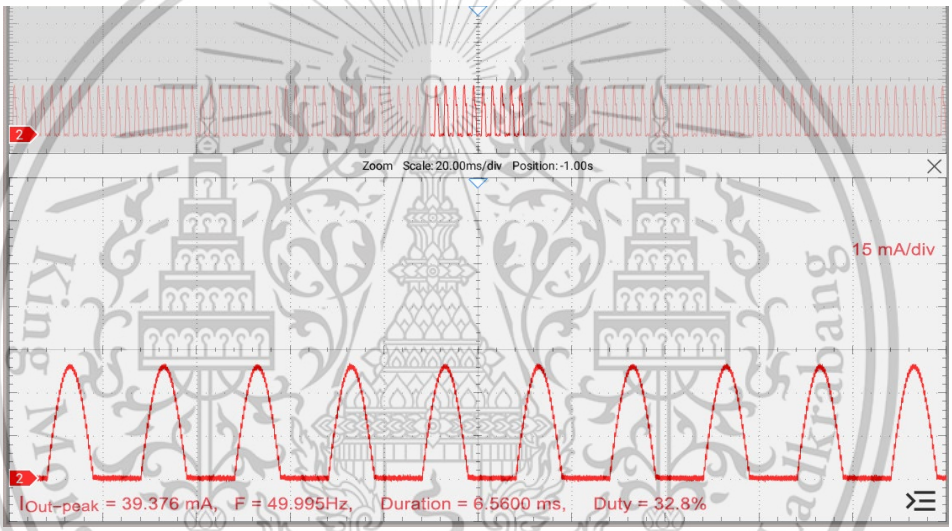
The target of output current amplitude was set at approximately 10%, 50%, and 100% of the rated output current for each pattern, with pulse duration and pulse repetitive frequency held constant. The experimental results confirm that the proposed ES device accurately generates the pulse amplitude as set for both sinusoidal-based and pulse-based output currents, with minimal to zero distortion in waveform shape, pulse duration, and pulse repetitive frequency.

In Figure 4.5, only the ASYM current pattern is used to demonstrate and validate the pulse duration adjustability of the proposed ES device. The sinusoidal-based current patterns were considered necessary only for amplitude adjustability, in alignment with actual clinical practice and the requirements of doctors and physiotherapists [22]. Pulse duration adjustability was tested and recorded at 50 µs, 500 µs, and 2,000 µs, with pulse amplitude and pulse repetitive frequency held constant. The experimental results confirm that pulse duration can be accurately adjusted and configured to meet a wide range of clinical needs.

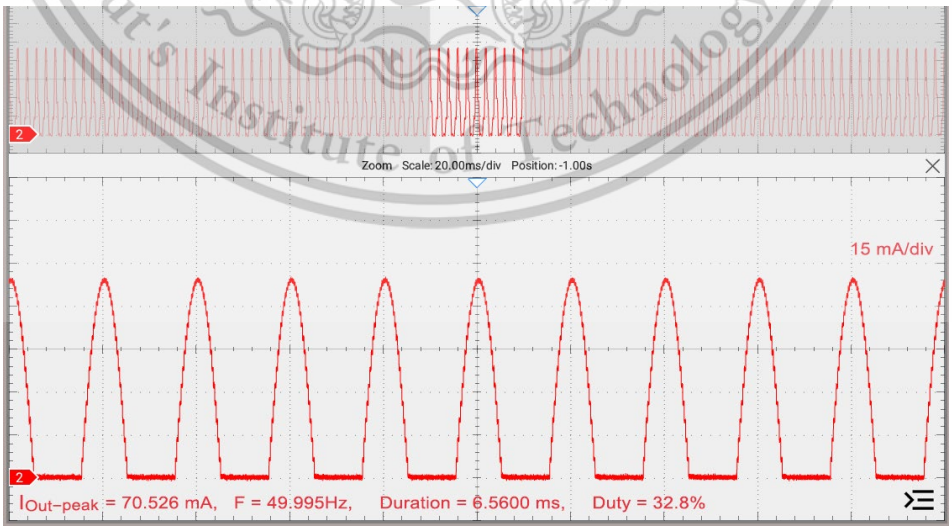
Figure 4.6 illustrates the experimental results for pulse repetitive frequency adjustability, using the RF current pattern as a representative at 50 Hz, 200 Hz, and 500 Hz. The experimental results verify that pulse repetitive frequency can be adjusted precisely without affecting the pulse amplitude or pulse duration, both of which were held constant.



(a) MF 10mA

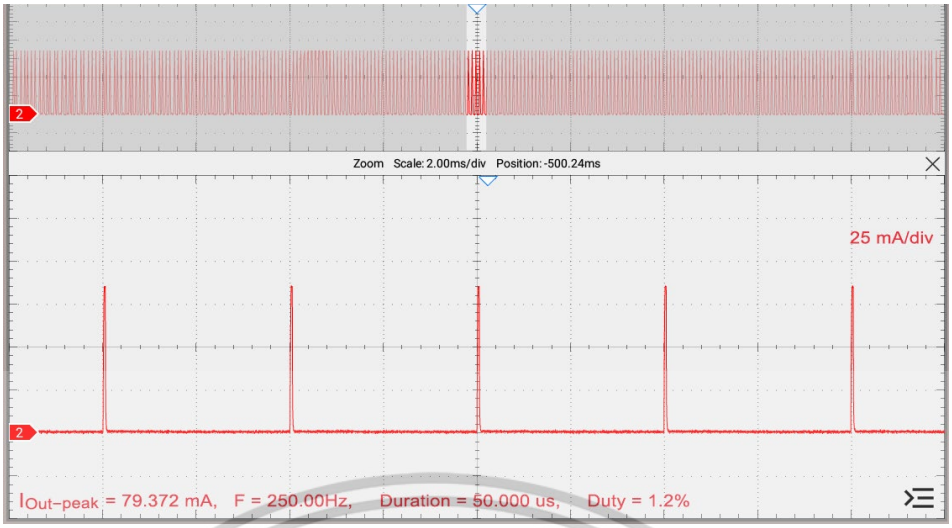


(b) MF 40mA

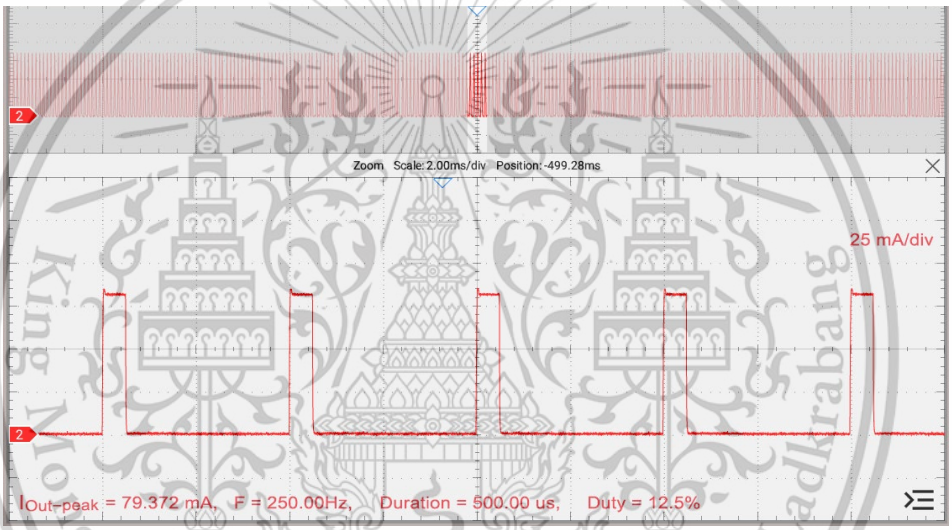


(c) MF 70mA

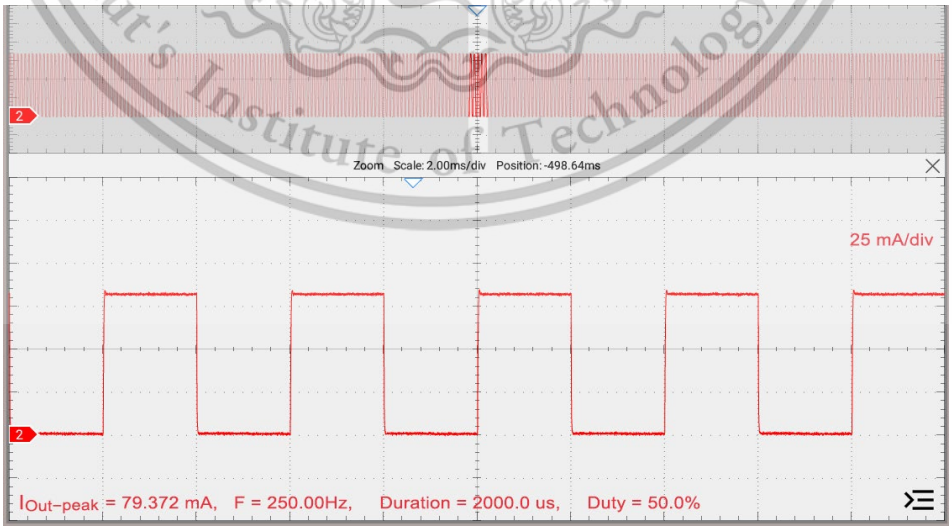
Figure 4.4 Demonstration of pulse amplitude adjustability



(a) ASYM 50 µs

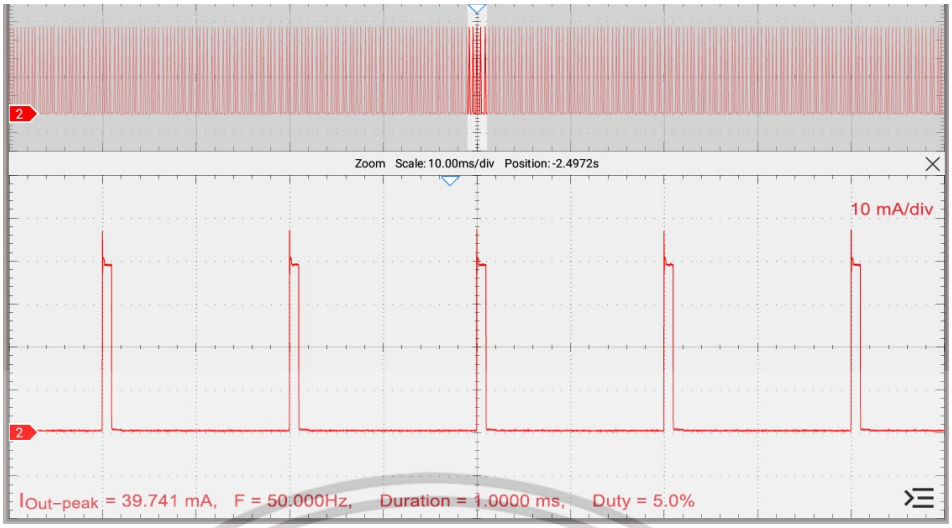


(b) ASYM 500 µs

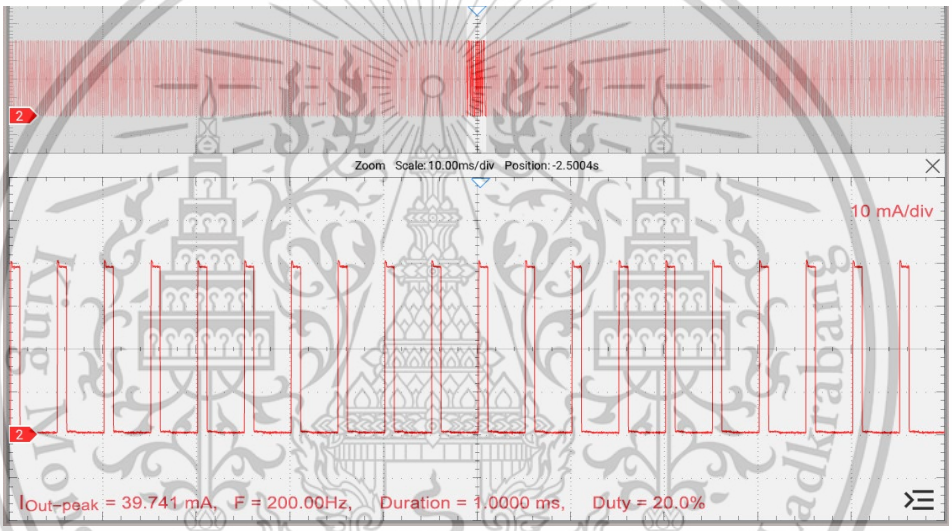


(c) ASYM 2,000 µs

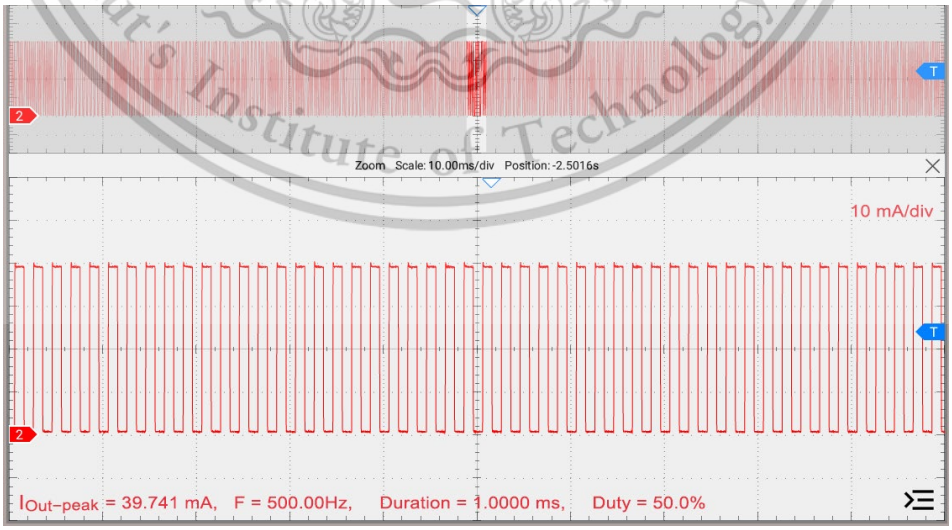
Figure 4.5 Demonstration of pulse duration adjustability



(a) RF 50 Hz



(b) RF 200 Hz

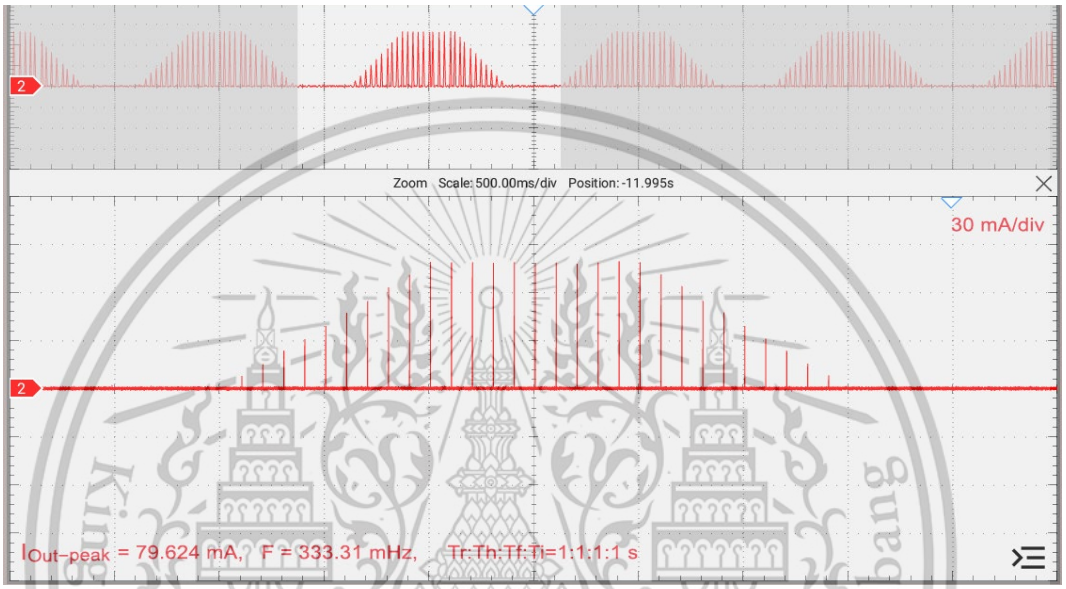


(c) RF 500 Hz

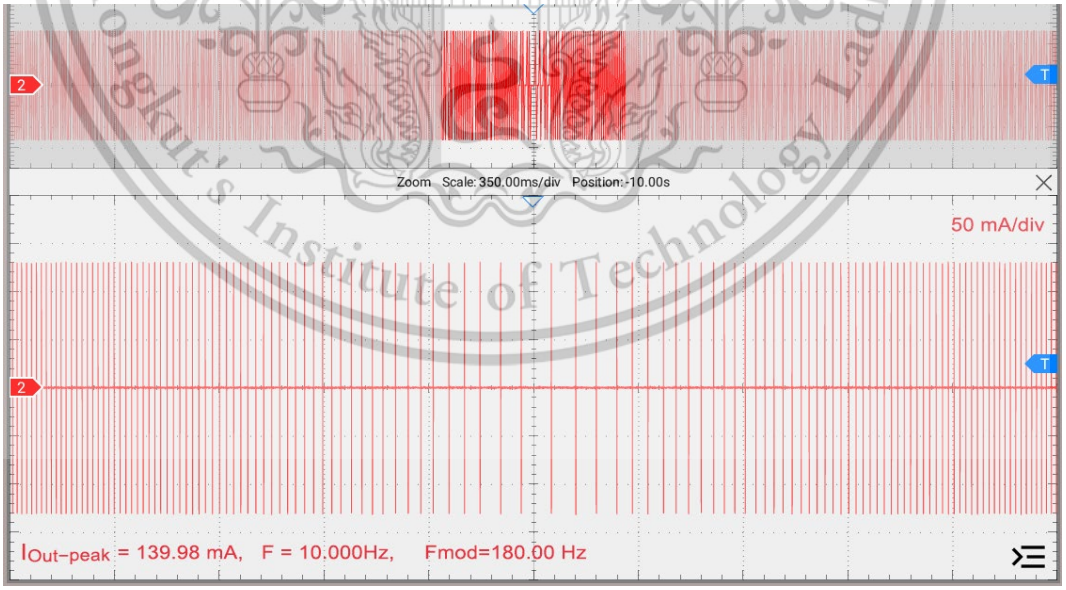
Figure 4.6 Demonstration of pulse repetitive frequency adjustability

4.2.3 Special Functions Demonstration

This experiment was conducted extensively across various modulated settings to ensure precise alignment and reliability in modulating each of the twelve essential output patterns using two special functions: Surge and Modulation. Figure 4.7 presents example results for some of these essential output waveform modulations achieved with the Surge and Modulation techniques.



