14

Mathematical model for predicting lifespan of non-rechargeable power sources for neurostimulators

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In this paper the problem of assessing the lifetime of a non-rechargeable power source of a neurostimulator with constant current stimulation was investigated. Mathematical models based on two different hypotheses about the energy conversion of the neurostimulator were developed. The first hypothesis is based on the assumption that all the energy stored in the non-rechargeable power source of the neurostimulator is converted into the energy transferred to biological tissues. The second hypothesis assumes that all the energy stored in the non-rechargeable power source of the neurostimulator is converted not only into the energy transferred to biological tissues, but also into the energy used in the control and monitoring unit and the energy losses in the pulse generation unit. Validation of the initial and extended mathematical models was performed against a clinician's manual documentation for the commercial neurostimulator Abbott Proclaim 3660 (USA). The area of applicability of the models based on the considered hypotheses was estimated. The extended mathematical model can be used to assess the lifetime of modern neurostimulators with high efficiency ($> 90\,\%$) at current amplitudes $\geq 3\,\text{mA}$.

Keywords: constant current neurostimulation, non-rechargeable power sources, total electrical energy delivered.

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Introduction

One of medical physics development areas is the investigation and optimization of functioning and operating principles of devices designed to deliver electric pulses from implanted electrodes to nervous tissue for therapeutic intervention, so-called neurostimulators [1–4]. Power supply of neurostimulators depending on operation conditions can be provided by rechargeable and non-rechargeable batteries. Sudden shutdown of a neurostimulator resulting from depletion of battery can negatively influence the patient's quality of life. Therefore, regardless of the established maintenance protocol for implantable medical devices, it is necessary to provide exact prediction of the lifespan of their batteries. This task is especially essential for systems with non-rechargeable batteries because power source depletion for these devices means shutdown of the whole system [5].

Currently, this problem can be solved for commercial neurostimulators by using a procedure described in the user manual supplied with a neurostimulator [6–8]. This procedure implies lifespan evaluation using the curves of this parameter on a dimensionless quantity related to neurostimulator power consumption, but is not the power consumption itself. This dimensionless quantity can be defined and denoted differently in documents of different manufacturers. However, it is generally a tabular parameter which depends on the stimulation signal properties such as therapeutic signal frequency, amplitude and duration, and electrode — nervous tissue interface impedance. However, the documented procedure doesn't contain analytical expressions and general considerations, which formalize correlation between the introduced dimensionless quantity, which is later used to determine the lifespan of non-rechargeable neurostimulator battery, and stimulation signal properties. This feature limits the scope of application of this procedure, making it applicable only to particular commercial types of neurostimulators, which generate a signal with specified properties. If the patient uses other therapeutic signal settings, then the neurostimulator lifespan will be estimated by the most closely related set of stimulation signal parameters available in the documents. This will lead to discrepancy between the real and estimated lifespans, which can affect the patient's quality of life.

Methods for estimating the neurostimulator battery power consumption and lifespan according to the user manual are hardly suitable for the development and testing new experimental types of neurostimulators. Research works often face a typical problem of estimating the battery lifespan of a neurostimulator with modified properties, for example, with alternative electrode configuration [9]. Limited applicability of the described procedure necessitates the development of new approaches to estimating neurostimulator battery lifespans.

Analytical calculation based on metering the total electrical energy delivered (TEED [J])) to biological tissues [9–15] is a commonly used method of estimating the lifespan of non-rechargeable batteries of neurostimulators. This quantity depends on the stimulation signal parameters: frequency, therapeutic signal amplitude and duration, and electrode–nervous tissue interface impedance. This method doesn't imply inclusion of other neurostimulator's energy properties

