ENERGY HARVESTING: POWERING CONNECTED DRUG DELIVERY DEVICES

Here, Charlotte Harvey, Consultant Mechanical Engineer, Sagentia, examines the opportunities and practicalities of using energy harvesting technologies in drug delivery devices. With a specific focus on enabling connectivity functionality, Ms Harvey runs through the various aspects of energy harvesting and offers insight on whether it is the right choice for a new device development.

INTRODUCTION

Connectivity has become a watchword for the drug delivery industry, but it's more than just the latest trend. There are many benefits to a device that can communicate externally; some are obvious, providing the ability to monitor patient behaviour and compliance with a treatment plan for example, but other benefits are less so. Connected users might be given access to a specialist portal, through which they can manage their condition and get advice remotely from healthcare professionals. The proliferation of smartphones and ubiquity of wireless technology makes connectivity an essential tool for doctors, who are increasingly involved in post-diagnostic care. With Bluetooth Low Energy (BLE) and near field communication (NFC) technologies now readily available, the race is on to connect drug delivery devices and so help improve patient outcomes.

Drug delivery devices have not traditionally been designed with a built-in power source. However, without power the device is unable to support the electronics required to incorporate BLE or NFC and enable connectivity. Next generation connected devices will therefore need printed circuit boards (PCBs) and batteries or an alternative means to generate energy. The product development process for such next generation devices will need to evaluate the trade-off between the benefits that connectivity offers versus any impact on usability, the environment, shipping and regulatory compliance.

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Introducing a battery to a device can create new design challenges, such as reducing shelf life, creating complications around disposal and determining the device's size. In some cases, the optimal solution may be simply to avoid the use of a battery altogether. Instead, the energy required to power the device could be generated by "harvesting" the energy in-use (Figure 1). Most connected device functions require low levels of power and thus are well-suited to energy harvesting, which provides energy naturally in small packets. However, to make the most of these energy harvesting technologies, it's best to keep the connectivity subsystem relatively simple. This article explores how energy harvesting could be applied to drug delivery devices to provide the power required for connectivity. It recognises that, rather than having broad applications, energy harvesting is most effective when applied in specific circumstances.

There are other methods which can be considered when batteries have been ruled out. These often require conversion to electrical power at point of use:

- Gas canister
- Osmotic drive
- Compressed spring
- Biocell.

The design of an energy harvesting subsystem can be broken down into source, storage and use. The energy must be sourced from either the environment or the user