(a) ASYM with Surge



(b) SYM with Modulation

Figure 4.7 Demonstration of two additional special functions for output currents.

4.3 OUTPUT ACCURACY VERIFICATION TEST

The experimental setup adhered to the guidelines outlined in Clause 201.12.1.102 of the IEC 60601-2-10 standard [33], which addresses the basic safety and essential performance requirements for nerve and muscle stimulators, specifically concerning pulse parameter accuracy control. The standard emphasizes that the accuracy of current outputs is critical for ensuring the safety and effectiveness of therapeutic applications. It specifies that pulse durations, pulse repetitive frequencies, and pulse amplitudes—including any DC components caused by offsets or asymmetrical waveforms—must not deviate by more than ±20% when measured with a specified load resistance. This tolerance is established to ensure that the proposed ES device functions within safe and effective parameters, thereby minimizing the risks associated with significant deviations in stimulation characteristics. The primary objective of this test was to verify that the proposed ES device consistently delivers the intended therapeutic output current across a range of test conditions and settings.

The testing procedure was conducted in three configurations: pulse amplitude test, pulse duration test, and pulse repetitive frequency test. Each stage focused on isolating a specific parameter while maintaining the other two parameters constant. Testing was performed across the entire operational range of each output current pattern, divided into ten incremental steps from the minimum to the maximum values within each range, using the specific load resistance specified in the standard. At each step, the output was measured, and the deviation percentage between the setting value and the measured value was calculated.

To evaluate the accuracy of the proposed method's output current in relation to the reference tolerance specified in the IEC 60601-2-10 standard, the percentage of deviation (similar to percentage of error) is a valuable metric [43, 44]. It helps quantify the difference between the output current and the reference value, providing a clear indication of how well the method adheres to the standard's tolerance requirements.

The percentage of deviation can be calculated as:

$$Percentage\ Deviation = \left(\frac{Measured\ value - Reference\ value}{Reference\ value} \right) \times 100 \qquad (4.1)$$

where in this context, the ***Measured value*** refers to the output values of amplitude, duration, or frequency from the proposed device, while the ***Reference value*** refers to the setting value for each corresponding parameter.

This calculation provides a percentage that indicates how much the output current deviates from the acceptable tolerance defined by the standard. Lower percentage deviations indicate closer adherence to the reference tolerance, ensuring compliance with the standard's requirements.

To assess the consistency of the percentage deviations computed from each current output pattern for a sample size of ten (with ten incremental steps from the minimum to the maximum setting value), standard deviation (SD) serves as a valuable statistical measure [43, 44]. SD quantifies the variation or dispersion of data points from the mean, providing insight into how closely the percentage deviations are clustered around the average value.

The standard deviation (SD) can be calculated as:

$$SD = \sqrt{\frac{1}{N}\sum_{i=1}^{N}\left(x_i - \overline{x}\right)^2} \tag{4.2}$$

where N is the number of samples (in this case, 10), x_i is each individual percentage deviation, and $\overline{x}$ is the mean of the percentage deviations.

A lower standard deviation indicates that the percentage deviations for the output current patterns are minimal, meaning that the data points are closely clustered around the mean. This suggests that the output currents are highly consistent and reliable across the ten samples for each pattern, as shown in Tables 4.1, Table 4.2, and Table 4.3. In this context, a small SD reflects well on the performance of the proposed method, as it demonstrates that the variations between the measured output currents and the reference tolerance are minimal, implying good accuracy and stability across different output patterns.

The experimental results, presented in Tables 4.1, Table 4.2, and Table 4.3, illustrate the deviations observed when varying pulse amplitudes, pulse durations, and pulse repetitive frequencies across all twelve essential output current patterns, respectively. These tables detail the percentage deviations for each parameter, including the minimum value, maximum value, average value, and standard deviation (SD) of the percentage deviations ob-served as the parameter settings of each pattern were varied.

Table 4.1 presents the percentage deviation in pulse amplitude, which was observed to be within the range of 0.04% to 8.14%, remaining well below the maximum allowable limit specified by the IEC standard. Additionally, the SD of the percentage deviation ranged from 0.44% to 1.70%, indicating a high level of consistency in generating outputs across different pulse amplitude levels.

Table 4.2 illustrates the percentage deviation in pulse duration, which was minimal, ranging from 0.00% to 1.25%, and remained within the IEC maximum allowable limit. The SD of the percentage deviation ranged from 0.15% to 0.46%, reflecting the system's consistency in generating the desired output currents across various pulse duration levels.

Table 4.3 shows the percentage deviation in pulse repetitive frequency, which was exceptionally low, ranging from 0.00% to 0.30%, again well within the IEC maximum allowable limit. The SD of the percentage deviation was below 0.1%, demonstrating the system's consistent performance across different pulse repetitive frequency levels.

Table 4.1 Deviation and compliance with IEC standards in pulse amplitude variations

	Output current patterns	Pulse amplitude setting range (mA)	Percentage deviation from 10-step increments of the proposed output current (%)			IEC 60601-2-10 Max. deviation (%)	Compli-ance
			Min – Max	SD	Avg		
1	IG	0-40	**2.05 – 6.00**	1.17	**3.49**	**20.00**	Complied
2	CG	0-40	**1.75 – 5.55**	1.19	**3.23**	**20.00**	Complied
3	MF	0-70	**0.13 – 3.93**	1.39	**1.01**	**20.00**	Complied
4	DF	0-70	**0.04 – 1.93**	0.63	**0.97**	**20.00**	Complied
5	CP	0-70	**0.27 – 4.00**	1.39	**1.05**	**20.00**	Complied
6	CPid	0-70	**0.23 – 4.00**	1.17	**1.23**	**20.00**	Complied
7	LP	0-70	**0.04 – 3.32**	1.14	**1.25**	**20.00**	Complied
8	TF	0-80	**0.13 – 1.31**	0.44	**0.60**	**20.00**	Complied
9	RF	0-80	**0.96 – 4.75**	1.18	**1.31**	**20.00**	Complied
10	ASYM	0-140	**1.62 – 8.14**	1.70	**4.33**	**20.00**	Complied
11	ASYM-A	0-140	**1.46 – 7.07**	1.47	**3.89**	**20.00**	Complied
12	SYM	0-140	**1.80 – 7.79**	1.64	**4.07**	**20.00**	Complied

Table 4.2 Deviation and compliance with IEC standards in pulse duration variations

Output current patterns		Pulse duration setting range (μs)	Percentage deviation from 10-step increments of the proposed output current (%)			IEC 60601-2-10 Max. deviation (%)	Compli-ance
			Min – Max	SD	Avg		
1	TF	20-1,000,000	**0.00 – 0.50**	0.15	**0.07**	**20.00**	Complied
2	RF	20-1,000,000	**0.00 – 0.50**	0.15	**0.07**	**20.00**	Complied
3	ASYM	20-400	**0.00 – 1.25**	0.46	**0.39**	**20.00**	Complied
4	ASYM-A	20-400	**0.00 – 1.12**	0.38	**0.32**	**20.00**	Complied
5	SYM	20-400	**0.00 – 1.05**	0.42	**0.37**	**20.00**	Complied

Table 4.3 Deviation and compliance with IEC standards in pulse frequency variations

Output current patterns		Pulse repetitive frequency setting range (Hz)	Percentage deviation from 10-step increments of the proposed output current (%)			IEC 60601-2-10 Max. deviation (%)	Compli-ance
			Min – Max	SD	Avg		
1	TF	0.2-1,000	**0.00 – 0.30**	0.09	**0.04**	**20.00**	Complied
2	RF	0.2-1,000	**0.00 – 0.30**	0.09	**0.04**	**20.00**	Complied
3	ASYM	1-200	**0.00 – 0.17**	0.05	**0.04**	**20.00**	Complied
4	ASYM-A	1-200	**0.00 – 0.14**	0.05	**0.03**	**20.00**	Complied
5	SYM	1-200	**0.00 – 0.14**	0.05	**0.03**	**20.00**	Complied

It should be noted that the experimental results presented in Table 4.2 and Table 4.3 do not include all twelve output current patterns. Instead, they only emphasize the current patterns that are most commonly adjusted by physiotherapists and therapeutic doctors, based the preliminary survey mentioned before. The remaining patterns are also capable of duration and frequency adjustment if desired.

One conclusion can be drawn from Table 4.1, Table 4.2, and Table 4.3 is that the proposed device demonstrates exceptionally high accuracy in generating various

output currents, regardless of variations in pulse amplitude, pulse duration, and pulse repetitive frequency. This is evident when comparing the results with the compliance requirements of the IEC standard. The deviations outlined in the standard have been adhered to and met efficiently. Additionally, a low percentage of SDs observed indicate the reliability of the output currents generated by the proposed ES device. This confirms the device's performance in achieving precise, predictable, and efficient output currents.

4.4 STABILITY ANALYSIS OF CONSTANT CURRENT OUTPUT

The stability of constant current output is a crucial factor in the reliable delivery of therapeutic currents to real-world patients, ensuring that the proposed ES device performs effectively without fluctuations, even when faced with changes in load resistance. This test aimed to evaluate the reliability of the proposed ES device in maintaining consistent and constant output currents under varying load conditions, which simulate the diversity and variability of patient-specific impedance during treatment.

The testing procedure involved setting the target output current at the maximum value of each current range limit, according to the individual output current patterns shown in Table 3.7. The output current amplitude of the proposed ES device was then measured while varying the resistive loads, which were simulated to represent different conditions of human tissues. The load conditions were set at 500, 1,000, and 2,000 ohms, respectively—a range typical of human tissue impedance, as reported by [1].

Then compared the output currents from the proposed ES device and calculated the percentage error (also referred to as percentage deviation) in amplitude using the same formula as in Equation (4.1). This allowed us to quantify the deviation between the 500-to-1,000-ohm load conditions, as well as between the 500-to-2,000-ohm load conditions. The primary focus was on observing the percentage amplitude deviation between these two pairs of experiments. A lower percentage of deviation between the two load conditions indicates greater stability in the device's ability to maintain a constant output current, demonstrating its capability to deliver the desired current despite variations in load resistance.

In addition to amplitude comparisons, the stability of the constant output current was further evaluated by analyzing the correlation between the current waveforms from the two pairs of load configurations. Raw data of the arbitrary output waveforms were collected as comma-separated value (CSV) files and used to compute the correlation between the two output currents, assessing the similarity in both pulse duration and pulse repetitive frequency under varying load conditions.

To compare the similarity between two discrete current output waveforms, the Pear-son correlation coefficient [43-45] provides a reliable measure of the linear relationship between the two signals. The Pearson correlation coefficient quantifies how well the varia-tions in one waveform correspond to the variations in another waveform, helping assess their similarity in terms of amplitude, duration and also repetitive frequency.

The Pearson correlation coefficient r can be calculated as:

$$r = \frac{\sum (y_i - \bar{y})(z_i - \bar{z})}{\sqrt{\sum (y_i - \bar{y})^2 \sum (z_i - \bar{z})^2}} \tag{4.3}$$

where y_i and z_i are the individual points of the two discrete waveforms, $\bar{y}$ and $\bar{z}$ are the mean values of the respective waveforms, r ranges from -1 to 1, where

r = 1 indicates a perfect positive correlation,

r = -1 indicates a perfect negative correlation,

r = 0 indicates no correlation.

By calculating the Pearson correlation coefficient, we assessed the degree of similarity between the two current output waveforms, with higher values of coefficient indicating a greater similarity in their patterns. Additionally, the Pearson correlation coefficient was employed to explore the interdependencies between key variables—pulse amplitude, pulse duration, and pulse repetitive frequency—to evaluate how changes in one variable may affect another. The results revealed a strong correlation between these parameters, indicating a significant relationship among them. This finding provides valuable insight into the broader performance and interaction of the system's variables.

These two comprehensive analyses ensured that the stability of the proposed ES device was not only assessed in terms of pulse amplitude but also in terms of the pulse durations and pulse repetitive frequencies of all 12 essential current patterns, providing a comprehensive evaluation of the system's performance under variable load conditions.

The experimental results presented in Table 4.4 and Table 4.5 clearly indicate that the pulse amplitude of the output current varied within a very narrow range, with deviations of less than ±2% regardless of how the load resistance was altered. Additionally, the computed Pearson correlation coefficient r between the two test configurations was exceptionally high, with values ranging from 0.9909 to 0.9994. This high correlation suggests that all of the amplitudes, duration and repetitive frequency of the output currents remained consistent even when load conditions were varied [43-45].

Table 4.4 Measured output currents with load variation from 500 Ω to 2000 Ω

No	Output current patterns	Output current settings (mA)	Measured output currents with different load impedances (mA)		
			500 Ω	1000 Ω	2000 Ω
1	IG	40	39.86	40.16	40.09
2	CG	40	39.76	39.69	39.79
3	MF	70	69.91	69.97	70.44
4	DF	70	69.97	69.20	68.96
5	CP	70	70.19	70.01	69.95
6	CPid	70	70.16	70.57	71.10
7	LP	70	69.97	70.14	70.38
8	TF	80	79.91	81.34	80.05
9	RF	80	79.23	79.03	80.08
10	ASYM	140	137.96	138.92	139.64
11	ASYM-A	140	138.40	139.13	138.64
12	SYM	140	138.65	139.62	140.23

Table 4.5 Amplitude deviation and correlation for load variation from 500Ω to 2000Ω

No	Output current patterns	Output current settings (mA)	Load variation from 500 Ω to 1000 Ω		Load variation from 500 Ω to 2000 Ω	
			Amplitude deviation	Pearson correlation coefficient (*r*)	Amplitude deviation	Pearson correlation coefficient (*r*)
1	IG	40	0.75%	0.9932	0.59%	0.9923
2	CG	40	-0.17%	0.9987	0.09%	0.9991
3	MF	70	0.09%	0.9989	0.76%	0.9988
4	DF	70	-1.11%	0.9985	-1.44%	0.9990
5	CP	70	-0.25%	0.9906	-0.34%	0.9909
6	CPid	70	0.59%	0.9985	1.34%	0.9921
7	LP	70	0.25%	0.9994	0.59%	0.9993
8	TF	80	1.79%	0.9905	0.17%	0.9978
9	RF	80	-0.25%	0.9996	1.07%	0.9994
10	ASYM	140	0.69%	0.9945	1.22%	0.9973
11	ASYM-A	140	0.53%	0.9966	0.17%	0.9958
12	SYM	140	0.70%	0.9982	1.14%	0.9982

4.5 USER INTERFACE (UI) TESTING

The User Interface (UI) was designed to serve as an integrated input, display, and notification system, consisting of five main components: a multipoint touchscreen display, push-button switches, a rotary switch, LED status indicators, and a buzzer for audio alerts. Testing was conducted in two phases: **design functionality** and **usability**.

4.5.1 Design Functionality Testing

Each UI component was tested to ensure proper operation according to the design specifications. The touchscreen, push-button switches, rotary switch, LED indicators, and buzzer were all assessed individually and as part of a combined system. The integration of these components was critical in determining if they functioned cohesively. Results, as presented in Tables 4.6, 4.7, and 4.8, confirmed that all components performed accurately, with no system malfunctions or interaction issues observed. The successful operation of the components, both individually and collectively, validated the effectiveness of the UI design.

4.5.2 Usability Testing

Preliminary usability tests were carried out with physiotherapists to evaluate the ease of operation and overall user experience. Key tasks, including waveform selection, parameter adjustment, and modification, were performed during testing. Physiotherapists provided positive feedback, highlighting the UI's intuitive layout and ease of operation. Specifically, they noted that the touchscreen interface was responsive, and the rotary switch and push-button controls were easy to understand and use, even for first-time users. This feedback underscored the system’s user-friendly design and its practicality for clinical use.

The UI passed both design functionality and usability tests, proving that it operates as intended and meets the needs of clinical practitioners. Its intuitive design, combined with smooth integration of components, ensures that the system is ready for real-world application, making it a reliable and user-friendly tool in physiotherapy.