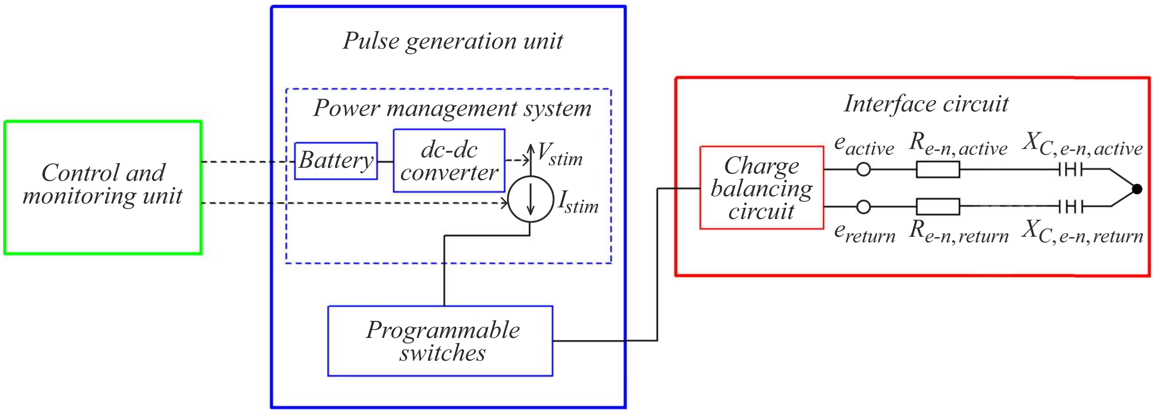

Figure 1. Flow chart of the neurostimulator–nervous tissue system with current stimulation.

and/or any design system parameters into the estimation of non-rechargeable battery lifespan.

The aim of this work is to develop a mathematical model for estimating the lifespan of non-rechargeable batteries of neurostimulators. The main results are mathematical formalization of two various hypotheses describing the conversion of neurostimulator battery energy for a general case of operation with time-variable stimulation signal characteristics, validation of mathematical model application results on the basis of two hypotheses using the data from secondary technical documents for the Abbott Proclaim 3660 (USA) commercial neurostimulator with non-rechargeable battery [7], and established scope of application of the created mathematical models.

1. Materials and methods

A neurostimulator with non-rechargeable battery is the object of study in this work. General flow chart of the neurostimulator–nervous tissue system with current-stimulation will be as shown in Figure 1. Three large modules can be distinguished: control and monitoring unit, pulse generation unit and interface circuit. Control and monitoring unit has a set of functional modules: telemetry, stimulation signal settings, current system state monitoring, etc. Pulse generation unit generates therapeutic signals with settings configured in the control and monitoring unit (amplitude, frequency and duration). Stabilization of voltage applied from the battery to the target level V_{stim}, [V], depending on the chosen stimulation current amplitude I_{stim}, [A], and electrode–nervous tissue impedance is implemented using the $dc-dc$-converter included in the power management system. In the case of current stimulation, the voltage-to-current converter, i.e. the voltage-controlled current source, will be included in the power management system also. Programmable switches configured by the control and monitoring unit are used to transmit prepared therapeutic pulse to the interface circuit connecting electrodes and nervous tissue. The system shall implement the following safety requirement: mean charge passing from the active electrode to tissues and back from tissues to the return electrode shall be equal to zero. To achieve this requirement, the interface circuit includes a charge balancing circuit.

Neurostimulator battery lifespan $t_{lifespan}$, [s], can be defined as the ratio of the energy $E_{battery}$, [J], stored in the battery to the power P_{total}, [W], consumed by the neurostimulator:

$$t_{lifespan} = E_{battery}/P_{total}. \quad (1)$$

Energy stored in a fully charged non-rechargeable battery can be calculated as a product of battery capacity Cbattery, [A·h], and nominal voltage Vbattery, [V]:

$$E_{battery} = 3600 \cdot V_{battery} \cdot C_{battery}. \quad (2)$$

Results described in this work were validated by comparing these calculations with the data from the manual for the non-rechargeable neurostimulator with current stimulation: Proclaim 3660 [7]. The Proclaim 3660 neurostimulator uses a non-rechargeable battery with a nominal capacity of 5.3 A·h and nominal voltage of 3.25 V.

Note also that above-mentioned dimensionless quantity, by which the neurostimulator battery lifespan is estimated, is referred to as the„energy factor“ (EF) in the documents of interest.

For the initial mathematical model, in turn, the power consumed by the neurostimulator $P_{total,initial}$, [W], was calculated considering the first hypothesis: all energy from the battery is converted into the energy delivered to biological tissues. According to this hypothesis, electric stimulation signal power P_{stim}, [W], is the only driving factor in power consumption [9–15]:

$$P_{total,initial} = \delta \cdot P_{stim}, \quad (3)$$

where δ is the dimensionless parameter, which shows the time span, during which the neurostimulator is used. For example, $\delta = 0.5$ means that the stimulator is used 12 h per day on average.