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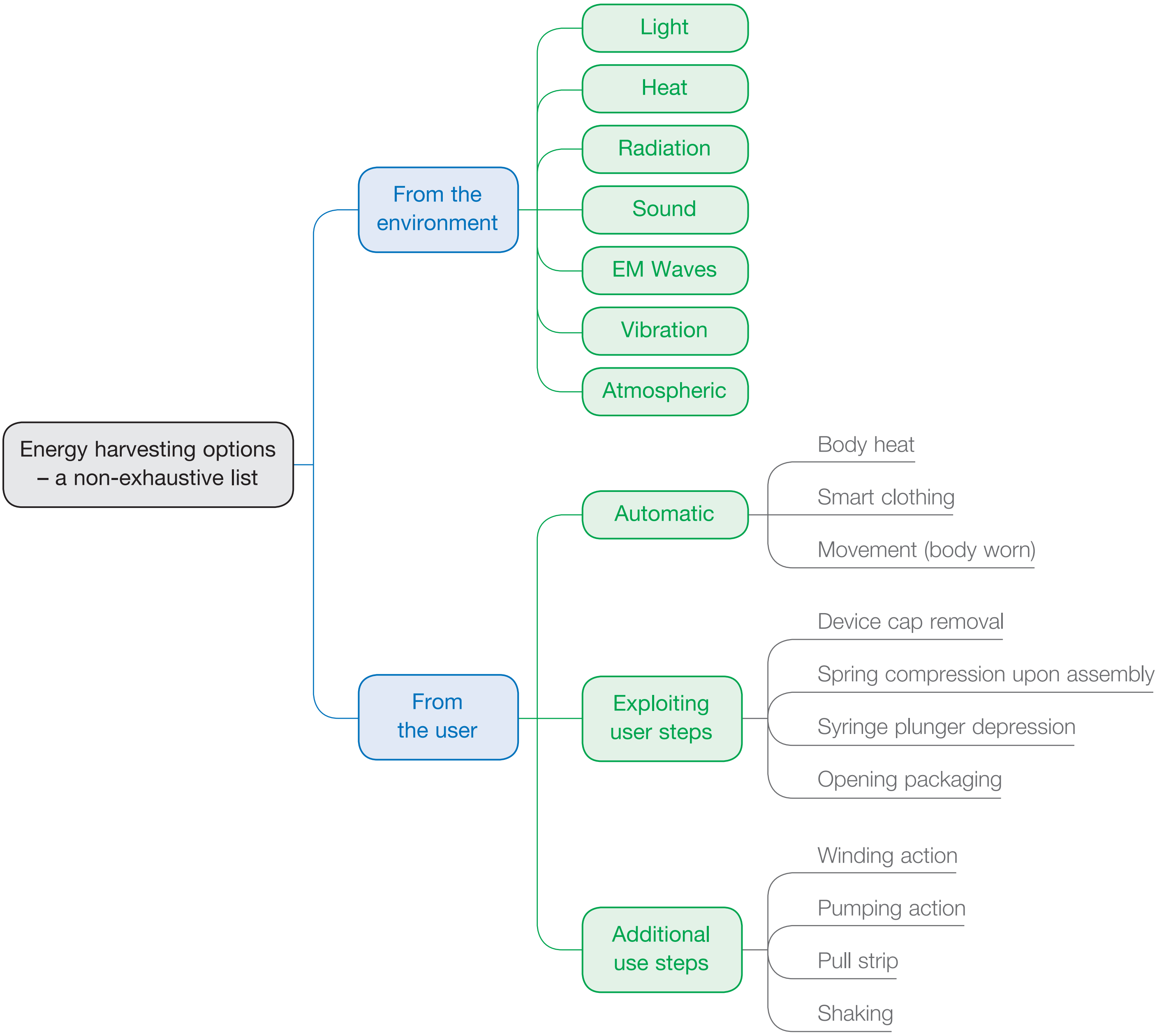

Figure 1: Sources of energy with the potential for harvesting.

themselves. Then it needs to be stored for use at the appropriate time and employed in a way that maximises its efficiency. Consideration also needs to be given to the disposal of the device and how the new embedded technology affects the end of the product lifecycle.

ENERGY SOURCING

There are a number of options when it comes to deciding where to source the energy needed. However, when the typical use case and environment for the device are taken into account the options quickly narrow. Energy harvesting should be the preferred option only when the overall device design will benefit.

Questions to consider:

- How much control do we as designers have over the use environment?
- Do we even know enough about the use environment at this point to ensure consistency and reliability?
- How much do we want to rely on the user to ensure that the energy harvesting technology is working properly?

Heat and light are the two most common forms of waste energy found in everyday environments.

Heat energy is primarily harvested through the use of thermo-electric generators (TEGs). TEGs are able to produce electrical energy when there is a temperature gradient across them, therefore care is needed not to allow the TEG to completely warm to ambient temperature as the necessary heat flux would be lost.

Due to the development of flexible TEGs, it is now easier to harvest heat from the body. These flexible TEGs can conform to the skin, improving the thermal interface. Human skin temperature is typically about 34°C, whilst room temperature is typically about 18-25°C. A drug delivery device held against a patient's skin could leverage this gradient and harvest the energy.

An alternative way to use heat energy would be if a drug cartridge is taken from a fridge and left to warm prior to injection. It may be possible to harvest enough energy as it warms to send a message

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via BLE that the drug is ready to inject. Additionally, such a signal could double as compliance monitoring.

Light can be transduced into electrical energy through the use of photovoltaic (PV) cells. In recent years the price per square metre of PV cells has come down significantly, due in part to national governments seeking to increase their renewable energy generation capability. There now exists a package that is capable of transmitting BLE signals using just the energy from indoor fluorescent lighting.