Table 4.6 User interface test result for channel 1

Page	Display			Touch Screen				Push button				Knob	Buzzer	LED
	Status	Value	Parameter	Home	Start/ Pause	Reset	Back	Home	Start/ Pause	Reset	Back			
1. Home	N/A	N/A	N/A	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
2. Channel Selection	N/A	N/A	N/A	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
3. Waveform Selection	N/A	N/A	N/A	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
4. SD Curve program	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
5. System Setting	N/A	✓	✓	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
6. Help	N/A	N/A	N/A	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
7. Galvanic Interrupted	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
8. Galvanic Continuous	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9. MF	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10. DF	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11. CP	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
12. CPid	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
13. LP	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
14. Triangular	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
15. Rectangular	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
16. Asymmetrical	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
17. Asymmetrical Alternating	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
18. Symmetrical	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
19. Surge Setting	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 4.7 User Interface test result for channel 2

Page	Display			Touch Screen				Push button				Knob	Buzzer	LED
	Status	Value	Parameter	Home	Start/ Pause	Reset	Back	Home	Start/ Pause	Reset	Back			
1. Home	N/A	N/A	N/A	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
2. Channel Selection	N/A	N/A	N/A	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
3. Waveform Selection	N/A	N/A	N/A	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
4. SD Curve program	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
5. System Setting	N/A	✓	✓	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
6. Help	N/A	N/A	N/A	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
7. Galvanic Interrupted	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
8. Galvanic Continuous	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9. MF	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10. DF	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11. CP	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
12. CPid	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
13. LP	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
14. Triangular	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
15. Rectangular	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
16. Asymmetrical	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
17. Asymmetrical Alternating	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
18. Symmetrical	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
19. Surge Setting	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Table 4.8 User interface test results for dependent mode (simultaneous operation of channel 1 and channel 2)

Page	Display		Touch Screen					Push button				Knob	Buzzer	LED
	Status	Value	Parameter	Home	Start/ Pause	Reset	Back	Home	Start/ Pause	Reset	Back			
1. Home	N/A	N/A	N/A	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
2. Channel Selection	N/A	N/A	N/A	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
3. Waveform Selection	N/A	N/A	N/A	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
4. SD Curve program	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
5. System Setting	N/A	✓	✓	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
6. Help	N/A	N/A	N/A	✓	N/A	N/A	✓	✓	N/A	N/A	✓	✓	N/A	N/A
7. Galvanic Interrupted	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
8. Galvanic Continuous	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9. MF	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10. DF	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
11. CP	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
12. CPid	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
13. LP	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
14. Triangular	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
15. Rectangular	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
16. Asymmetrical	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
17. Asymmetrical Alternating	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
18. Symmetrical	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
19. Surge Setting	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

4.6 VERIFICATION OF COMPLIANCE WITH IEC STANDARDS FOR MEDICAL EQUIPMENT

The primary objective of this testing procedure was to verify that the proposed electrical stimulation (ES) device complies with relevant international medical equipment standards and regulatory requirements. Compliance with these standards is critical to ensure the device's safety, efficiency, and reliability in clinical therapeutic applications. A comprehensive evaluation was carried out in accordance with established guidelines, covering assessments of electrical safety, electromagnetic compatibility (EMC), and performance benchmarks. This process aimed to confirm that the proposed ES device meets all necessary criteria for safe and effective operation in real-world clinical environments.

In this study, the proposed 2-channel multi-functional therapeutic electrical stimulator was rigorously tested for compliance with key International Electrotechnical Commission (IEC) standards. These include IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-10, which define the basic safety, essential performance, requirements for medical electrical equipment. Meeting these standards ensures that the device operates safely and reliably within clinical settings.

The device successfully underwent the certification process, carried out by PTEC, official testing bodies in Thailand responsible for evaluating electrical and electronic equipment. The proposed ES device has been officially certified as compliant with the IEC standards, as detailed in the relevant test reports. The following sections outline the certified standards and the corresponding tests that were conducted.

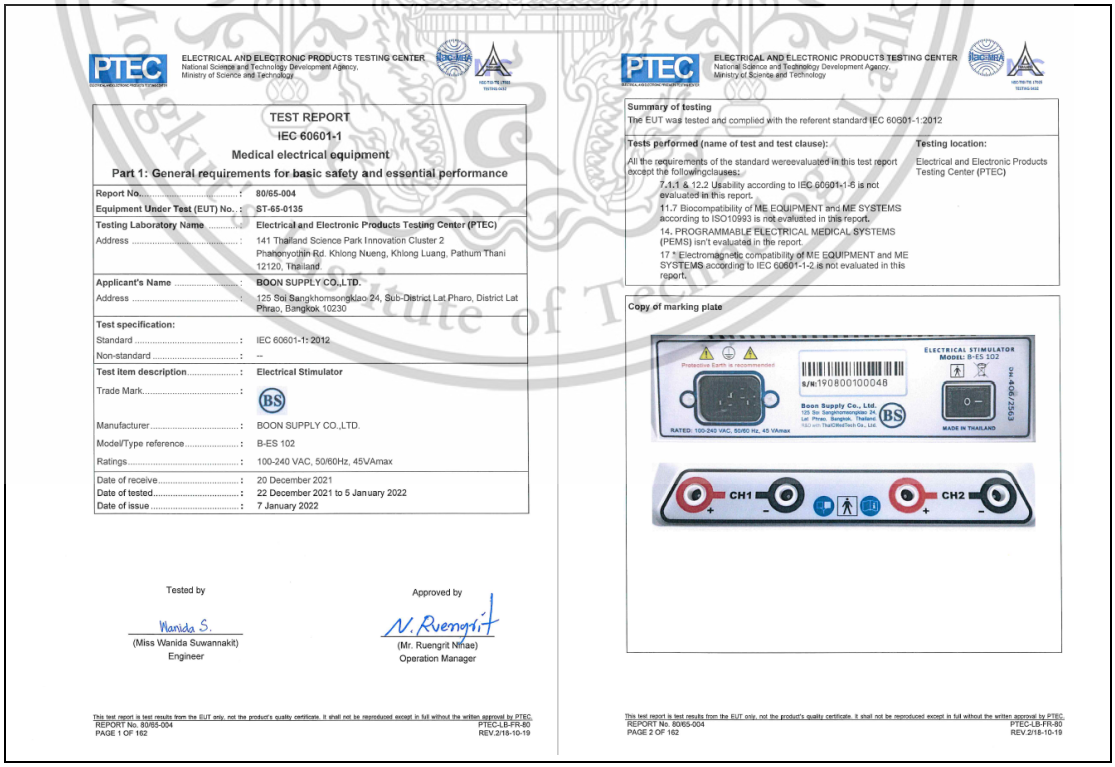
Conformity with these IEC standards ensures that the proposed ES device operates reliably and safely in environments with electromagnetic disturbances, without interfering with the functionality of other devices. Additionally, it demonstrates that the device delivers electrical stimulation output within safe limits, thereby safeguarding patients from potential hazards associated with electrical currents.

4.6.1 IEC 60601-1: General Requirements for Basic Safety and Essential Performance

IEC 60601-1 is the fundamental standard governing the safety and performance requirements for medical electrical equipment. The ES device underwent thorough testing to ensure compliance with this standard, focusing on key aspects such as electrical safety, mechanical integrity, and protection against hazardous outputs. The device demonstrated full compliance with these safety protocols, ensuring reliable and safe operation in clinical environments.

Key areas of testing included electrical safety, where the device was verified for proper insulation, creepage distances, and protection against electric shock. Mechanical safety was also evaluated, ensuring the device's structural integrity under normal usage conditions. Additionally, protection against hazardous output was tested to confirm that the device's output currents remain within safe limits during both normal and fault conditions. These tests ensure the ES device is equipped with safety mechanisms that prevent harm to patients and clinicians in case of malfunction.

The results confirming that the device meets the stringent safety and performance standards. Figure 4.8 presents example pages from the official test report to document the certification.



ELECTRICAL AND ELECTRONIC PRODUCTS TESTING CENTER
National Science and Technology Development Agency
Ministry of Science and Technology

TEST REPORT
IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report No.	:	80/65-004
Equipment Under Test (EUT) No.	:	ST-65-0135
Testing Laboratory Name	:	Electrical and Electronic Products Testing Center (PTEC)
Address	:	141 Thailand Science Park Innovation Cluster 2 Phahonyothin Rd. Khlong Nueng, Khlong Luang, Pathum Thani 12120, Thailand
Applicant's Name	:	BOON SUPPLY CO.,LTD.
Address	:	125 Soi Sangkhomsongklao 24, Sub-District Lat Pharo, District Lat Phrao, Bangkok, 10230
Test specification:		
Standard	:	IEC 60601-1: 2012
Non-standard	:	--
Test item description	:	Electrical Stimulator
Trade Mark	:	
Manufacturer	:	BOON SUPPLY CO.,LTD.
Model/Type reference	:	B-ES 102
Ratings	:	100-240 VAC, 50/60Hz, 45VAmax
Date of receive	:	20 December 2021
Date of tested	:	22 December 2021 to 5 January 2022
Date of issue	:	7 January 2022

Tested by
Wanida S.
(Miss Wanida Suwannakit)
Engineer

Approved by
N. Ruengrit
(Mr. Ruengrit Nihae)
Operation Manager

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REPORT No. 80/65-004 PTEC-LB-FR-80
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National Science and Technology Development Agency
Ministry of Science and Technology

Summary of testing
The EUT was tested and complied with the referent standard IEC 60601-1:2012

Tests performed (name of test and test clause):
All the requirements of the standard wereevaluated in this test report except the followingclauses:
7.1.1 & 12.2 Usability according to IEC 60601-1-6 is not evaluated in this report.
11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS according to ISO10993 is not evaluated in this report.
14. PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) isn't evaluated in the report.
17 1 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS according to IEC 60601-1-2 is not evaluated in this report.

Testing location:
Electrical and Electronic Products Testing Center (PTEC)

Copy of marking plate

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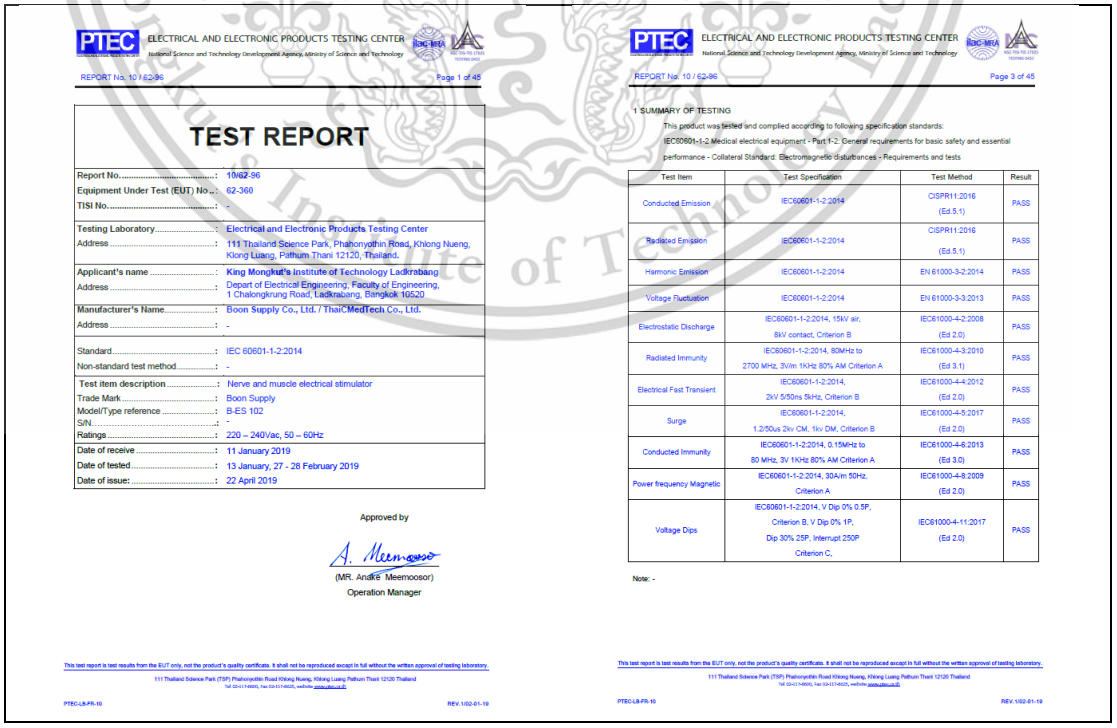
Figure 4.8 Example pages of IEC 60601-1 Test Report [46]

4.6.2 IEC 60601-1-2: Electromagnetic Compatibility

IEC 60601-1-2 establishes the requirements for electromagnetic compatibility (EMC) in medical devices, ensuring they function reliably without being affected by electromagnetic interference (EMI) or causing interference with other equipment. This standard focuses on the ability of the device to withstand external electromagnetic disturbances while limiting its own electromagnetic emissions, which is critical in clinical environments where multiple medical devices operate simultaneously.

The electrical stimulator was rigorously tested for EMC, including assessments of radiated emissions to ensure that it does not emit harmful electromagnetic radiation. The device's resilience to electrostatic discharges (ESD) commonly found in clinical settings was also evaluated. In addition, radiated RF immunity was tested to confirm the device's ability to maintain functionality when exposed to radio-frequency electromagnetic fields. Lastly, the stimulator underwent conducted immunity testing, ensuring its capacity to resist interference conducted through the power supply.

The results demonstrated that the device fully adhered to EMC requirements, showing strong immunity to external interference and emitting negligible radiation that could affect nearby medical equipment. These findings confirm that the device is safe for use in medical environments. Figure 4.9 provides example pages from the test report, documenting the successful certification of the device.



PTEC ELECTRICAL AND ELECTRONIC PRODUCTS TESTING CENTER
National Science and Technology Development Agency, Ministry of Science and Technology

REPORT No. 10 / 62-96 Page 1 of 45

TEST REPORT

Report No.	10/62-96
Equipment Under Test (EUT) No.	62-360
TISI No.	-
Testing Laboratory	Electrical and Electronic Products Testing Center
Address	111 Thailand Science Park, Phahonyothin Road, Khlong Nueng, Klong Luang, Pathum Thani 12120, Thailand.
Applicant's name	King Mongkut's Institute of Technology Ladkrabang
Address	Depart of Electrical Engineering, Faculty of Engineering, 1 Chalongkrung Road, Ladkrabang, Bangkok 10520
Manufacturer's Name	Boon Supply Co., Ltd. / ThaiCMedTech Co., Ltd.
Address	-
Standard	IEC 60601-1-2:2014
Non-standard test method	-
Test item description	Nerve and muscle electrical stimulator
Trade Mark	Boon Supply
Model/Type reference	B-ES 102
S/N	-
Ratings	220 – 240Vac, 50 – 60Hz
Date of receive	11 January 2019
Date of tested	13 January, 27 - 28 February 2019
Date of issue:	22 April 2019

Approved by

(MR. Andke Meemoosor)
Operation Manager

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111 Thailand Science Park (TSP) Phahonyothin Road Khlong Nueng, Khlong Luang Pathum Thani 12120 Thailand

PTEC-LB-FR-10 REV. 1/02-01-19

PTEC ELECTRICAL AND ELECTRONIC PRODUCTS TESTING CENTER
National Science and Technology Development Agency, Ministry of Science and Technology

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1 SUMMARY OF TESTING

This product was tested and complied according to following specification standards:

IEC60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Test Item	Test Specification	Test Method	Result
Conducted Emission	IEC60601-1-2:2014	CISPR11:2016 (Ed.5.1)	PASS
Radiated Emission	IEC60601-1-2:2014	CISPR11:2016 (Ed.5.1)	PASS
Harmonic Emission	IEC60601-1-2:2014	EN 61000-3-2:2014	PASS
Voltage Fluctuation	IEC60601-1-2:2014	EN 61000-3-3:2013	PASS
Electrostatic Discharge	IEC60601-1-2:2014, 15kV air, 8kV contact, Criterion B	IEC61000-4-2:2008 (Ed 2.0)	PASS
Radiated Immunity	IEC60601-1-2:2014, 80MHz to 2700 MHz, 3V/m 1KHz 80% AM Criterion A	IEC61000-4-3:2010 (Ed 3.1)	PASS
Electrical Fast Transient	IEC60601-1-2:2014, 2kV 5/50ns 5kHz, Criterion B	IEC61000-4-4:2012 (Ed 2.0)	PASS
Surge	IEC60601-1-2:2014, 1.2/50us 2kv CM, 1kv DM, Criterion B	IEC61000-4-5:2017 (Ed 2.0)	PASS
Conducted Immunity	IEC60601-1-2:2014, 0.15MHz to 80 MHz, 3V 1KHz 80% AM Criterion A	IEC61000-4-6:2013 (Ed 3.0)	PASS
Power frequency Magnetic	IEC60601-1-2:2014, 30A/m 50Hz, Criterion A	IEC61000-4-8:2009 (Ed 2.0)	PASS
Voltage Dips	IEC60601-1-2:2014, V Dip 0% 0.5P, Criterion B, V Dip 0% 1P, Dip 30% 25P, Interrupt 250P Criterion C,	IEC61000-4-11:2017 (Ed 2.0)	PASS

Note: -

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111 Thailand Science Park (TSP) Phahonyothin Road Khlong Nueng, Khlong Luang Pathum Thani 12120 Thailand