Note that such parameter as energy delivered to biological tissues 1 s is often used for formalizing the neurostimulator energy properties:

$$TEED = P_{stim} \cdot 1\,\text{s}.$$

Stimulation signal is a series of periodic square pulses. Neurostimulator operation is determined by the properties of this signal: amplitude I_{stim}, pulse width t_{pulse}, [s], pulse frequency f_{pulse}, [Hz], and electrode–nervous tissue interface impedance Z_{e-n}, [Ω]. Thus, the electric stimulation signal power of the neurostimulator with current stimulation can be calculated as follows:

$$P_{stim} = \frac{1}{\tau}\int_0^{\tau} I^2_{stim}(t)t_{pulse}(t)f_{pulse}(t)Z_{e-n}(t)dt, \quad (4)$$

where τ, [s] is the time interval, in which the electric stimulation signal power is estimated.

Electrode–nervous tissue interface impedance characterizes biological tissue resistance to electric signal propagation [16–18]. Electric signal, via which neurostimulation acts on tissues, is a series of square pulses. This signal is nonharmonic. At the same time an assumption on prevalence of the first signal harmonic is widely spread in the literature devoted to neurostimulator impedance analysis. Consequently, further analysis of the stimulation signal flowing through a biological tissue is performed for the first harmonic. This assumption makes it possible to treat the therapeutic neurostimulation signal as a harmonic one [16,19–21]. Thus, the following expression can be used for calculation:

$$\begin{aligned} Z_{e-n} &= \sqrt{R^2_{e-n} + X^2_{C,e-n}} \\ &= \sqrt{(R_{e-n,active}+R_{e-n,return})^2+(X_{C,e-n,active}+X_{C,e-n,return})^2} \\ &= \sqrt{R^2_{e-n} + \frac{1}{(2\pi f_{pulse}C_{e-n})^2}}, \end{aligned}$$

where R_{e-n}, [Ω], is the active resistance of the electrode–nervous tissue interface; $R_{e-n,active}$, [Ω], is the active resistance component of the electrode–nervous tissue interface corresponding to the active electrode-nervous tissue path; $R_{e-n,return}$, [Ω], is the active resistance component of the electrode–nervous tissue interface corresponding to the nervous tissue-return electrode path; $X_{C,e-n}$, [Ω], is the reactive resistance of the electrode–nervous tissue interface, which will be capacitive; $X_{C,e-n,active}$, [Ω], is the reactive resistance component of the electrode–nervous tissue interface corresponding to the active electrode-nervous tissue path; $X_{C,e-n,return}$, [Ω], is the reactive resistance component of the electrode–nervous tissue interface corresponding to the nervous tissue-return electrode path; C_{e-n}, [F], is the parameter reflecting the capacitive properties of the electrode–nervous tissue interface.

Substituting (4) into (3), and then the result of this substitution and (2) into (1), we derive an expression for estimating the non-rechargeable neurostimulator battery lifespan $t_{lifespan,initial}$, [s], on the basis of the hypothesis described in (3):

$$t_{lifespan,initial} = \frac{E_{battery}}{\frac{1}{\tau}\delta\int_0^{\tau} I^2_{stim}(t)t_{pulse}(t)f_{pulse}(t)Z_{e-n}(t)dt}. \quad (5)$$

The comparison was supplemented with another proposed mathematical model based on the hypothesis that all energy stored in the non-rechargeable battery is converted not only into the energy delivered to biological tissues, but also into the energy used for energizing the control and monitoring unit and the energy consumed in the pulse generation unit. Accordingly, the neurostimulator power consumption $P_{total,extended}$, [W], in this case is defined not only by the electric stimulation signal power, but also by the loss of power P_{losses}, [W], in the pulse generation unit and the power $P_{internal}$, [W], spent for energizing the control and monitoring unit. This hypothesis can be formalized as follows:

$$P_{total,extended} = \delta \cdot (P_{stim} + P_{losses} + P_{internal}). \quad (6)$$