A solar powered device has an availability issue however, in that the device may be stored in a dark place (fridge, bathroom cabinet), or may typically be only used at night (user injects before bed). It might be possible to require the user to leave the device in the light to charge, for they would charge any other device, but this risks the user forgetting to do so.

THE USE ENVIRONMENT

Previous examples illustrate the importance of fully understanding the use environment prior to designing the device. To control for the edge cases, we should also consider how much responsibility is entrusted to the user. The standard in human factors engineering is to reduce user responsibility and, certainly for devices a patient is more dependent on, this should be the aim. In such cases, the reasons behind any decision to design out a battery should be re-assessed to consider whether other options present different, more onerous challenges.

By focusing on the user and their interaction with the device we can arrive at alternative solutions. The simplest way to harness energy from the user is to exploit activities the user would have performed anyway. For instance, the action of opening packaging or pushing a syringe plunger could be used as an energy source. If so, it is likely that this natural step in operating the device may need to be designed in a way which ensures it produces the required energy. This, however, may be at odds with the need to keep operation of the device as simple as possible. For example, care must be taken not to over-exert particular patient populations with manual dexterity or strength issues.

Where more power is required (or on a device where there are only a few user steps), a user action might need to be added solely for the purpose of harvesting energy. This could be in the form of a manual step such as winding, pumping or shaking. Although these methods will create more energy, they are also more taxing for the user and have knock-on effects on usability. It may be difficult for users to accept this approach therefore, particularly in cases where there is a competing device which asks less of them. On the other hand, if there is a clear pay-off for the user the device is more likely to be more readily adopted.

Many devices already take advantage of energy harvesting from user actions for functions other than those related to connectivity. The most common is priming a spring for the delivery of a drug product using a rotary or direct pull/push motion. The energy stored in the spring is then released by a button press, or similar, when the energy is needed. Such an approach could also be used to both harvest energy and store what's generated.

With all user-based energy harvesting technologies, careful consideration will have to be given to the ISO 62366 guidelines which specify the usability requirements around the development of medical devices. Any design approach which could be seen as compromising usability will need to be justified. Since batteries already exist as a safe technology option, this could be a challenge.

ENERGY STORAGE

In an ideal world, the generation of power via energy harvesting would occur just before the energy is needed. For instance, a Bluetooth signal triggered and powered by the user attaching a vial to a high-volume pump. Unfortunately, in practice there will frequently be a delay between when the energy is harvested and when it is needed. Storage solutions must account for this.

Considerations when looking for a storage solution:

- Efficiency – not losing the energy which has been gathered.
- Availability – connectivity applications typically require small bursts of energy at specific times. The energy must therefore be readily available for use.
- Delivery parameters – there will be power requirements dependent on the specific use of the energy. Storage solutions vary in how they perform.

At first glance, supercapacitors seem like an ideal energy storage medium for energy harvesting – they bridge the gap between traditional electrolytic capacitors and Li-ion cells. This makes them capable of much more rapid charging than a traditional cell whilst having a much greater energy density than capacitors. This capability to rapidly absorb power is important since the power available for harvest can be highly unpredictable and may feature large spikes.

On further inspection, supercapacitors have some noteworthy disadvantages which make it important to consider their use carefully. Whilst they are far more energy dense than electrolytic capacitors, they typically have 1-5% of the capacity of Li-ion. They also suffer from a high self-discharge rate. This combination makes them unsuitable for use as long term storage, and as such should be restricted to situations where energy is harvested and used in a similar time frame. Beyond this scenario they tend to be significantly more expensive than a battery. Typically, the maximum allowable voltage of a supercapacitor is around 2.7 V which can create the need for DC-DC converters,

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as the voltages required for BLE can be higher, or additional supercapacitors and a balancing network. All of this can increase size, cost, inefficiency and complexity.

These considerations imply that, if a device needs to communicate often and straight off the shelf, a supercapacitor would not be the correct storage medium. For applications where power is only required for a short duration or enough energy can be harvested from the environment to perform infrequent tasks, a supercapacitor may be the right choice.