PTEC-LB-FR-10 REV. 1/02-01-19

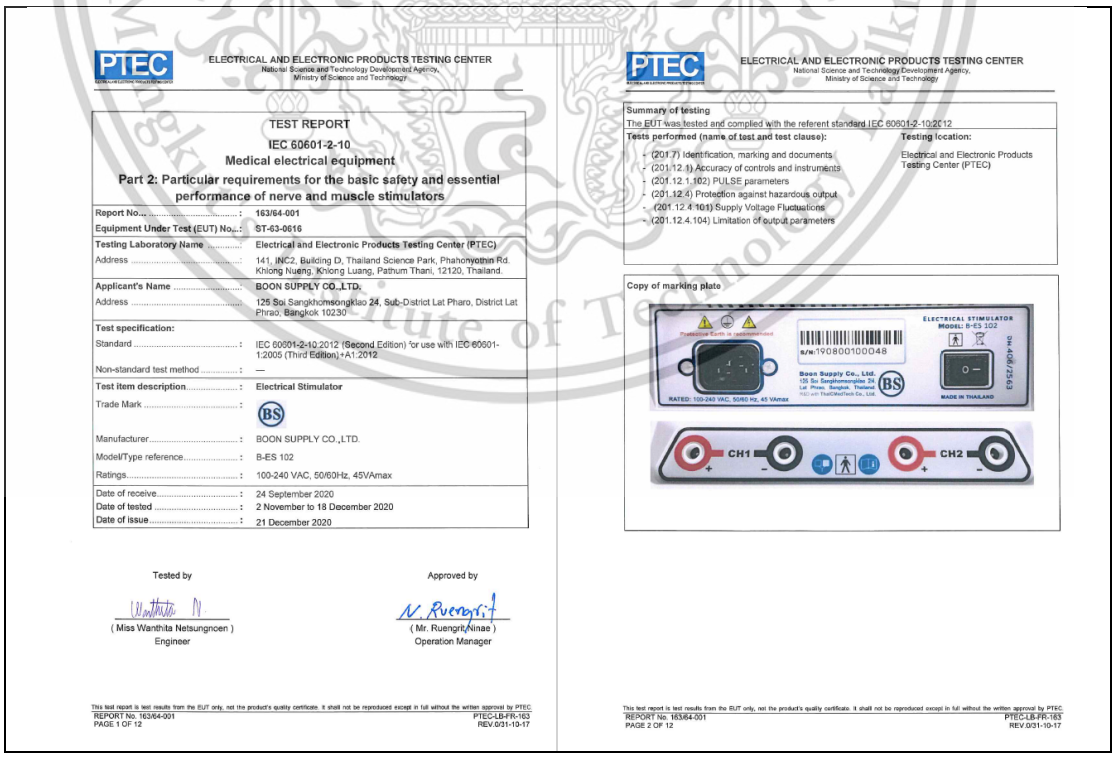
Figure 4.9 Example pages of IEC 60601-1-2 Test Report [47]

4.6.3 IEC 60601-2-10: Particular Requirements for Nerve and Muscle Stimulators

IEC 60601-2-10 focuses on the specific safety and performance requirements for nerve and muscle stimulators, classified as medical electrical equipment. Compliance with this standard is crucial to ensure the therapeutic electrical outputs, such as amplitude, frequency, and duration, remain safe and effective for clinical use.

The proposed ES was rigorously tested in several key areas. First, the accuracy of pulse parameters, including amplitude, duration, and frequency, was verified under different load conditions. The results showed that the device's output consistently met the IEC tolerance limits, with deviations well below the ±20% threshold. Additionally, the device was evaluated for protection against hazardous output, ensuring that automatic safety mechanisms, such as output shutdown in case of electrode detachment or excessive current, functioned correctly to maintain patient safety.

The device also underwent environmental and power supply fluctuation testing to confirm stable performance in non-ideal conditions. Overall, the results confirmed full compliance with IEC 60601-2-10, ensuring the device meets stringent safety and performance standards required for medical applications. Figure 4.10 presents example pages from the test report, documenting the successful certification of the device.



PTEC ELECTRICAL AND ELECTRONIC PRODUCTS TESTING CENTER
National Science and Technology Development Agency, Ministry of Science and Technology

TEST REPORT
IEC 60601-2-10
Medical electrical equipment
Part 2: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

Report No.	163/64-001
Equipment Under Test (EUT) No.	ST-63-0616
Testing Laboratory Name	Electrical and Electronic Products Testing Center (PTEC)
Address	141, INC2, Building D, Thailand Science Park, Phahonyothin Rd. Khlong Nueng, Khlong Luang, Pathum Thani, 12120, Thailand.
Applicant's Name	BOON SUPPLY CO.,LTD.
Address	125 Soi Sangkhomsongklao 24, Sub-District Lat Phrao, District Lat Phrao, Bangkok 10230
Test specification:	
Standard	IEC 60601-2-10:2012 (Second Edition) "or use with IEC 60601-1:2005 (Third Edition)+A1:2012
Non-standard test method	—
Test item description	Electrical Stimulator
Trade Mark	BS
Manufacturer	BOON SUPPLY CO.,LTD.
Model/Type reference	B-ES 102
Ratings	100-240 VAC, 50/60Hz, 45VAmax
Date of receive	24 September 2020
Date of tested	2 November to 18 December 2020
Date of issue	21 December 2020

Tested by
(Miss Wanthita Netsungnoen)
Engineer

Approved by
(Mr. Ruengrit Ninae)
Operation Manager

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REPORT No. 163/64-001 PAGE 1 OF 12 PTEC-LB-FR-163 REV.0/31-10-17

PTEC ELECTRICAL AND ELECTRONIC PRODUCTS TESTING CENTER
National Science and Technology Development Agency, Ministry of Science and Technology

Summary of testing
The EUT was tested and complied with the referent standard IEC 60601-2-10:2012

Tests performed (name of test and test clause):
- (201.7) Identification, marking and documents
- (201.12.1) Accuracy of controls and instruments
- (201.12.1.102) PULSE parameters
- (201.12.4) Protection against hazardous output
- (201.12.4.101) Supply Voltage Fluctuations
- (201.12.4.104) Limitation of output parameters

Testing location:
Electrical and Electronic Products Testing Center (PTEC)

Copy of marking plate

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REPORT No. 163/64-001 PAGE 2 OF 12 PTEC-LB-FR-163 REV.0/31-10-17

Figure 4.10 Example pages of IEC 60601-2-10 Test Report [48]

4.6.4 Thailand FDA Certification

The proposed ES device has successfully obtained certification from the Thailand Food and Drug Administration (FDA), demonstrating its compliance with the country's stringent regulatory standards for medical devices. This certification ensures that the device meets all necessary requirements for safety, efficacy, and quality before being deployed in clinical settings throughout Thailand.

With Thailand FDA certification, the proposed ES device is now approved for clinical use in hospitals, clinics, and other healthcare facilities nationwide. The certification also mandates ongoing postmarket surveillance to monitor the device's performance in real-world conditions, ensuring it continues to meet the required safety and quality standards throughout its lifecycle.

Achieving this certification marks a significant milestone in bringing the device to market in Thailand, underscoring its adherence to the highest standards of safety and performance. This approval fosters confidence in its application for various therapeutic purposes. Figure 4.11 presents the certification.

แบบ บ.จ.ผ. ๑

ใบรับแจ้งรายการละเอียดผลิตเครื่องมือแพทย์

ใบรับแจ้งรายการละเอียดที่ จผ. 406/2563

ใบรับแจ้งรายการละเอียดฉบับนี้ให้ไว้แก่

บริษัท บุญ ชัพพลาย จำกัด

ผู้จดทะเบียนสถานประกอบการผลิตเครื่องมือแพทย์ ใบจดทะเบียนที่ สผ. 19/2555

เพื่อแสดงว่าเป็นผู้แจ้งรายการละเอียดผลิตเครื่องมือแพทย์ตามมาตรา ๑๘ แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๔๑ สำหรับเครื่องมือแพทย์

เครื่องกระตุ้นกล้ามเนื้อด้วยไฟฟ้า บี-อีเอส 102

(Electrical Stimulator B-ES 102)

รายละเอียดเครื่องมือแพทย์ เป็นเครื่องที่ให้กระแสไฟฟ้า ในหัวข้อ เครื่องหรืออุปกรณ์ที่ให้ผล

ในการบำบัดโดยกระตุ้นเส้นประสาทผ่านผิวหนังด้วยกระแสไฟฟ้า

ณ สถานที่ผลิตเครื่องมือแพทย์ชื่อ บริษัท บุญ ชัพพลาย จำกัด

ตั้งอยู่เลขที่ 125

ตรอก/ซอย สังคมสงเคราะห์ 24 ถนน - หมู่ที่ -

ตำบล/แขวง ลาดพร้าว อำเภอ/เขต ลาดพร้าว จังหวัด กรุงเทพมหานคร

รหัสไปรษณีย์ 10230 โทรศัพท์ 0 2539 3534 โทรสาร 0 2539 3998

ใบรับแจ้งรายการละเอียดฉบับนี้ใช้ได้จนถึงวันที่ ๓๑ ธันวาคม พ.ศ. 2567 และให้ใช้เฉพาะสถานที่ซึ่งระบุไว้ในใบรับแจ้งรายการละเอียดเท่านั้น

ออกให้ ณ วันที่ 5 เดือน กุมภาพันธ์ พ.ศ. 2563

(ลายมือชื่อ)

ตำแหน่ง

ผู้อนุญาต

(นายสุริยะ ตางวิรัฒน์)

รองเลขาธิการ ปฏิบัติราชการแทน

เลขาธิการคณะกรรมการอาหารและยา

Figure 4.11 Thailand FDA certification for the proposed ES device

CHAPTER 5

DISCUSSION

5.1 PERFORMANCE AND THERAPEUTIC OUTCOMES

The accuracy of the pulse generator in our proposed device is a critical aspect of performance, particularly when compared to other systems on the market or in previous studies. However, direct comparisons of accuracy are challenging due to the limited availability of detailed data on output current accuracy in existing publications and commercial reports. Most studies focus on operating ranges, such as pulse amplitude, duration, and frequency, without specifying exact accuracy.

For example, Bosques et al. [26] reviewed 37 articles on therapeutic electrical stimulation (ES) and reported effective frequency ranges for NMES, FES, TENS, and TES between 10-150 Hz, with pulse durations ranging from 50-1,000 μs. Broderick et al. [6] examined seven commercial surface-type ES devices, noting frequency ranges from 1-140 Hz and pulse durations between 50-250,000 μs. Wu et al. [1] developed a multi-channel ES system with frequency ranges of 3-100 Hz and pulse duration adjustability from 50-1,000 μs, while Chang et al. [12] proposed a microprocessor-based ES device with output currents between -3 to 3 mA, frequency ranges from 10-500 Hz, and pulse duration from 50-2,000 μs.

In comparison, our proposed ES device offers significantly enhanced performance, with a frequency adjustability range of 0.2-1,000 Hz and pulse durations from 20-1,000,000 μs. Additionally, our device incorporates special functions like Surge and Modulation, which few other devices offer [31]. These functions allow the generation of twelve essential waveforms specifically tailored for various therapeutic needs. Moreover, the device is compliant with IEC 60601-2-10 standards, ensuring that pulse parameter accuracy meets regulatory thresholds, providing confidence in its reliability and performance. Our device offers significant improvements over existing systems in two key areas:

Performance: The device achieves high levels of accuracy and reliability by complying with all relevant IEC standards, specifically sections 4.6, ensuring precise and consistent output. Additionally, its wide range of adjustability in pulse amplitude, duration, and frequency allows for greater flexibility, enabling a broader range of therapeutic applications compared to other devices on the market.

Therapeutic Outcomes: The combination of enhanced accuracy, flexibility, and adaptability makes the device more effective in delivering treatments across various clinical settings, including hospitals, clinics, and other healthcare facilities. This versatility ensures that the device can meet the diverse therapeutic needs of patients, making it suitable for a wide range of treatment protocols.

5.2 USER INTERFACE AND PRACTICAL IMPLEMENTATION

The user interface (UI) of our therapeutic electrical stimulator was designed with ease of use and efficiency in mind. The graphical user interface (GUI) features intuitive, touch-based controls that allow clinicians to quickly select waveforms, adjust treatment modes, and modify parameters as needed. Realtime feedback is provided through visual indicators, enabling clinicians to monitor therapy progress and make necessary adjustments without interrupting treatment.

Preliminary usability tests with clinicians have yielded positive feedback. The system was noted to be intuitive and easy to operate, even for users with minimal training. The ability to adjust parameters mid-treatment, such as waveform characteristics or pulse intensity, was highlighted as particularly beneficial in clinical settings. Future usability testing will further assess the UI's performance across a wider range of clinical environments, with the goal of refining the interface to improve the user experience and reduce setup times.

5.3 POWER CONSUMPTION AND MINIATURIZATION

The design of this therapeutic electrical stimulator is optimized for stationary use in clinical environments such as hospitals and clinics, where a stable power supply is available. Consequently, power efficiency and miniaturization were not primary concerns in this study. Instead, the focus was placed on ensuring accuracy and reliability in the device's therapeutic output. However, for future iterations of this device, particularly if portable or wearable versions are considered, power management and miniaturization will become key factors to address.

5.4 LIMITATIONS

While the results of this study demonstrate the effectiveness of the proposed therapeutic electrical stimulator, there are several limitations.

First, the device has been primarily tested under controlled laboratory conditions, and additional clinical trials are required to validate its performance across diverse patient populations and real-world clinical environments. Expanding trials to include a more varied demographic will be essential for assessing the device's efficacy in different therapeutic contexts.

Second, while preliminary tests suggest that the user interface is intuitive, comprehensive usability trials are necessary to ensure that clinicians with varying levels of technical expertise can effectively operate the device. Future development should focus on refining the user interface and creating comprehensive training protocols for clinical staff.

Lastly, while the special functions Surge and Modulation were incorporated based on input from physiotherapists and doctors, further investigation is needed to assess their long-term benefits compared to standard modes. Additional studies are required to evaluate these features across a broader range of clinical conditions to determine their clinical superiority.

5.5 FUTURE DIRECTIONS

Future work will focus on expanding clinical trials to include a wider range of patient populations to assess the device's performance across various demographics and therapeutic applications. Broader testing will provide further insights into the device's generalizability and ensure its effectiveness in diverse clinical environments. Additionally, future development may involve enhancing the device’s usability, power efficiency, and adaptability, especially for potential portable or wearable versions.

CHAPTER 6

CONCLUSION

This study presents the design and successful implementation of a 2-channel, multi-functional therapeutic electrical stimulator tailored for clinical applications. The device's capabilities are demonstrated through the generation of twelve essential therapeutic waveforms and two special functions, Surge and Modulation, providing enhanced flexibility and precision in therapeutic treatments. By utilizing an advanced R-2R ladder DAC and an optimized driving stage unit, the proposed device ensures accurate and consistent output across varying load conditions, thereby meeting the stringent safety and performance requirements outlined by the IEC 60601 standards.

Our experimental results validate the device's ability to maintain stable output currents, showcasing high levels of accuracy, minimal deviation, and adherence to international medical equipment standards. The system's adjustability in pulse amplitude, duration, and frequency, coupled with the integration of special functions, positions it as a versatile tool for a wide range of therapeutic applications, from pain management to muscle rehabilitation. Furthermore, the use of in-house technology and locally sourced components ensures that the device is both cost-effective and accessible, making it particularly suitable for resource-limited healthcare settings.

Overall, the proposed device not only advances the field of therapeutic electrical stimulation but also provides a practical, reliable, and adaptable solution for clinical environments. Future research will focus on broader clinical trials to assess the device's performance across diverse patient populations, further refining its usability and expanding its potential applications in physiotherapy and rehabilitation.