Neurostimulator operation mode is selected in such a way that the electric pulse applied to nervous tissues produces the desired therapeutic effect, however, the value of the characteristics providing this effect to the patient may vary with time. Thus, for example, the electrode–nervous tissue impedance can increase. This is due the factors such as electrode encapsulation, irreversible damage of the stimulated tissue, edema in the electrode implantation area, etc. [16–18]. Therefore, to maintain the therapeutic effect, it will be necessary to increase the current amplitude of pulses applied to tissues. Also, as has been noted earlier, the power management system will include a voltage-controlled current source, whose voltage headroom can vary depending on the design parameters of the neurostimulator's electric circuit. In addition, the power management module will include the $dc-dc$-converter, efficiency of which can also vary depending on the chosen model and input/output voltages. Also note that the active charge balancing function existing in the neurostimulator circuit affects the neurostimulator power consumption. These components will contribute to the loss of power in the pulse generation unit and to the electric stimulation signal power:

$$P_{stim} = \frac{\frac{1}{\tau}(1+\gamma)\int_0^{\tau} I^2_{stim}(t)t_{pulse}(t)f_{pulse}(t)Z_{e-n}(t)dt}{\eta_{dc-dc}}, \quad (7)$$

$$P_{losses} = \frac{\frac{1}{\tau}(1+\gamma)\int_0^{\tau} I_{stim}(t)t_{pulse}(t)f_{pulse}(t)Z_{e-n}(t)dt}{\eta_{dc-dc}}, \quad (8)$$

where γ is the dimensionless binary variable equal to „1", if the active charge balancing is implemented in the neurostimulator, and to „0" for passive charge balancing, V_H, [V], is the voltage headroom on the current source, η_{dc-dc} is the $dc-dc$-converter efficiency. Voltage headroom V_H describes the typical current source property, which denotes the voltage between the active element inlet and outlet (for example, of a field-effect transistor) necessary to support the main property of the battery (i.e. independence of the battery current on load intensity). When the voltage headroom is very low, the main property of current source will be degraded (battery current will start showing the dependence on load).

Power spent for energizing the control and monitoring unit $P_{internal}$, [W], will be considered to be a constant related to the energy margin of the non-rechargeable neurostimulator battery via the following expression:

$$P_{internal} = \frac{k}{\delta} \frac{E_{battery}}{t_{lifespan,extended}}, \tag{9}$$

where k is the dimensionless coefficient showing which part of the neurostimulator battery energy is spent for energizing the control and monitoring unit. Power spent for energizing the control and monitoring unit doesn't depend on whether there is an active stimulation or not. This is due to the fact that the control and monitoring module functionality (telemetry, current system state monitoring, etc.) is implemented independently of the current stimulation mode (active stimulation or state of rest). Therefore, for further correct substitution of (9) into (6), k is divided by δ. Within the current study, k is considered to be known and equal to 75 % of the total neurostimulator power consumption [5].

Thus, substitution of (7)–(9) into (6) gives an expression for the total neurostimulator power consumption required to produce the therapeutic action:

$$P_{total,extended} = \frac{\frac{1}{\tau}(1+\gamma)\int_0^\tau I_{stim}^2(t)t_{pulse}(t)f_{pulse}(t)Z_{e-n}(t)dt}{\eta_{dc-dc}} + \frac{\frac{1}{\tau}(1+\gamma)V_H\int_0^\tau I_{stim}(t)t_{pulse}(t)f_{pulse}(t)Z_{e-n}(t)dt}{\eta_{dc-dc}} + k\frac{E_{battery}}{t_{lifespan,extended}}. \tag{10}$$

The extended mathematical model version for simulating the non-rechargeable neurostimulator battery lifespan $t_{lifespan,extended}$, [s], proposes the following equation expressed from (10):

$$t_{lifespan,extended} = \frac{(1-k)E_{battery}\eta_{dc-dc}}{\frac{1}{\tau}(1+\gamma)\delta\int_0^\tau I_{stim}^2(t)t_{pulse}(t)f_{pulse}(t)Z_{e-n}(t)dt + V_H\int_0^\tau I_{stim}(t)t_{pulse}(t)f_{pulse}(t)dt}. \tag{11}$$