The optimal choice of supercapacitor and/or battery for the application will depend upon how the energy is generated and used. In the instance where energy harvesting is being used to make way for a smaller battery, it may be difficult to match the energy harvesting output generated to the battery specification. In the cases where user activity is the source of energy, direct transference to a supercapacitor is difficult if the user action is slow and steady because a supercapacitor is better at storing energy released in a burst. To get around this issue the energy generated from harvesting could be stored in an intermediary, such as a spring or a compressed gas, and then transferred to the battery at the appropriate rate.

ENERGY USE

Harvesting energy in a handheld drug delivery device is far easier if the manner in which the generated power is put to use is kept flexible. For example, ideally data transmission would wait until the requisite energy is available.

If the device has strict power requirements, or requires a significant amount of power to function, it may be tempting to rule out energy harvesting as an option. However, even devices with rigid or high power requirements can benefit from an energy harvesting approach. It may be possible to compartmentalise different activities within a device and use energy harvesting for some of those functions. This may then enable simplification of the overall system. Alternatively, it may be sensible to separate a device out into its re-usable and disposable components. The disposable element can operate independently if an energy harvesting technology is used, dramatically reducing instances of battery disposal.

Finally, it is important to ensure that any critical device functions are being powered by a reliable energy source. As many connectivity functions are not typically critical, they may be well suited to energy harvesting. However, this design decision should be well understood as it can be tempting to then expand the use of this energy to other functions which are essential to the effective use of the device, which could put the patient at risk.

DISPOSAL

The fact that batteries can be difficult to dispose of is often the reason for their exclusion from a new product design. If that is the case it is vital that any alternative option for powering the device does not present similar challenges.

Disposal of some of these alternative technologies is also poorly catered for, particularly in domestic settings. For instance, it is easier for a user to recycle a battery than it is to recycle a biocell. Furthermore, consumers will also find solar cells challenging to dispose of, as this normally takes place on an industrial scale. If the disposal process becomes part of the device manufacturer’s responsibility these problems can be dealt with effectively, although it would place an additional burden on the manufacturer.

Whilst Li-ion cells are classed as hazardous waste and require special disposal processes, supercapacitors are classed as non-hazardous waste and could be disposed of with the rest of the device.

Disposal concerns are not the only reason to remove batteries from a device design. Whatever the deciding factors for excluding batteries are, the new energy harvesting technology needs to be analysed against those same criteria. As these technologies are typically fairly novel and complex to implement (in comparison with a battery), there should be a clear benefit to their introduction.

HOLISTIC DESIGN

Energy harvesting is not an approach which should be universally adopted across all drug delivery devices; it supplies only small amounts of energy and can introduce design complexities. A thorough review of all the options available must be carried out for each project to ensure that energy harvesting is right for the design and that the correct technology is being implemented for maximum efficiency. It is important to match the technology with the right system design and use case, using energy harvesting in place of battery technologies for the right reasons. In specific applications, such as when the only powered device function is connectivity, it can be exactly what is needed.

ABOUT THE COMPANY

Sagentia is a global science, product and technology development company, assisting companies in maximising the value of their investments in R&D. Sagentia partners with clients in the consumer, industrial, medical and oil & gas sectors to help them understand the technology and market landscape, decide their future strategy, solve complex science and technology challenges and deliver commercially successful products.

Sagentia employs more than 150 scientists, engineers and market experts and is a Science Group company. Science Group provides independent advisory and cutting-edge product development services focused on science and technology initiatives. It has seven offices globally, two UK-based dedicated R&D innovation centres and more than 470 employees. Other Science Group companies include OTM Consulting, Oakland Innovation, Leatherhead Food Research and TSG Consulting.

ABOUT THE AUTHOR

Charlotte Harvey is a consultant mechanical engineer at Sagentia. Her experience lies predominantly in managing medical product developments, specifically those in the surgical and injectable drug delivery fields. As such, she has recently experienced the issues related to incorporating connectivity functions into these devices first-hand. Recent projects have included front-end innovation in the drug delivery space, user interviewing for human factors, and development of reconstitution-based auto-injectors. Ms Harvey graduated from the University of Cambridge (UK) with a Masters in Mechanical Engineering.