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APPENDIX A)

Device Specification

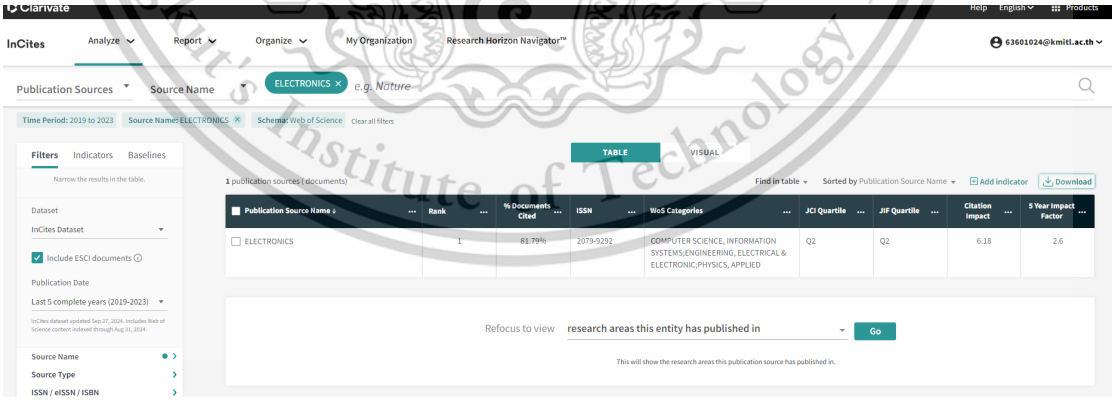
No.	Descriptions/Capabilities/Functions		ES-1	ES-2	Proposed Device
1	**Electrical Signal Generation**		Analog	Digital	**Digital**
2	**Output Support (Channel)**		1	2	**2**
3	**Signal Distortion/Accuracy/Tolerance**		25%	10%	**<5%**
4	**Multi-function Touch Screen Control**		-	Yes	**Yes**
5	**Multi-function Touch Screen Display**		-	Yes	**Yes**
6	**Firmware/Software Upgradable**		-	-	**Yes**
7	**Features/Functions Modifications**		-	-	**Possible**
8	**Product of**		Thailand	Import	**Thailand**
9	**Ownership of Technology**		-	-	**Yes**
10	**Galvanic Current**	*Interrupted*	-	✓	✓
		Continuous	✓	✓	✓
11	**Diadynamic Current**	*MF*	-	✓	✓
		DF	-	✓	✓
		CP	-	✓	✓
		CPid	-	✓	✓
		LP	-	✓	✓
12	**Faradic Current**	*Rectangular*	✓	✓	✓
		Triangular	✓	✓	✓
13	**TENS Current**	*Asymmetrical*	-	✓	✓
		Asym. A	-	✓	✓
		Symmetrical	-	✓	✓
14	**Special Program**	*Surge*	-	✓	✓
		Modulation	-	✓	✓

APPENDIX B)

Academic Publication

Lakatem R, Boontaklang S, Chompoo-inwai C. Advanced Design and Implementation of a 2-Channel, Multi-Functional Therapeutic Electrical Stimulator. *Electronics*. 2024; 13(19):3793. https://doi.org/10.3390/electronics13193793

Web of Science (WoS-SCIE, Journal Ranking: Q2 as of Sept 2024)



electronics

IMPACT FACTOR 2.6

CITESCORE 5.3

Article

Advanced Design and Implementation of a 2-Channel, Multi-Functional Therapeutic Electrical Stimulator

Rujira Lakatem, Suttipong Boontaklang and Chow Chompoo-inwai

MDPI

https://doi.org/10.3390/electronics13193793

electronics

MDPI

Article

Advanced Design and Implementation of a 2-Channel, Multi-Functional Therapeutic Electrical Stimulator

Rujira Lakatem, Suttipong Boontaklang and Chow Chompoo-inwai *

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Abstract: This research introduces the design, implementation, and rigorous evaluation of a novel 2-channel, multi-functional therapeutic electrical stimulator, meticulously engineered to meet the stringent demands of contemporary clinical applications. The device integrates a high-speed R-2R ladder DAC and a sophisticated pulse generator unit, capable of producing twelve essential current waveforms with fully adjustable parameters, including pulse amplitude, pulse duration, and pulse repetitive frequency. The proposed driving stage unit ensures precise voltage-to-current conversion, delivering stable and accurate output currents even under varying load conditions, which effectively simulate the diverse impedance characteristics of human tissue. Extensive testing confirmed the compliance with international medical standards, notably IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-10. The experimental results underscore the device's consistent operation within prescribed safety and performance thresholds, with all deviations in pulse parameters remaining well below the permissible limits. Furthermore, the proposed electrical stimulator demonstrated exceptional stability across variable load conditions, as evidenced by minimal amplitude errors and high correlation between waveform characteristics. These findings highlight the proposed device's robustness and its potential as a versatile tool for a wide range of therapeutic applications, including pain management, muscle stimulation, and nerve rehabilitation, thus marking a significant advancement in the field of therapeutic electrical stimulation.

Keywords: therapeutic electrical stimulator; pulse generator unit; driving stage unit; multi-functional stimulator; IEC 60601-1; IEC 60601-1-2; IEC 60601-2-10

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1. Introduction

Electrical Stimulation (ES) is a widely recognized therapeutic technique that applies electrical impulses to stimulate nerves, muscles, or tissues. Historically, ES devices have played a significant role in clinical settings, particularly in physiotherapy and rehabilitation. Their initial application primarily targeted aging populations to address conditions such as muscle atrophy, pain management, and mobility enhancement [1]. However, in recent years, the scope of ES has expanded significantly beyond this demographic.

Today, younger generations increasingly benefit from ES technology due to modern lifestyle factors such as muscle injuries, office syndrome, and conditions associated with prolonged sitting, such as neck and back pain. This growing demand demonstrates the versatility of ES in addressing various medical conditions and highlights its importance across a broader age spectrum. As a result, ES has emerged as a vital tool not only for therapeutic applications but also for preventive care, with its relevance expected to expand further in the coming years. This shift underscores the necessity for adaptable, efficient, and user-friendly ES devices to meet the evolving needs of diverse populations.

The continuous expansion of ES applications has driven significant technological advancements. Since its first recorded use in 1791, ES has become integral to treatments such as physiotherapy, pain relief, muscle strengthening, cardiac pacing, iontophoretic

drug delivery, and functional electrical stimulation (FES) [1,2]. The introduction of the first commercially available ES device in 1969, which facilitated motor function recovery [3], marked the beginning of rapid technological evolution. These developments have since paved the way for more sophisticated and versatile devices suitable for both clinical and non-clinical applications [1–21].

Modern ES devices generate a variety of waveforms, including square, rectangular, sinusoidal, triangular, and Gaussian shapes. These waveforms are often given specific technical names within therapeutic settings; for example, rectangular waveforms are referred to as faradic waves, while sinusoidal waveforms are known as diadynamic waves [22]. The therapeutic outcomes of ES are highly dependent on parameters such as pulse amplitude, pulse duration, pulse frequency, and polarity [23]. Customizing these parameters allows ES devices to target specific treatment goals, significantly enhancing their effectiveness in treating a wide range of medical conditions.

ES devices can be categorized based on several criteria: the mode of application (surface vs. implanted stimulators) [24], the type of waveform (monophasic or biphasic), and the clinical application (e.g., Neuromuscular Electrical Stimulation (NMES), Functional Electrical Stimulation (FES), or Transcutaneous Electrical Nerve Stimulation (TENS)) [25]. The flexibility to generate diverse waveforms with varying durations and frequencies is critical to the adaptability of ES devices in therapeutic contexts, thereby improving clinical outcomes [26].

The core components of ES devices include the user interface (UI), controller, pulse generator, and driving stage/output circuit [1,3–7,10,12–18,20,25]. The UI translates user inputs into parameters for waveform generation, the controller manages system operations, the pulse generator creates the waveforms, and the driving stage amplifies these waveforms into output currents delivered to the target tissues. While this study focuses primarily on the pulse generator and driving stage—as they play pivotal roles in ensuring the precision and efficacy of the ES device—the UI and controller will not be discussed in detail in this paper.

One of the key challenges in designing ES devices is generating non-linear signals for various stimulation patterns. Early analog pulse generators were limited in flexibility, providing fixed waveform parameters [1]. The advent of digital microcontrollers (MCUs) enabled the programmable generation of waveforms, offering greater control for multi-channel and multi-functional devices [24]. However, generating precise signals remains a challenge due to memory constraints [2,7] and real-time processing limitations in MCUs [1,4]. This study addresses these issues by exploring a real-time synthesizing approach that bypasses traditional Look-Up Tables (LUTs) [5], enabling more efficient waveform generation with higher resolution and minimal distortion.

Another critical challenge in ES design is converting digital signals into analog form. Traditional Digital-to-Analog Converters (DACs) are commonly used with MCUs to generate the necessary output signals [1,4,5,10,12,20]. However, typical DAC chips have limitations in terms of output range, customization, and speed, all of which are crucial for generating non-linear signals [27,28]. To overcome these limitations, this study proposes the use of a discrete R-2R ladder DAC circuit, which provides higher slew rates and faster operation compared to conventional DAC chips, ensuring more precise signal generation.

The driving stage circuit is equally important, as it is responsible for delivering the required output currents to the target tissues. Constant current circuits are generally preferred for maintaining consistent stimulation, despite variations in tissue impedance [25]. Various designs have been proposed to enhance the efficiency of driving circuits, including H-bridge configurations and voltage-controlled current sources (VCCS), which offer improved operational efficiency and scalability for multi-channel applications [1–3,8–11,13,17,18,21]. This study integrates a constant current driving stage with H-bridge networks and feedback control, ensuring stable output currents across a wide range of therapeutic applications [25].

Addressing the need for versatile, locally accessible ES devices is crucial, particularly in regions like Thailand, where high costs and limited access to advanced medical tech-

nologies present significant challenges for smaller hospitals and clinics. While current research often focuses on portable or wearable ES devices, which prioritize miniaturization, cost-effectiveness, low power consumption, and personalization [15,18–20], the proposed stationary ES device remains equally important. There is still significant demand for stationary systems in clinical settings, where adaptability, high performance, and versatility are essential to meet a wide range of therapeutic needs. By utilizing in-house technology and locally sourced components, the proposed device not only reduces costs but also enhances accessibility, ensuring that healthcare providers in resource-limited areas can deliver comprehensive and effective treatments.

The key contributions of this work lie in the development of a multi-functional and cost-efficient ES device that addresses several limitations inherent in existing technologies. By incorporating high-resolution signal generation, flexible waveform patterns, and precise control, the proposed device significantly improves upon conventional systems. Additionally, the use of a discrete R-2R ladder DAC circuit and an advanced driving stage configuration ensures superior performance in generating non-linear signals necessary for various therapeutic applications. This research not only advances the field of electrical stimulation technology but also provides practical solutions for improving healthcare accessibility, particularly in regions with limited resources.

The scope of this study focuses on the design, implementation, and evaluation of the proposed multi-functional ES device. Emphasis is placed on the pulse generator and driving stage units, which are critical in ensuring the precision and effectiveness of the device's output signals. While this study primarily targets applications in physiotherapy, rehabilitation, and pain management, it also lays the groundwork for future innovations in the field of electrical stimulation. A comprehensive assessment of the device's capabilities, including its waveform generation, signal precision, and adaptability to various therapeutic needs, is conducted with the aim of enhancing the versatility of ES applications.

The structure of this paper is as follows: Section 1 presents the background and significance of the research, establishing the rationale and context for the development of the proposed electrical stimulation (ES) device. Section 2 provides a detailed account of the methodologies employed in the design and implementation of the system, with particular emphasis on the technical aspects of the pulse generator and driving stage. Section 3 describes the experimental setup, configurations, and results. Section 4 offers a comprehensive discussion of the findings. Finally, Section 5 concludes the paper by summarizing the key insights and contributions of the study.

2. Methodology

2.1. System Overview

This section provides an overview of the proposed 2-channel, multi-functional therapeutic ES device, as depicted in Figure 1. The system comprises four main units: (A) the user interface (UI) and controller unit, (B) the pulse generator unit, (C) the driving stage unit, and (D) the protection unit. Each unit plays a critical role in ensuring the device's functionality, reliability, and safety across diverse therapeutic applications.

(A) UI and Controller Unit

The UI has been designed to fulfill three primary functions: input peripheral, display, and system notification. There are five components in this UI design: a multipoint touchscreen, push-button switches, a rotary switch, LED indicators, and a buzzer. A multipoint touchscreen integrated with a rotary switch was designed to serve as the primary input peripheral in this sub-unit. However, additional physical push buttons may be employed according to user preferences or as a contingency in the event of a multipoint touchscreen malfunction. The display sub-unit was designed to present essential information, such as system configurations, parameter settings, operating time and status, notification status, system help, and the user manual. The notification sub-unit integrates LED indicators, an audible buzzer, and on-screen status alerts to notify users.

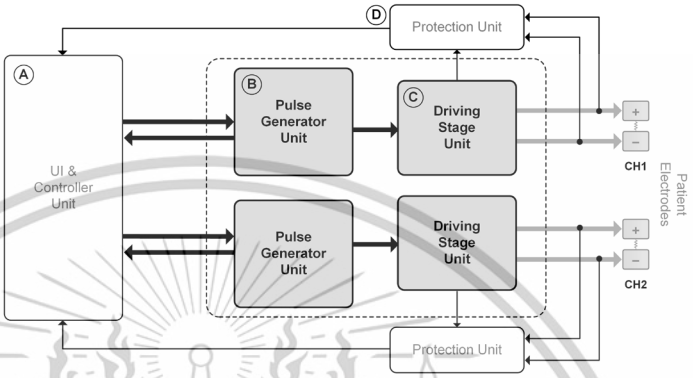


Figure 1. System overview of the proposed ES design.

The dsPIC33EP512MU810 microcontroller was selected as the core MCU and controller for this design, responsible for managing all operational functions and co-ordinating communication across three key units: the user interface (UI), the pulse generator, and the driving stage. This controller processes inputs from various sub-units, executes control algorithms, manages computations, accesses memory and storage, and interacts with peripheral devices. By overseeing the entire system's operation, the microcontroller ensures seamless communication between components and maintains the proper functioning of the system. Specifically, it plays a central role in interfacing with the UI, pulse generator, and system protection units, ensuring effective and reliable performance.

(B) Pulse Generator Unit

The unit is responsible for synthesizing pulses corresponding to parameters provided by (A). This unit must possess the capability to generate highly nonlinear waveforms at a high-resolution level, allowing for flexible adjustments of various pulse train amplitudes, durations, and frequencies. The specifications of this design must incorporate the twelve essential waveforms commonly used in physiotherapy, as identified through a preliminary survey of a large group of physiotherapists and rehabilitation doctors for effective treatment, as mentioned in [28].

These waveforms include IG, CG, MF, DF, CP, CPid, LP, TF, RF, ASYM, ASYM-A, and SYM. Additionally, two extra special functions have been incorporated. Each essential waveform allows for pulse amplitude adjustment within a range of 0–140 mA, pulse duration within ranges of 20–1,000,000 µs, and pulse repetitive frequency within a range of 0–1000 Hz. Furthermore, the two special functions enable modulation of the twelve essential waveforms using Surge and Modulation techniques, facilitating the generation of a wider variety of stimulation patterns.

(C) Driving Stage Unit

This unit has two primary functions: (1) amplifying the analog voltage signals from (B) to the necessary levels and (2) converting amplified voltage signals into current signals with identical shapes for delivery to the patient electrodes. By integrating these two key functions, the proposed driving stage unit, in conjunction with an H-bridge circuit, functions as a constant current source, ensuring precise voltage-to-current conversion and maintaining stable current outputs under varying load conditions.

(D) Protection Unit

The unit is responsible for ensuring the safety and well-being of patients or users. It monitors real-time input signals from the patient electrodes and sends to (A) for real-time

analysis and appropriate actions. It is designed to prevent potentially unsafe conditions during ES operation, which could occur due to various causes; for example, the detachment of electrodes during use, inadequate contact between electrodes and human skin, or other electrical circuit malfunctions/faults. This unit was designed such that if either overvoltage/overcurrent problems or electrical faults occur, the unit will transmit logic 0 to (A), resulting in stopping operation of the entire ES device to assure the patient safety.

This research paper will primarily concentrate on, and provide an in-depth analysis of, the (B) pulse generator unit and the (C) driving stage unit. Figure 2 illustrates the scope of work emphasized in this paper.

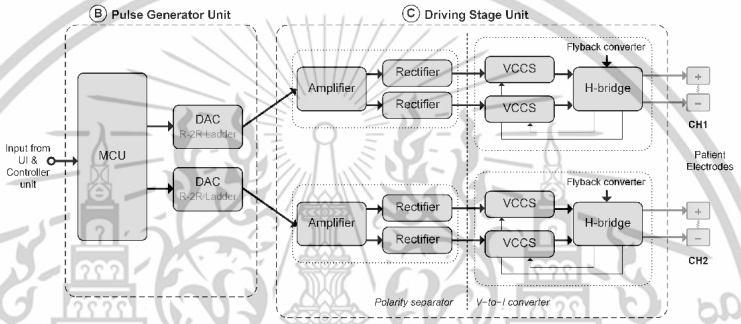


Figure 2. Scope of work emphasized in this paper.

2.2. *Proposed Pulse Generator Unit*

The pulse generator design in this research consists of two key components which includes the microcontroller (MCU) and the digital-to-analog converter (DAC).

2.2.1. MCU

This work applied a real-time technique in generating desired discrete digital signals. This design incorporates the dsPIC-33EP512MU810, a 16-bit DSP and high-speed microcontroller from Microchip Inc. (Chandler, AZ, USA). This MCU receives commands from the UI unit and generates discrete digital pulses corresponding to these commands. These digital pulses are mathematically computed and then transmitted directly to the DAC.

In this study, we utilized our proprietary in-house algorithms to generate the required waveforms. These algorithms are based on creating four fundamental signal types: direct current (DC) signal, sinusoidal signal, square wave, and triangular wave. By combining these four algorithms, our approach effectively generates and covers all twelve essential waveforms specified by our proposed multi-functional ES design, along with the two special functions previously mentioned. This method offers significant advantages over the traditional Look-Up Table (LUT) algorithm [1,2,4,7]. It is computationally inexpensive, faster, and requires fewer resources, thus enhancing speed, efficiency, and performance.

2.2.2. DAC

In this work, an R-2R ladder circuit, consisting of resistors with values of either R or 2R, was selected as the DAC. This choice meets the design requirements for resolution, speed, continuity, and notably higher slew rates compared to conventional DAC chips [29]. The proposed R-2R ladder DAC was paired with a high-speed operational amplifier (Op-Amp) to generate analog output signals, $V_{Ra}(t)$.

This design achieves a very high slew rate of 350 V/µs, and a bandwidth of 50 MHz [30], which is sufficient for generating highly non-linear signals with minimal distortion. Figure 3 illustrates the proposed R-2R ladder DAC developed in this work. Another advantage of employing an R-2R ladder circuit is its ability to interface with the MCU using

a parallel peripheral interface (PPI) via the MCU's input/output ports. This interface offers significantly faster communication speeds compared to the Serial Peripheral Interface (SPI) typically used in most of the DAC chips [31]. The enhanced speed provided by the PPI used in this work ensures more efficient data transmission, which is crucial for high-speed applications and complex waveform generation in therapeutic ES devices.

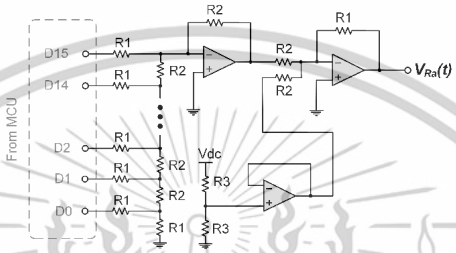


Figure 3. The proposed R-2R ladder DAC circuit.