It is impossible to identify which type of the $dc-dc$-converter is used in the Proclaim 3660 neurostimulator. The most suitable types can be selected on the basis of battery voltage analysis and stimulation signal output voltage. Efficiency of the $dc-dc$-converter depends on its type and varies depending on the input/output voltage range. Proclaim 3660 non-rechargeable neurostimulators are energized from non-rechargeable Li/CFx-SVO batteries, nominal voltage of which is 3.25 V. Voltage variation range on the stimulation electrodes for the given stimulation signal parameters and electrode–nervous tissue interface impedance is within $0.35-10$ V. Therefore, the$dc-dc$-converter shall be both step-up and step-down. It has been determined that for the set out conditions, the most typical averaged efficiency of the $dc-dc$-converter will be equal to 90 %. An assumption is made in this work that the $dc-dc$-converter efficiency is constant for all given settings of the stimulating signal.

It has been also assumed that the voltage headroom of the current source is a constant equal to 1.2 V. This value was chosen as the most typical averaged voltage headroom of the current source used in the implantable biomedical devices [5].

Lifespan of neurostimulators with different modes of operation was estimated via mathematical simulation, results of which are shown in Figure 2. The following assumptions were used: neurostimulator operation mode is constant, $\delta = 0.5$ (active stimulation lasts 12 h per day) and $\gamma = 0$ (passive charge balancing is implemented in the system). Four sets of parameters characterizing the neurostimulator operation mode were evaluated: base mode ($Z_{e-n} = 350\,\Omega$, $t_{pulse} = 200\,\mu$s, $f_{pulse} = 30$ Hz), and three alternative configurations, each of which differs from the base set by the magnitude of one of the parameters:

1) alternative configuration №1: $Z_{e-n} = 350\,\Omega$, $t_{pulse} = 200\,\mu$s, $f_{pulse} = 90$ Hz;
2) alternative configuration №2: $Z_{e-n} = 350\,\Omega$, $t_{pulse} = 500\,\mu$s, $f_{pulse} = 30$ Hz;
3) alternative configuration №3: $Z_{e-n} = 700\,\Omega$, $t_{pulse} = 200\,\mu$s, $f_{pulse} = 30$ Hz.

The findings were compared with lifespan data $t_{lifespan,doc}$, [s], from the user manuals for the Proclaim 3660 neurostimulator.

Linearity of the neurostimulator power consumption was also estimated. The need for this study is driven by the fact that the model based on hypothesis (3) is linear — variation of the model input parameters leads to proportional variation of the output parameters. At the same time, commercial neurostimulator operation mode and lifespan are correlated in the user manual through a variable, which characterizes the energy, and a curve demonstrating the correlation between this tabular quantity and lifespan. The following dimensionless parameter was used to estimate the linearity of values justified for the initial mathematical

Table 1. Lifespans and energy factors for four sets of parameters of the stimulation signal from the user manual for the Proclaim 3660 neurostimulator

Current amplitudeI_{stim}, mA	1	2	3	4	5	6	7	8	9	10
$Z_{e-n} = 350\,\Omega$Basic set of parameters:, $t_{pulse} = 200\,\mu$s, $f_{pulse} = 30$ Hz										
Energy factorEF	14	17	19	22	30	33	44	49	64	69
Lifespan$t_{lifespan,doc}$, year	9.8	9.5	9.2	8.7	7.7	7.4	6.4	5.9	5.2	5.0
Alternative configuration №1: $Z_{e-n} = 350\,\Omega$, $t_{pulse} = 200\,\mu$s, $f_{pulse} = 90$ Hz										
Energy factorEF	24	34	41	47	71	81	115	129	173	190
Lifespan$t_{lifespan,doc}$, year	8.3	7.3	6.6	6.1	4.9	4.5	3.4	3.15	2.6	2.3
Alternative configuration №2: $Z_{e-n} = 350\,\Omega$, $t_{pulse} = 500\,\mu$s, $f_{pulse} = 30$ Hz										
Energy factorEF	15	24	30	47	55	81	92	125	139	182
Lifespan$t_{lifespan,doc}$, year	9.8	8.3	7.7	6.1	5.6	4.5	4.05	3.35	3.05	2.4
Alternative configuration №3: $Z_{e-n} = 700\,\Omega$, $t_{pulse} = 200\,\mu$s, $f_{pulse} = 30$ Hz										
Energy factorEF	14	17	23	31	41	47	60	76	98	119
Lifespan$t_{lifespan,doc}$, year	9.8	9.5	8.4	7.6	6.6	6.1	5.4	4.75	3.9	3.4