The actual schematic of the proposed pulse generator unit implementation is depicted in Figure 4.

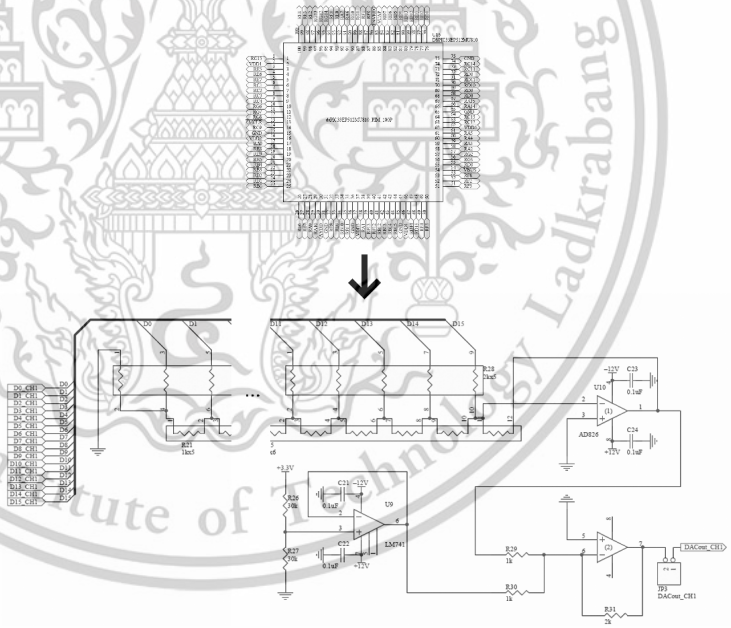


Figure 4. The actual schematic of the proposed pulse generator unit implementation.

2.3. Proposed Driving Stage Unit

The driving stage unit, commonly referred to as the ES power or ES output circuit, is primarily responsible for delivering the appropriately transformed current pulses to the targeted patient tissues, ensuring the intensity settings prescribed by the physiotherapist

are met. This unit comprises two essential components: (1) the polarity separator and (2) the voltage-to-current (V-to-I) converter, as depicted in Figure 2.

2.3.1. Polarity Separator

The polarity separator, shown in Figure 2, generates control signals for the Voltage-Controlled Current Source (VCCS) and H-bridge circuit within the V-to-I converter. This separator utilizes an inverting amplifier and two half-wave rectifier circuits, as depicted in Figure 5, to decompose any analog input voltage, $V_{Ra}(t)$, from the previous DAC into its positive and negative components, $V_{Ra}+(t)$ and $V_{Ra}-(t)$. These decomposed signals are then sent to the V-to-I converter for further processing.

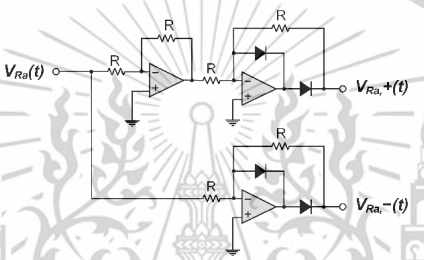


Figure 5. The signal polarity separator circuit in this design.

2.3.2. V-to-I Converter

The V-to-I converter in this study was designed using two VCCS circuits in conjunction with an H-bridge circuit, as illustrated in Figure 6. The VCCS circuits are essential for controlling the pulse shapes, amplitudes, and polarities of the desired output currents. The H-bridge circuit, which contains four transistors (Q1, Q2, Q3, and Q4), operates in pairs and is controlled by the two VCCS circuits. The right-hand VCCS circuit, consisting of U1 and Q5, controls transistors Q1 and Q2 to produce a positive-directional current flow. Conversely, the left-hand VCCS circuit, consisting of U2 and Q6, controls transistors Q3 and Q4 to produce a negative-directional current flow.

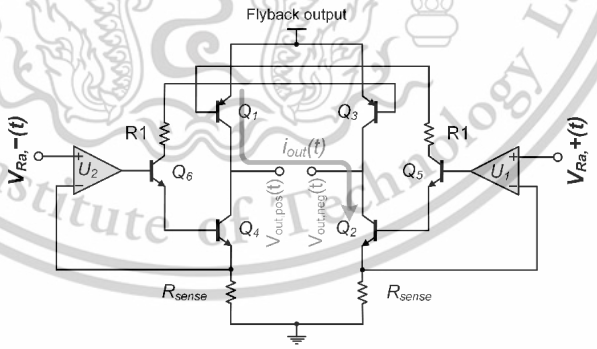


Figure 6. V-to-I converter in this work.

The H-bridge circuit outputs for each channel are directly connected to two electrodes, which attach to the patient's skin or targeted tissues. Two feedback signals from *R-sense* resistors in the H-bridge outputs, along with the two polarized output signals from the DAC, are simultaneously compared and adjusted to maintain a constant current output

as set by the users. This ensures accurate and consistent delivery of therapeutic output currents [25]. The proposed driving stage unit, as in Figure 6, is designed to generate a maximum output current of 150 mA on both the negative and positive sides. The output characteristics of this driving stage unit can be derived by the following equation:

$$i_{out}(t) = \frac{V_{out,pos}(t)}{R_{sense}} + \frac{V_{out,neg}(t)}{R_{sense}} \quad (1)$$

The flyback converter in Figure 6 is integrated as the power supply for the H-bridge circuit. Given the direct interface of the H-bridge with human skin, ensuring safety is paramount. To this end, an isolated flyback converter, depicted in Figure 7, has been utilized for its robust safety features. This converter produces an output voltage of 150 volts and can deliver a maximum current of 200 mA. Safety is ensured through the use of a transformer with a 13:115 turns ratio. The flyback circuit is regulated by the TL494 IC, operating at a switching frequency of 50 kHz, and employs a constant voltage with pulse width modulation (PWM) controller. This configuration ensures stable and reliable power delivery while maintaining stringent safety standards [32].

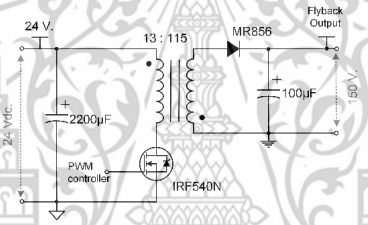


Figure 7. The flyback converter circuit.

The actual schematic of the proposed driving stage unit implementation is depicted in Figure 8. This figure provides a detailed illustration of the circuitry and components involved in achieving the desired voltage-to-current conversion.

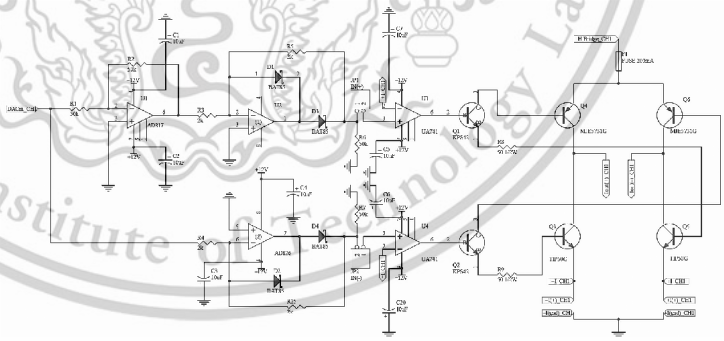


Figure 8. The actual schematic of the proposed driving stage unit implementation.

2.4. Proposed Target Outputs: Essential Waveforms and Special Functions

In this section, we provide a brief definition and description of the essential waveforms and special functions that form the foundation of the proposed ES device. These target outputs were carefully selected based on the recommendations and requests gathered from a preliminary survey of a large group of local physiotherapists and rehabilitation doctors.

Their input has shaped the design to ensure that the device meets the practical needs of therapeutic applications. Specifically, the twelve essential waveforms identified in the survey will serve as mandatory output options for this device.

A key advantage of our design, which leverages in-house technology, proprietary algorithms, and a versatile hardware configuration, is its flexibility for future expansion. Should additional therapeutic waveforms or specialized output current requirements arise, the system can be easily modified to accommodate more than the initial twelve waveforms. Furthermore, the adjustability of both existing and future waveforms can be expanded as needed, ensuring that the design remains adaptable to evolving clinical demands.

2.4.1. Twelves Essential Waveforms [22,27,28,33,34]

(1) Interrupted Galvanic (IG) Waveform: The IG waveform is a direct current (DC) that is periodically interrupted, producing a series of short pulses. This waveform is particularly beneficial for deep tissue stimulation and is effective in inducing muscle contractions. It is commonly used for rehabilitating paralyzed muscles and improving blood circulation, making it ideal for patients with muscle atrophy or peripheral nerve injuries. The IG waveform promotes better muscle tone and enhances tissue oxygenation, which aids in recovery and rehabilitation.

(2) Continuous Galvanic (CG) Waveform: The CG waveform consists of a continuous, unmodulated direct current (DC). It is primarily used for pain relief in chronic conditions such as arthritis and inflammatory diseases. The continuous nature of the CG waveform helps reduce inflammation, and it is also utilized in iontophoresis treatments, where it facilitates the delivery of medications into tissues. This targeted approach provides localized therapeutic effects, making CG an effective solution for patients requiring pain management and anti-inflammatory therapy.

(3) Monophase Fixed (MF) Waveform: The MF waveform is a single-phase, rectified sinusoidal current with a frequency of 50 Hz. Its consistent, unidirectional current reduces skin resistance, allowing deeper tissue penetration. This makes the MF waveform especially useful for pain relief in deep muscles and muscle strengthening. It is frequently employed in the treatment of patients with muscle weakness or those recovering from injury, as it delivers targeted stimulation to the affected muscle groups.

(4) Diphase Fixed (DF) Waveform: The DF waveform features a dual-phase, rectified sinusoidal current with a frequency of 100 Hz. By alternating between positive and negative phases, the DF waveform ensures balanced muscle stimulation. It is highly effective for pain relief, improving circulation, and treating muscle spasms. This waveform is particularly useful in post-operative recovery, as it reduces pain while promoting faster muscle recovery and rehabilitation.

(5) Courted Period (CP) Waveform: The CP waveform alternates rapidly between one second of Monophase Fixed (MF) current and one second of Diphase Fixed (DF) current. This alternating current is highly effective for muscle re-education and strengthening, as it generates consistent muscle contractions without causing discomfort. The CP waveform is particularly beneficial for patients recovering from stroke or neurological injuries, as it supports muscle recovery without excessive fatigue.

(6) Courted Period Iso-Dynamic (CPid) Waveform: Similar to the CP waveform, the CPid waveform alternates between MF and DF currents, but with the MF phase having 12.5% lower amplitude than the DF phase. This configuration helps to prevent muscle fatigue while providing intermittent muscle contractions, making the CPid waveform ideal for muscle strengthening and functional rehabilitation. It is commonly used in neuromuscular training, where controlled and alternating stimulation is required for effective recovery.

(7) Long Period (LP) Waveform: The LP waveform alternates between six seconds of Monophase Fixed (MF) current and six seconds of Diphase Fixed (DF) current. During the DF phase, additional pulses with gradually increasing and decreasing amplitude

are introduced. This gradual modulation makes the LP waveform particularly useful for activating larger muscle groups, such as those in the legs and back. It is highly beneficial for lower limb rehabilitation, posture correction, and spinal cord injury recovery, as it provides deeper and more sustained stimulation.

(8) Triangular Faradic (TF) Waveform: The TF waveform is a saw-tooth shaped current with adjustable parameters for amplitude, duration, and frequency. Its gradual rise and fall pattern provides a smooth stimulation, which is particularly effective for muscle re-education and tissue healing. This waveform is ideal for patients recovering from injury or surgery, where muscle strength needs to be regained gradually and progressively.

(9) Rectangular Faradic (RF) Waveform: The RF waveform is a rectangular-shaped pulsed current with adjustable settings for amplitude, duration, and frequency. It is commonly used for targeted muscle stimulation and nerve activation, particularly in Functional Electrical Stimulation (FES). The RF waveform helps restore movement in patients with neurological disorders such as stroke or multiple sclerosis by delivering precise, controlled stimulation to specific muscle groups.

(10) Asymmetrical (ASYM) Waveform: The ASYM waveform is a monophasic, asymmetrical pulsed current. It is particularly effective for preventing muscle fatigue and improving endurance during long-term therapy. The asymmetrical pulse reduces skin irritation, making it suitable for patients who require chronic pain management or muscle rehabilitation over extended periods. Its gentle, continuous stimulation helps sustain therapy without causing discomfort.

(11) Asymmetrical Alternating (ASYM-A) Waveform: The ASYM-A waveform is a biphasic, asymmetrical pulsed current that provides greater control over the intensity of stimulation. This waveform is beneficial for gradual muscle strengthening and preventing muscle atrophy. It is particularly effective in progressive rehabilitation programs, as clinicians can adjust the intensity and balance of the pulses as the patient's muscle strength improves over time.

(12) Symmetrical (SYM) Waveform: The SYM waveform is a biphasic, symmetrical pulsed current that ensures equal stimulation across muscle groups. This balanced stimulation reduces the risk of muscle fatigue and tissue irritation, making it ideal for muscle reconditioning. The SYM waveform is commonly used in bilateral limb rehabilitation, where balanced muscle development on both sides of the body is crucial for recovery and overall functionality.

2.4.2. Two Special Functions [33–35]

The following section explains the two special functions, Surge and Modulation, emphasizing their necessity and the contributions they bring to standard therapeutic protocols. These functions are designed to enhance conventional therapy by offering more controlled and dynamic stimulation options, improving both the flexibility and efficacy of treatment.

(1) Surge provides a gradual increase and decrease in intensity, allowing for deeper tissue targeting while minimizing abrupt changes in stimulation. This function is particularly beneficial for pain management and muscle stimulation, offering patients a smoother and more comfortable therapeutic experience.

(2) Modulation introduces variations in the frequency or intensity of the current, preventing the body from adapting or habituating to the therapy. By maintaining the body's response to stimulation over extended periods, Modulation enhances the effectiveness of long-term treatments.

In comparison to standard therapy, the integration of Surge and Modulation offers greater flexibility and adaptability, enhancing patient comfort and potentially leading to better therapeutic outcomes. These functions are especially valuable in personalized treatments, where static waveforms may be less effective. Electrical stimulation devices

without these features may still provide effective therapy but are often limited in terms of comfort, adaptability, and long-term efficacy.

2.5. Design Specifications and Operational Ranges of the Proposed ES Device

Table 1 below presents the design specifications of the proposed ES device, offering a comprehensive overview of its capabilities. It highlights the intricate relationship between the device's adjustable parameters and their respective operational ranges. Given the device's twelve essential output current patterns, understanding these interactions is crucial for optimizing its performance. The table is structured to clarify how each parameter can be tuned within its specific limits, offering a detailed matrix that captures the nuanced relationships between the various output patterns and their respective adjustable ranges. This organized approach shown in Table 1 will help readers navigate the complexities of the proposed ES device's specifications and its operational ranges with greater ease and precision.

Table 1. Design specifications and operational ranges of the proposed es device.

Output Current Patterns	Group	Operational Ranges and Its Adjustability			Special Functions Availability	
		Pulse Amplitude (mA)	Pulse Duration (μs)	Pulse Repetitive Frequency (Hz)	Surge	Modulation
1	IG	0–40	-	-	-	-
2	CG	0–40	-	-	-	-
3	MF	0–70	-	-	Yes	-
4	DF	0–70	-	-	Yes	-
5	CP	0–70	-	-	-	-
6	CPid	0–70	-	-	-	-
7	LP	0–70	-	-	-	-
8	TF	0–80	20–1,000,000	0.2–1000	Yes	Yes
9	RF	0–80	20–1,000,000	0.2–1000	Yes	Yes
10	ASYM	0–140	20–400	1–200	Yes	Yes
11	ASYM-A	0–140	20–400	1–200	Yes	Yes
12	SYM	0–140	20–400	1–200	Yes	Yes

2.6. Implementation

Each component mentioned in Sections 2.2 and 2.3 has undergone extensive testing to ensure its functionality. The circuits and printed circuit board (PCB) designs were deliberately optimized for a wide range of scenarios, ensuring reliability across various essential waveforms and the two special functions. Eventually, all the components were integrated into two PCBs, each dedicated to its specific functions, as shown in Figure 9.

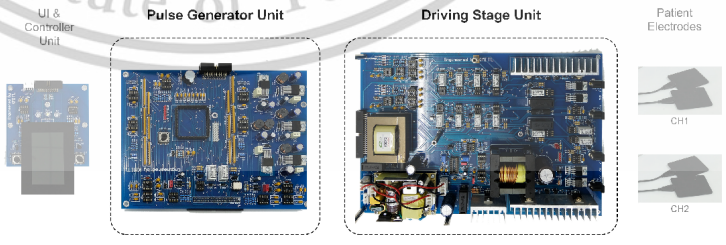


Figure 9. Two integrated PCBs of the key components in the proposed ES design.

3. Experiments and Results

This section presents the experimental evaluation of the proposed ES device. The experiments were designed to assess the device's performance across various critical dimensions, including its ability to generate diverse therapeutic waveforms, maintain precise and stable output currents, and adhere to stringent international standards for medical electrical equipment. The experimental setup was carefully configured to imitate several clinical conditions, ensuring that the experimental results obtained are meaningful and applicable to practical therapeutic treatment scenarios [6,26]. The following sections provide a comprehensive assessment of the device's performance and reliability covering test configurations, output demonstration and accuracy, stability under variable load conditions, and compliance with the relevant IEC standards.

3.1. Test Configurations

The experimental setup, as illustrated in Figure 10, was meticulously configured to evaluate the performance of the proposed ES device across various tests. Figure 11 illustrates the actual experimental setup including all equipment used. The process began with the pulse generator unit, which received input configuration settings from the UI and controller unit. These settings were processed to generate voltage pulse signals, denoted as V_{Ra}, which were subsequently fed into the driving stage unit. The driving stage unit converted these voltage pulse signals into output currents I_{Out}, which were then delivered directly to a resistive load R, simulating the impedance of human tissue [1].

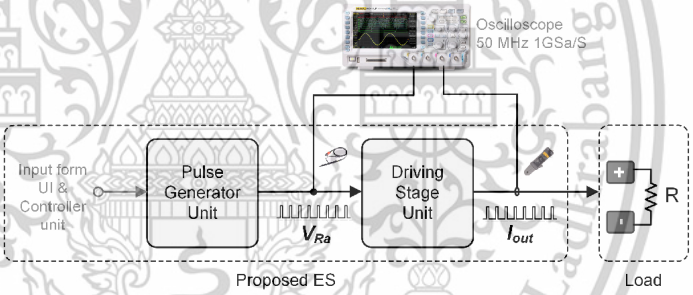


Figure 10. The experimental configuration diagram.

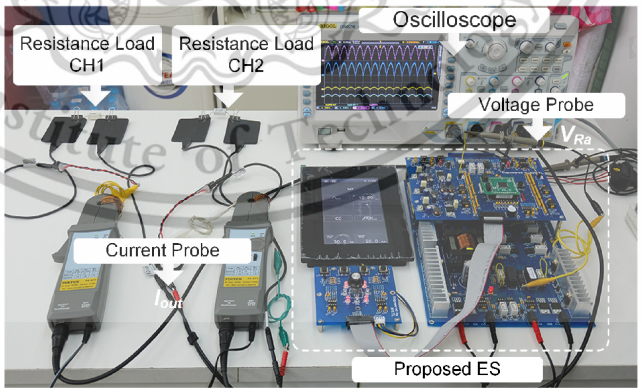


Figure 11. The actual experimental setup.

To monitor and record the waveforms of both V_{Ra} and I_{Out}, a high-precision 50 MHz, 1 GSa/s oscilloscope was employed. Channel 1 of the oscilloscope was equipped with a 150 MHz voltage probe, specifically to monitor the voltage signal V_{Ra} (t) in real time. Meanwhile, Channel 2 was connected to a high-precision current probe with a bandwidth ranging from DC to 50 MHz, enabling accurate measurement of the output current $I_{Out}(t)$ also in real time. The oscilloscope captured these signals both graphically and as raw data in comma-separated value (CSV) format for further analysis. This setup ensured that both the voltage and current waveforms were captured with high fidelity, facilitating a detailed and precise analysis of the device's performance.

3.2. Demonstration of Proposed ES Output Currents: Essential Waveforms, Adjustability, and Special Functions

The main objective for this test was to demonstrate and evaluate capabilities of the proposed ES device in generating all twelve essential therapeutic output currents, including its adjustability and also two special functions (Surge and Modulation).

3.2.1. Essential Waveforms Demonstration

Figure 12 presents the experimental results where the proposed ES device was configured to deliver a constant 40 mA across each of the twelve essential current outputs (IG, CG, ME, DF, CP, CPid, LP, TF, RF, ASYM, ASYM-A, and SYM). The voltage signal, V_{Ra}, generated by the pulse generator unit, and the corresponding output currents, I_{Out}, produced by the driving stage unit, were captured via Channel 1 (blue) and Channel 2 (red) of the oscilloscope, respectively.

The results across all twelve sub-figures confirm the close alignment between V_{Ra} and I_{Out} waveforms, with consistent similarities in shape, pulse duration, and pulse repetitive frequency. Additionally, the current output amplitudes are precisely aligned with the gain, as can be derived from Equation (1).

It is important to note that Figure 12 provides examples of each essential current output waveform. Given the wide range and variability of output adjustability, it is not feasible to display every possible variation of the twelve waveforms.

3.2.2. Adjustability Demonstration

The experimental results presented in Figures 13–15 highlight the performance of the proposed ES device across three main adjustable parameters, including pulse amplitude, pulse duration, and pulse repetitive frequency. These figures demonstrate the proposed ES device's ability to be precisely configured to achieve the target outputs for each parameter.

In Figure 13, the MF current pattern was selected as a representative of sinusoidal-based current signals, while the ASYM current pattern was chosen as a representative of pulse-based current signals to illustrate the pulse amplitude adjustability of the proposed ES device. The target of output current amplitude was set at approximately 10%, 50%, and 100% of the rated output current for each pattern, with pulse duration and pulse repetitive frequency held constant. The experimental results confirm that the proposed ES device accurately generates the pulse amplitude as set for both sinusoidal-based and pulse-based output currents, with minimal to zero distortion in waveform shape, pulse duration, and pulse repetitive frequency.

In Figure 14, only the ASYM current pattern is used to demonstrate and validate the pulse duration adjustability of the proposed ES device. The sinusoidal-based current patterns were considered necessary only for amplitude adjustability, in alignment with actual clinical practice and the requirements of doctors and physiotherapists [22]. Pulse duration adjustability was tested and recorded at 50 µs, 500 µs, and 2000 µs, with pulse amplitude and pulse repetitive frequency held constant. The experimental results confirm that pulse duration can be accurately adjusted and configured to meet a wide range of clinical needs.

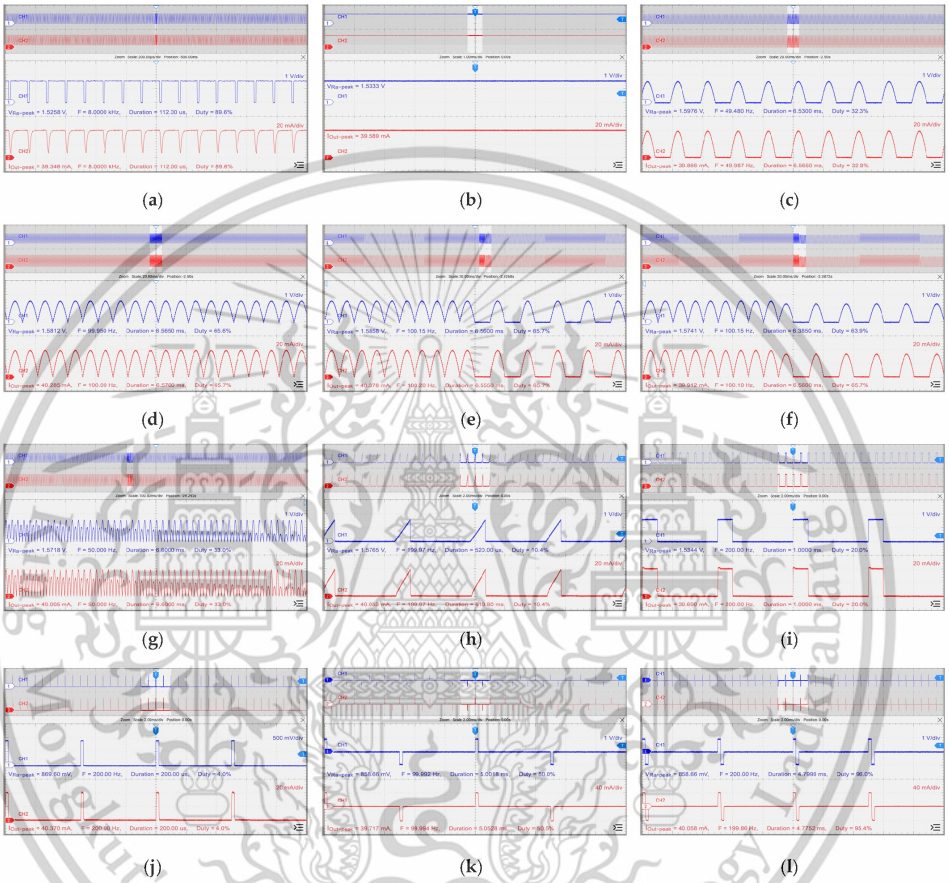
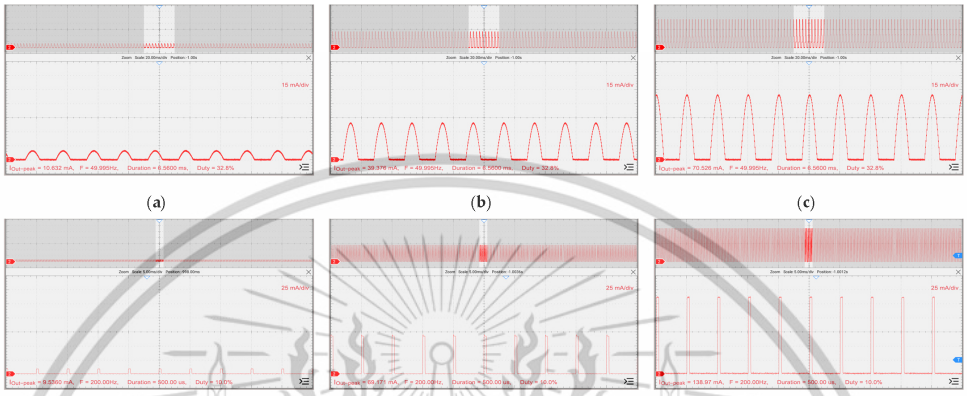


Figure 12. Demonstration of twelve essential output currents (I_{Out}) compared to controlled voltage (V_{Ra}) of the proposed ES device: (**a**) IG; (**b**) CG; (**c**) MF; (**d**) DF; (**e**) CP; (**f**) CPid; (**g**) LP; (**h**) TF; (**i**) RF; (**j**) ASYM; (**k**) ASYM-A; and (**l**) SYM.

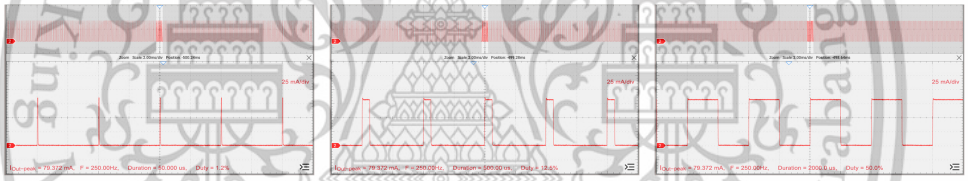
Figure 15 illustrates the experimental results for pulse repetitive frequency adjustability, using the RF current pattern as a representative at 50 Hz, 200 Hz, and 500 Hz. The experimental results verify that pulse repetitive frequency can be adjusted precisely without affecting the pulse amplitude or pulse duration, both of which were held constant.



(**a**) (**b**) (**c**)

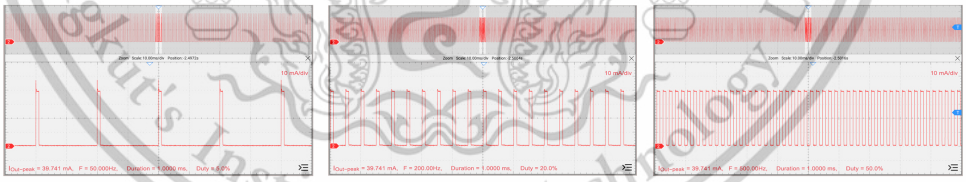
(**d**) (**e**) (**f**)

Figure 13. Demonstration of pulse amplitude adjustability: (**a**) MF 10 mA; (**b**) MF 40 mA; (**c**) MF 70 mA; (**d**) ASYM 10 mA; (**e**) ASYM 70 mA; and (**f**) ASYM 140 mA.



(**a**) (**b**) (**c**)

Figure 14. Demonstration of pulse duration adjustability (ASYM): (**a**) 50 µs; (**b**) 500 µs; and (**c**) 2000 µs.

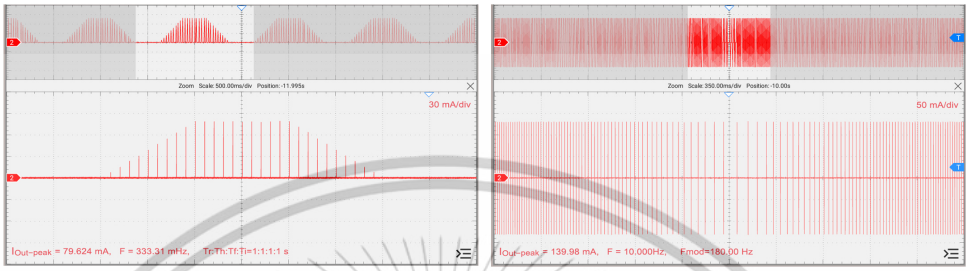


(**a**) (**b**) (**c**)

Figure 15. Demonstration of pulse repetitive frequency adjustability (RF): (**a**) 50 Hz; (**b**) 200 Hz; and (**c**) 500 Hz.

3.2.3. Special Functions Demonstration

This experiment was conducted extensively across various modulated settings to ensure precise alignment and reliability in modulating each of the twelve essential output patterns using two special functions: Surge and Modulation. Figure 16 presents example results for some of these essential output waveform modulations achieved with the Surge and Modulation techniques.



(**a**) (**b**)

Figure 16. Demonstration of two additional special functions for output currents.: (**a**) ASYM with Surge; and (**b**) SYM with Modulation.

3.3. Output Accuracy Verification Test in Compliance with IEC Standards

The experimental setup adhered to the guidelines outlined in Clause 201.12.1.102 of the IEC 60601-2-10 standard [36], which addresses the basic safety and essential performance requirements for nerve and muscle stimulators, specifically concerning pulse parameter accuracy control. The standard emphasizes that the accuracy of current outputs is critical for ensuring the safety and effectiveness of therapeutic applications. It specifies that pulse durations, pulse repetitive frequencies, and pulse amplitudes—including any DC components caused by offsets or asymmetrical waveforms—must not deviate by more than ±20% when measured with a specified load resistance. This tolerance is established to ensure that the proposed ES device functions within safe and effective parameters, thereby minimizing the risks associated with significant deviations in stimulation characteristics. The primary objective of this test was to verify that the proposed ES device consistently delivers the intended therapeutic output current across a range of test conditions and settings.

The testing procedure was conducted in three configurations: pulse amplitude test, pulse duration test, and pulse repetitive frequency test. Each stage focused on isolating a specific parameter while maintaining the other two parameters constant. Testing was performed across the entire operational range of each output current pattern, divided into ten incremental steps from the minimum to the maximum values within each range, using the specific load resistance specified in the standard. At each step, the output was measured, and the deviation percentage between the setting value and the measured value was calculated.

To evaluate the accuracy of the proposed method's output current in relation to the reference tolerance specified in the IEC 60601-2-10 standard, the percentage of deviation (similar to percentage of error) is a valuable metric [37,38]. It helps quantify the difference between the output current and the reference value, providing a clear indication of how well the method adheres to the standard's tolerance requirements.

The percentage of deviation can be calculated as:

$$Percentage\ Deviation = \left(\frac{Measured\ value - Reference\ value}{Reference\ value} \right) \times 100 \quad (2)$$

where in this context, the Measured value refers to the output values of amplitude, duration, or frequency from the proposed device, while the Reference value refers to the setting value for each corresponding parameter.

This calculation provides a percentage that indicates how much the output current deviates from the acceptable tolerance defined by the standard. Lower percentage deviations indicate closer adherence to the reference tolerance, ensuring compliance with the standard's requirements.

To assess the consistency of the percentage deviations computed from each current output pattern for a sample size of ten (with ten incremental steps from the minimum to the maximum setting value), standard deviation (SD) serves as a valuable statistical measure [37,38]. SD quantifies the variation or dispersion of data points from the mean, providing insight into how closely the percentage deviations are clustered around the average value.

The standard deviation (SD) can be calculated as:

$$\mathrm{SD} = \sqrt{\frac{1}{N}\sum_{i=1}^{N}(x_i - \bar{x})^2} \tag{3}$$

where N is the number of samples (in this case, 10), x_i is each individual percentage deviation, and $\bar{x}$ is the mean of the percentage deviations.

A lower standard deviation indicates that the percentage deviations for the output current patterns are minimal, meaning that the data points are closely clustered around the mean. This suggests that the output currents are highly consistent and reliable across the ten samples for each pattern, as shown in Tables 2–4.

Table 2. Deviation and compliance with IEC standards in pulse amplitude variations.

	Output Current Patterns	Pulse Amplitude Setting Range [22,39,40] (mA)	Percentage Deviation from 10-Step Increments of the Proposed Output Current (%)			IEC 60601-2-10 Maximum Deviation [36] (%)	Compliance [41–43]
			Min–Max	SD	Avg		
1	IG	0–40	2.05–6.00	1.17	3.49	20.00	Complied
2	CG	0–40	1.75–5.55	1.19	3.23	20.00	Complied
3	MF	0–70	0.13–3.93	1.39	1.01	20.00	Complied
4	DF	0–70	0.04–1.93	0.63	0.97	20.00	Complied
5	CP	0–70	0.27–4.00	1.39	1.05	20.00	Complied
6	CPid	0–70	0.23–4.00	1.17	1.23	20.00	Complied
7	LP	0–70	0.04–3.32	1.14	1.25	20.00	Complied
8	TF	0–80	0.13–1.31	0.44	0.60	20.00	Complied
9	RF	0–80	0.96–4.75	1.18	1.31	20.00	Complied
10	ASYM	0–140	1.62–8.14	1.70	4.33	20.00	Complied
11	ASYM-A	0–140	1.46–7.07	1.47	3.89	20.00	Complied
12	SYM	0–140	1.80–7.79	1.64	4.07	20.00	Complied

Table 3. Deviation and compliance with IEC standards in pulse duration variations.