model:

$$\Delta_{lifespan,initial_m} = \frac{t_{lifespan,initial_m}}{t_{lifespan,initial_0}}, \qquad (12)$$

where m is the alternative configuration number ($m = 0$ is the base value). This parameter was compared with the change of lifespan according to the data from the user manuals for the Proclaim 3660 neurostimulator for the same four sets of stimulation signal parameters. Linearity of values taken from the manuals was estimated using the following dimensionless parameter:

$$\Delta_{lifespan,doc} = \frac{t_{lifespan,doc_m}}{t_{lifespan,doc_0}}.$$

2. Findings

Equation (2) was used to determine that the energy headroom of the non-rechargeable battery of the Proclaim 3660 neurostimulator was 62010 J.

For validation of models using user manuals for the Proclaim 3660, commercial neurostimulator, lifespans were determined from curves in these manuals for four sets of stimulation signal parameters in order to determine the scope of application. The obtained values are listed in Table 1.

Figure 2 shows the main simulation results of the non-rechargeable battery of the Proclaim 3660 neurostimulator for four sets of stimulation signal parameters. Note that values obtained using the initial model (equation (5)) for four sets of the stimulation signal parameters throughout the range of stimulation current amplitudes differ from the values given in the manuals. Thus, depending on the generated stimulation current, relative lifespan deviation $t_{lifespan,initial}/t_{lifespan,doc}$ can vary from the maximum value approximately equal to 19100 % (for 1 mA for the basic set of parameters) to the minimum value approximately equal to 270 % (for 10 mA for alternative configuration №1). The following absolute deviations are also typical for these boundary points: 22 355 months for the maximum deviation and 47 months for the minimum deviation. It can be suggested that this mathematical model is applicable to earlier neurostimulator versions. Functionality of the control and monitoring module of such devices is not so wide, which leads to a lower power consumption of this functional unit. It is also suggested that earlier neurostimulator versions have a simpler design, which in turn can reduce the loss of energy in the system. These hypotheses allow us to explain the discrepancy of the obtained lifespans and to determine the scope of application of the initial mathematical model.

In the case when the extended mathematical model is used, better compliance is observed: obtained lifespans (equation (11)) with higher current amplitudes (≥ 3 mA). For ≥ 3 mA ,depending on the generated stimulation current amplitude, relative lifespan deviation $t_{lifespan,extended}/t_{lifespan,doc}$ can vary from the maximum value approximately equal to 45 % (for 10 mA for alternative configuration №1) to the minimum value approximately equal to 0 % (for each set of the stimulation signal parameters of interest, intersection of two curves is observed). The following absolute deviations are also typical for these boundary points: 15 months for the maximum deviation and 0 months for the minimum deviation. Note that due to the chosen scale of the y axis, difference in the behavior of the given curves is clearly visible. Behavior of the values obtained from the manuals is similar to a linear inverse proportional dependence on the stimulation signal

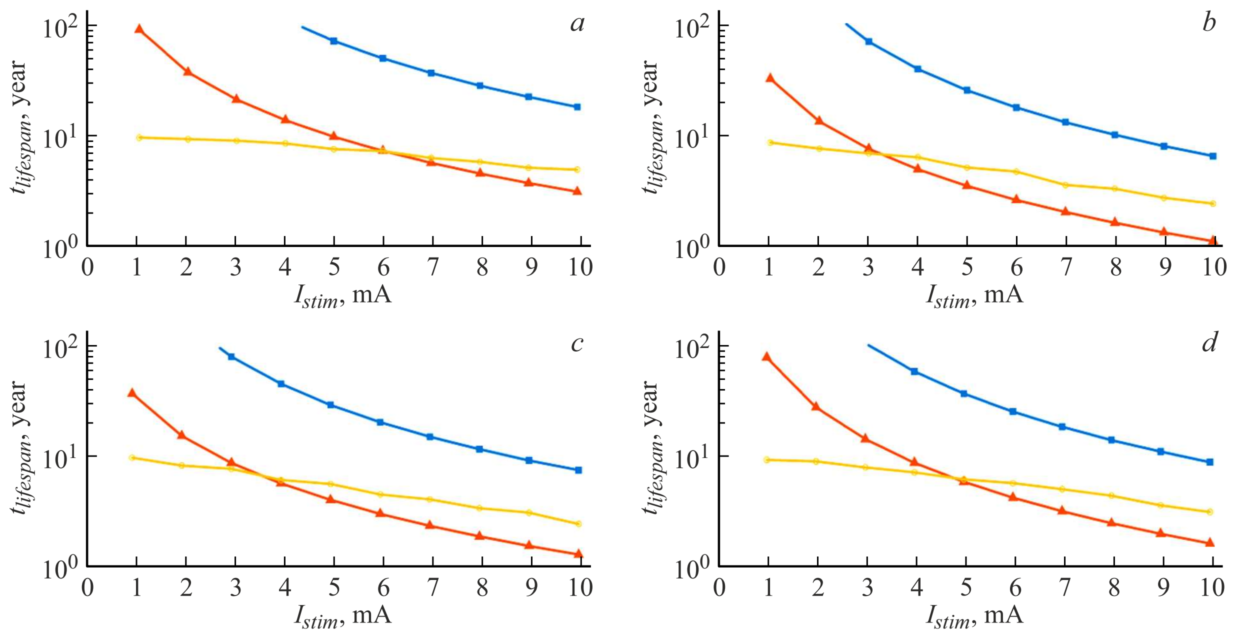

Figure 2. Simulated lifespan of the Proclaim 3660 neurostimulator for various sets of the stimulation signal parameters: *a* — $Z_{e-n} = 350\,\Omega$, $t_{pulse} = 200\,\mu$s, $f_{pulse} = 30$ Hz; *b* — $Z_{e-n} = 350\,\Omega$, $t_{pulse} = 200\,\mu$s, $f_{pulse} = 90$ Hz; *c* — $Z_{e-n} = 350\,\Omega$, $t_{pulse} = 500\,\mu$s, $f_{pulse} = 30$ Hz; *d* — $Z_{e-n} = 700\,\Omega$, $t_{pulse} = 200\,\mu$s, $f_{pulse} = 30$ Hz; yellow curve (symbol „•") — values from the manuals, blue curve (symbol „■") — initial mathematical model, red curve (symbol „▲") — extended mathematical model.

current amplitude. Values obtained using the extended mathematical model in turn have the inverse proportional dependence on the squared stimulation signal current amplitude. The difference in the curve behaviors may be presumably associated with the variability of $dc-dc$-converter efficiency, which is not accounted for in the mathematical model. Efficiency of the $dc-dc$-converter depends in a complicated manner on the voltage, to which the input voltage shall be stabilized, and as noted earlier, the target voltage depends on the chosen amplitude of the stimulation signal current. Thus, the $dc-dc$-converter used in the Proclaim 3660 neurostimulator presumably has a higher efficiency at current amplitudes ≥ 3 mA. Also note that curves corresponding to the values from the manuals and values calculated from the extended model for the four sets of stimulation signal parameters intersect in points with different stimulation signal current amplitudes. This suggests that the neurostimulator power consumption and, therefore, lifespan depend in a complicated manner not only on the current amplitude, but also on other stimulation signal parameters.

To determine the behavior of dependence between the stimulation signal parameters and lifespan of the non-rechargeable neurostimulator battery, three alternative configurations were evaluated, where two of three stimulation signal parameters in each configuration were fixed, and one parameter was variable. The following values were obtained using equation (12):

1. For alternative configuration №1:

$$\Delta_{lifespan,initial_1} = \frac{t_{lifespan,initial_1}}{t_{lifespan,initial_0}} = \frac{f_{rate_0}}{f_{rate_1}} = \frac{30}{90} = 0.33.$$

2. For alternative configuration №2:

$$\Delta_{lifespan,initial_2} = \frac{t_{lifespan,initial_2}}{t_{lifespan,initial_0}} = \frac{t_{width_0}}{t_{width_2}} = \frac{200}{500} = 0.4.$$

3. For alternative configuration №3:

$$\Delta_{lifespan,initial_3} = \frac{t_{lifespan,initial_3}}{t_{lifespan,initial_0}} = \frac{Z_{e-n_0}}{Z_{e-n_3}} = \frac{350}{700} = 0.5.$$