	Output Current Patterns	Pulse Duration Setting Range [22,39,40] (µs)	Percentage Deviation from 10-Step Increments of the Proposed Output Current (%)			IEC 60601-2-10 Maximum Deviation [36] (%)	Compliance [41–43]
			Min–Max	SD	Avg		
1	TF	20–1,000,000	0.00–0.50	0.15	0.07	20.00	Complied
2	RF	20–1,000,000	0.00–0.50	0.15	0.07	20.00	Complied
3	ASYM	20–400	0.00–1.25	0.46	0.39	20.00	Complied
4	ASYM-A	20–400	0.00–1.12	0.38	0.32	20.00	Complied
5	SYM	20–400	0.00–1.05	0.42	0.37	20.00	Complied

Table 4. Deviation and compliance with IEC standards in pulse repetitive frequency variations.

	Output Current Patterns	Pulse Repetitive Frequency Setting Range [22,39,40] (Hz)	Percentage Deviation from 10-Step Increments of the Proposed Output Current (%)			IEC 60601-2-10 Maximum Deviation [36] (%)	Compliance [41–43]
			Min–Max	SD	Avg		
1	TF	0.2–1000	0.00–0.30	0.09	0.04	20.00	Complied
2	RF	0.2–1000	0.00–0.30	0.09	0.04	20.00	Complied
3	ASYM	1–200	0.00–0.17	0.05	0.04	20.00	Complied
4	ASYM-A	1–200	0.00–0.14	0.05	0.03	20.00	Complied
5	SYM	1–200	0.00–0.14	0.05	0.03	20.00	Complied

In this context, a small SD reflects well on the performance of the proposed method, as it demonstrates that the variations between the measured output currents and the reference tolerance are minimal, implying good accuracy and stability across different output patterns.

The experimental results, presented in Tables 2–4, illustrate the deviations observed when varying pulse amplitudes, pulse durations, and pulse repetitive frequencies across all twelve essential output current patterns, respectively. These tables detail the percentage deviations for each parameter, including the minimum value, maximum value, average value, and standard deviation (SD) of the percentage deviations observed as the parameter settings of each pattern were varied.

Table 2 presents the percentage deviation in pulse amplitude, which was observed to be within the range of 0.04% to 8.14%, remaining well below the maximum allowable limit specified by the IEC standard. Additionally, the SD of the percentage deviation ranged from 0.44% to 1.70%, indicating a high level of consistency in generating outputs across different pulse amplitude levels.

Table 3 illustrates the percentage deviation in pulse duration, which was minimal, ranging from 0.00% to 1.25%, and remained within the IEC maximum allowable limit. The SD of the percentage deviation ranged from 0.15% to 0.46%, reflecting the system's consistency in generating the desired output currents across various pulse duration levels.

Table 4 shows the percentage deviation in pulse repetitive frequency, which was exceptionally low, ranging from 0.00% to 0.30%, again well within the IEC maximum allowable limit. The SD of the percentage deviation was below 0.1%, demonstrating the system's consistent performance across different pulse repetitive frequency levels.

It should be noted that the experimental results presented in Tables 3 and 4 do not include all twelve output current patterns. Instead, they only emphasize the current patterns that are most commonly adjusted by physiotherapists and therapeutic doctors, based the preliminary survey mentioned before. The remaining patterns are also capable of pulse duration adjustment if desired.

One conclusion can be drawn from Tables 2–4 is that the proposed device demonstrates exceptionally high accuracy in generating various output currents, regardless of variations in pulse amplitude, pulse duration, and pulse repetitive frequency. This is evident when comparing the results with the compliance requirements of the IEC standard. The deviations outlined in the standard have been adhered to and met efficiently. Additionally, a low percentage of SDs observed indicate the reliability of the output currents generated by the proposed ES device. This confirms the device's performance in achieving precise, predictable, and efficient output currents.

3.4. Stability Analysis of Constant Current Output

The stability of constant current output is a crucial factor in the reliable delivery of therapeutic currents to real-world patients, ensuring that the proposed ES device performs effectively without fluctuations, even when faced with changes in load resistance. This test

aimed to evaluate the reliability of the proposed ES device in maintaining consistent and constant output currents under varying load conditions, which simulate the diversity and variability of patient-specific impedance during treatment.

The testing procedure involved setting the target output current at the maximum value of each current range limit, according to the individual output current patterns shown in 5. The output current amplitude of the proposed ES device was then measured while varying the resistive loads, which were simulated to represent different conditions of human tissues. The load conditions were set at 500, 1000, and 2000 ohms, respectively—a range typical of human tissue impedance, as reported by [1].

We then compared the output currents from the proposed ES device and calculated the percentage error (also referred to as percentage deviation) in amplitude using the same formula as in Equation (2). This allowed us to quantify the deviation between the 500-to-1000-ohm load conditions, as well as between the 500-to-2000-ohm load conditions. The primary focus was on observing the percentage amplitude deviation between these two pairs of experiments. A lower percentage of deviation between the two load conditions indicates greater stability in the device's ability to maintain a constant output current, demonstrating its capability to deliver the desired current despite variations in load resistance.

In addition to amplitude comparisons, the stability of the constant output current was further evaluated by analyzing the correlation between the current waveforms from the two pairs of load configurations. Raw data of the arbitrary output waveforms were collected as comma-separated value (CSV) files and used to compute the correlation between the two output currents, assessing the similarity in both pulse duration and pulse repetitive frequency under varying load conditions.

To compare the similarity between two discrete current output waveforms, the Pearson correlation coefficient [37,38,44] provides a reliable measure of the linear relationship between the two signals. The Pearson correlation coefficient quantifies how well the variations in one waveform correspond to the variations in another waveform, helping assess their similarity in terms of amplitude, duration, and also repetitive frequency.

The Pearson correlation coefficient r can be calculated as:

$$r = \frac{\sum(y_i - \overline{y})(z_i - \overline{z})}{\sqrt{\sum(y_i - \overline{y})^2 \sum(z_i - \overline{z})^2}} \quad (4)$$

where y_i and z_i are the individual points of the two discrete waveforms, $\overline{y}$ and $\overline{z}$ are the mean values of the respective waveforms, and r ranges from -1 to 1, where

$r = 1$ indicates a perfect positive correlation,
$r = -1$ indicates a perfect negative correlation,
$r = 0$ indicates no correlation.

By calculating the Pearson correlation coefficient, we assessed the degree of similarity between the two current output waveforms, with higher values of coefficient r indicating a greater similarity in their patterns. Additionally, the Pearson correlation coefficient was employed to explore the interdependencies between key variables—pulse amplitude, pulse duration, and pulse repetitive frequency—to evaluate how changes in one variable may affect another. The results revealed a strong correlation between these parameters, indicating a significant relationship among them. This finding provides valuable insight into the broader performance and interaction of the system's variables.

These two comprehensive analyses ensured that the stability of the proposed ES device was not only assessed in terms of pulse amplitude but also in terms of the pulse durations and pulse repetitive frequencies of all 12 essential current patterns, providing a comprehensive evaluation of the system's performance under variable load conditions.

The experimental results presented in Table 5 clearly indicate that the pulse amplitude of the output current varied within a very narrow range, with deviations of less than $\pm 2\%$ regardless of how the load resistance was altered. Additionally, the computed Pearson

correlation coefficient *r* between the two test configurations was exceptionally high, with values ranging from 0.9909 to 0.9994. This high correlation suggests that all of the amplitudes, durations, and repetitive frequencies of the output currents remained consistent, even when load conditions were varied [37,38,44].

Table 5. Amplitude deviation and correlation for load variation from 500 Ω to 2000 Ω.

No	Output Current Patterns	Output Current Settings (mA)	Measured Output Currents with Different Load Impedances (mA)			Load Variation from 500 Ω to 1000 Ω		Load Variation from 500 Ω to 2000 Ω	
			500 Ω [1]	1000 Ω [1]	2000 Ω [1]	Amplitude Deviation	Pearson Correlation Coefficient (*r*)	Amplitude Deviation	Pearson Correlation Coefficient (*r*)
1	IG	40	39.86	40.16	40.09	0.75%	0.9932	0.59%	0.9923
2	CG	40	39.76	39.69	39.79	−0.17%	0.9987	0.09%	0.9991
3	MF	70	69.91	69.97	70.44	0.09%	0.9989	0.76%	0.9988
4	DF	70	69.97	69.20	68.96	−1.11%	0.9985	−1.44%	0.9990
5	CP	70	70.19	70.01	69.95	−0.25%	0.9906	−0.34%	0.9909
6	CPid	70	70.16	70.57	71.10	0.59%	0.9985	1.34%	0.9921
7	LP	70	69.97	70.14	70.38	0.25%	0.9994	0.59%	0.9993
8	TF	80	79.91	81.34	80.05	1.79%	0.9905	0.17%	0.9978
9	RF	80	79.23	79.03	80.08	−0.25%	0.9996	1.07%	0.9994
10	ASYM	140	137.96	138.92	139.64	0.69%	0.9945	1.22%	0.9973
11	ASYM-A	140	138.40	139.13	138.64	0.53%	0.9966	0.17%	0.9958
12	SYM	140	138.65	139.62	140.23	0.70%	0.9982	1.14%	0.9982

3.5. Verification of Compliance with IEC Standards for Medical Equipment

The aim of this testing procedure was to verify that the proposed ES device meets the relevant international medical equipment standards and regulatory requirements. Compliance with these standards is essential to ensure the safety, efficiency, and reliability of the ES device in clinical therapeutic applications. A comprehensive evaluation of the device was conducted in strict accordance with established guidelines, including assessments of electrical safety, electromagnetic compatibility (EMC), and performance benchmarks, to confirm that the proposed ES device meets all necessary criteria for safe and effective operation in real-world ES applications.

The proposed ES device successfully underwent the process of obtaining international certification in accordance with the medical equipment standards including IEC 60601-1 [45], IEC 60601-1-2 [46] and IEC 60601-2-10 [36]. These certifications were conducted by the PTEC, Thailand, a government agency responsible for testing electrical and electronic equipment. The device was certified as meeting the requirements specified by those standards, as documented in the reports [41–43]. The following list of certified standards and corresponding details is provided below.

3.5.1. IEC 60601-1: 2012 (General Requirements for Basic Safety and Essential Performance)

The verification conducted in accordance with this standard include all clauses.

3.5.2. IEC 60601-1-2: 2014 (General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Disturbances)

The verification conducted in accordance with this standard included the following:

- Conducted emission;
- Radiated emission;
- Harmonics emission;
- Voltage fluctuation;
- Electrostatic discharge;

- Radiated RF electromagnetic field immunity;
- Electrical fast transient;
- Electrical surge tolerance;
- Conducted immunity;
- Power frequency magnetic;
- Voltage dips.

3.5.3. IEC 60601-2-10: 2012 (Amendment 2, Particular Requirements for the Basic Safety and Essential Performance of Nerve and Muscle Stimulators)

The verification conducted in accordance with this standard included the following:

- Identification, marking and documents;
- Accuracy of controls and instruments;
- Pulse parameters;
- Protection against hazardous output;
- Supply voltage fluctuations;
- Limitation of output parameters.

Conformity with these three IEC standards ensures that the proposed ES device operates reliably and safely in environments with electromagnetic disturbances, without interfering with the functionality of other devices. Additionally, it demonstrates that the device delivers electrical stimulation output within safe limits, thereby safeguarding patients from potential hazards associated with electrical currents [36,41–43,45,46].

4. Discussion

4.1. Performance and Therapeutic Outcomes

The accuracy of the pulse generator in our proposed device is a critical aspect of performance, particularly when compared to other systems on the market or in previous studies. However, direct comparisons of accuracy are challenging due to the limited availability of detailed data on output current accuracy in existing publications and commercial reports. Most studies focus on operating ranges, such as pulse amplitude, duration, and frequency, without specifying exact accuracy.

For example, Bosques et al. [26] reviewed 37 articles on therapeutic electrical stimulation (ES) and reported effective frequency ranges for NMES, FES, TENS, and TES between 10 and 150 Hz, with pulse durations ranging from 50 to 1000 µs. Broderick et al. [6] examined seven commercial surface-type ES devices, noting frequency ranges from 1 to 140 Hz and pulse durations between 50 and 250,000 µs. Wu et al. [1] developed a multi-channel ES system with frequency ranges of 3–100 Hz and pulse duration adjustability from 50 to 1000 µs, while Chang et al. [12] proposed a microprocessor-based ES device with output currents between −3 and 3 mA, frequency ranges from 10 to 500 Hz, and pulse duration from 50 to 2000 µs.

In comparison, our proposed ES device offers significantly enhanced performance, with a frequency adjustability range of 0.2–1000 Hz and pulse durations from 20 to 1,000,000 µs. Additionally, our device incorporates special functions like Surge and Modulation, which few other devices offer [40]. These functions allow the generation of twelve essential waveforms specifically tailored for various therapeutic needs. Moreover, the device is compliant with IEC 60601-2-10 standards, ensuring that pulse parameter accuracy meets regulatory thresholds, providing confidence in its reliability and performance.

Our device offers significant improvements over existing systems in two key areas:

Performance: The device achieves high levels of accuracy and reliability by complying with all relevant IEC standards, specifically Sections 3.5.1–3.5.3, ensuring precise and consistent output. Additionally, its wide range of adjustability in pulse amplitude, duration, and frequency allows for greater flexibility, enabling a broader range of therapeutic applications compared to other devices on the market.

Therapeutic Outcomes: The combination of enhanced accuracy, flexibility, and adaptability makes the device more effective in delivering treatments across various clinical

settings, including hospitals, clinics, and other healthcare facilities. This versatility ensures that the device can meet the diverse therapeutic needs of patients, making it suitable for a wide range of treatment protocols.

4.2. User Interface and Practical Implementation

The user interface (UI) of our therapeutic electrical stimulator was designed with ease of use and efficiency in mind. The graphical user interface (GUI) features intuitive, touch-based controls that allow clinicians to quickly select waveforms, adjust treatment modes, and modify parameters as needed. Real-time feedback is provided through visual indicators, enabling clinicians to monitor therapy progress and make necessary adjustments without interrupting treatment.

Preliminary usability tests with clinicians have yielded positive feedback. The system was noted to be intuitive and easy to operate, even for users with minimal training. The ability to adjust parameters mid-treatment, such as waveform characteristics or pulse intensity, was highlighted as particularly beneficial in clinical settings. Future usability testing will further assess the UI's performance across a wider range of clinical environments, with the goal of refining the interface to improve the user experience and reduce setup times.

4.3. Power Consumption and Miniaturization

The design of this therapeutic electrical stimulator is optimized for stationary use in clinical environments such as hospitals and clinics, where a stable power supply is available. Consequently, power efficiency and miniaturization were not primary concerns in this study. Instead, the focus was placed on ensuring accuracy and reliability in the device's therapeutic output. However, for future iterations of this device, particularly if portable or wearable versions are considered, power management and miniaturization will become key factors to address.

4.4. Limitations

While the results of this study demonstrate the effectiveness of the proposed therapeutic electrical stimulator, there are several limitations. First, the device was primarily tested under controlled laboratory conditions, and additional clinical trials are required to validate its performance across diverse patient populations and real-world clinical environments. Expanding trials to include a more varied demographic will be essential for assessing the device's efficacy in different therapeutic contexts.

Second, while preliminary tests suggest that the user interface is intuitive, comprehensive usability trials are necessary to ensure that clinicians with varying levels of technical expertise can effectively operate the device. Future development should focus on refining the user interface and creating comprehensive training protocols for clinical staff.

Lastly, while the special functions Surge and Modulation were incorporated based on input from physiotherapists and doctors, further investigation is needed to assess their long-term benefits compared to standard modes. Additional studies are required to evaluate these features across a broader range of clinical conditions to determine their clinical superiority.

4.5. Future Directions

Future work will focus on expanding clinical trials to include a wider range of patient populations to assess the device's performance across various demographics and therapeutic applications. Broader testing will provide further insights into the device's generalizability and ensure its effectiveness in diverse clinical environments. Additionally, future development may involve enhancing the device's usability, power efficiency, and adaptability, especially for potential portable or wearable versions.

5. Conclusions

This study presented the design and successful implementation of a two-channel, multi-functional therapeutic electrical stimulator tailored for clinical applications. The device's capabilities were demonstrated through the generation of twelve essential therapeutic waveforms and two special functions, Surge and Modulation, providing enhanced flexibility and precision in therapeutic treatments. By utilizing an advanced R-2R ladder DAC and an optimized driving stage unit, the proposed device ensured accurate and consistent output across varying load conditions, thereby meeting the stringent safety and performance requirements outlined by the IEC 60601 standards [36,45,46].

Our experimental results validate the device's ability to maintain stable output currents, demonstrating high levels of accuracy, minimal deviation, and adherence to international medical equipment standards. The system's adjustability in pulse amplitude, duration, and frequency, coupled with the integration of special functions, positions it as a versatile tool for a wide range of therapeutic applications, from pain management to muscle rehabilitation. Furthermore, the use of in-house technology and locally sourced components ensures that the device is both cost-effective and accessible, making it particularly suitable for resource-limited healthcare settings.

Overall, the proposed device not only advances the field of therapeutic electrical stimulation but also provides a practical, reliable, and adaptable solution for clinical environments. Future research will focus on broader clinical trials to assess the device's performance across diverse patient populations, further refining its usability and expanding its potential applications in physiotherapy and rehabilitation.

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