Changes in the lifespan found from the user manuals for the neurostimulator for each alternative configuration with respect to the basic one are shown in Table 2. If there were a linearly inverse proportional dependence between the lifespan and stimulating signal parameters, then the three-fold increase in the stimulation signal frequency would lead to the three-fold decrease in the lifespan (similar for other alternative configurations), which is true for the values calculated using equation (12). But for values contained in the user manuals for the Proclaim 3660 neurostimulator, there is no such dependence. Thus, depending on the generated stimulation current, relative lifespan deviation $\Delta_{lifespan,initial_m}/\Delta_{lifespan,doc_m}$ can vary from the maximum value approximately equal to 83 % (for alternative configuration №2) to the minimum value approximately equal to 39 % (or alternative configuration №1). This proves that in practice there is a correlation, but no linear dependence, between the lifespan and input system parameters such as the stimulation signal parameters. This additionally proves that the scope of application of the initial mathematical model is limited for estimating the lifespan of non-rechargeable neurostimulator batteries.

Table 2. Relative lifespan variation according to the user manuals for the Proclaim 3660 neurostimulator for each alternative configuration

I_{stim}, mA	1	2	3	4	5	6	7	8	9	10
$\Delta_{lifespan,doc_1}$	0.85	0.77	0.72	0.70	0.64	0.61	0.53	0.53	0.5	0.46
$\Delta_{lifespan,doc_2}$	1	0.87	0.84	0.70	0.73	0.61	0.63	0.57	0.59	0.48
$\Delta_{lifespan,doc_3}$	1	1	0.91	0.87	0.86	0.82	0.84	0.81	0.75	0.68

3. Discussion

Note that non-rechargeable battery lifespans estimated using the mathematical model based on the first hypothesis differ considerably from the data used for validation of models. Minimum and maximum deviations of the values obtained using this model are substantial compared with the data from the manuals and are equal to 270 % and 19100 %, which corresponds to 47 and 22355 months of absolute deviation. This deviation can be explained by the fact that the use of this hypothesis was reasonable for estimating the lifespan of non-rechargeable batteries of earlier neurostimulator types with limited functionality and simpler design. In such case, power consumption by the control and monitoring unit and loss of power at the pulse generation unit are much lower than the energy delivered to tissues via electrodes.

Further, non-rechargeable battery lifespans estimated using the mathematical model based on the first hypothesis with the stimulation current amplitude ≥ 3 mA differ to a lesser extent from the data used for validation of models. In some scenarios (for stimulation current amplitudes ≥ 3 mA), data obtained using this model coincide with the data from the manuals. Maximum deviation of the values obtained using this model for the stimulation current amplitudes ≥ 3 mA with respect to the data from the manuals is not higher than 45 %, which corresponds to 15 months of the absolute deviation. This can be explained by the fact that the Proclaim 3660 neurostimulator has high efficiency at the stimulation current amplitudes ≥ 3 mA, i.e. efficiency of the $dc - dc$-converter used in these devices depends in a complicated manner on the stimulation signal current amplitude, which is not considered in the extended mathematical model of interest. Besides the discrepancy between values, this hypothesis also explains the difference in the behavior of the given curves.

Note also that applicability of the given mathematical models can be extended through their adaptation for neurostimulators with voltage stimulation. For this, exclude a component characterizing the battery loss from equation (11). Other analytical expressions are true for voltage-stimulation systems.

Conclusion

This study formalizes two hypotheses allowing description of correlation between the non-rechargeable battery lifespan and neurostimulator power consumption for the development and further comparison of the scope of application of two mathematical models based on these hypotheses. The first hypothesis: all energy stored in the non-rechargeable neurostimulator battery is converted into the energy delivered to biological tissues. The second hypothesis: all energy stored in the non-rechargeable neurostimulator battery is converted not only into the energy delivered to biological tissues, but also into the energy used for energizing the control and monitoring unit and the energy consumed in the pulse generation unit. Mathematical models based on the data from the user manuals for the Proclaim 3660 commercial neurostimulator have been validated. The extended mathematical model is suitable for estimating non-rechargeable battery lifespans of modern types of neurostimulators with high efficiency at current amplitudes ≥ 3 mA.

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Conflict of interest

The authors declare no conflict of interest.

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