VERSION [1.0]

MAY 24, 2017

paingone*

the original TENS pen

POST MARKET SURVEY

RESULTS AND ANALYSIS

medi direct international

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POST MARKET SURVEY

ABOUT THE COMPANY

Medi-Direct International is dedicated to bringing unique, scientifically proven new therapies to market and helping to improve quality of life without drugs or medications. Medi-Direct International have been providing alternative health solutions since 2002 and we have come a long way since the first sale of our Paingone Pen device; the product which started it all.

The unqualified success of Paingone Pen has permitted the expansion of the business and a new mission: dedication to researching, manufacturing and distributing only the highest quality and most effective health solutions available.

ABOUT THE PAINGONE PEN

FAST, EFFECTIVE, DRUG-FREE PAIN RELIEF

It allows the user to relieve all types of chronic pain without using drugs, leads pads, or gels – just a simple 30 second treatment straight to the point of pain.

Shaped like a large pen, the Paingone Pen is practical, fast to work and easy to use. It functions on the principles of Transcutaneous Electrical Nerve Stimulation (also known as TENS or TNS) but, unlike ordinary TENS machines, it has no wires or sticky pads and can be used anywhere, anytime.

Paingone Pen uses a low-frequency electrical charge produced by a piezo-crystal to provide prolonged pain relief which is clinically proven to work. Remarkably, it requires no batteries for its operation.

TECHNICAL SPECIFICATION

- Piezo Electric Therapy – Dimensions: 132 x 20 x 20mm
- Weight: 30g
- Frequency: 1-2Hz Manual Operation
- Output voltage: Nominal 15Kv
- Battery powered: No
- Product Life: Average 1 to 2 years
- Treatment duration: 30-60 seconds
- Frequency of Treatment: As often as required
- Maintenance: No significant maintenance required
- Accessories: None required
- CE Marked Class IIa Medical Device

EXECUTIVE SUMMARY

Medi-Direct international, established in 2002, has successfully sold over 1.5million devices to date. This is the first Post Market Survey implemented by the company to establish direct customer feedback on product usability. The results of this feedback will be used to influence future product design.

The survey sample size of 360 respondents was determined using a statistics package. The survey itself was carried out, over the months of March and April 2017, by phone.

A brief overview of the results is given below:

- There is an equal distribution of respondents relating to gender and a predominant usage of the Paingone device in the over 60's age group. There is, however, strong evidence of use across the age ranges.
- The majority of respondents had purchased the device within 6 months of the survey. It was interesting to note that some respondents had purchased the device as long ago as 2010, indicating good device longevity of action and durability.
- The most common conditions are: arthritis, joint pain, and associated back pain
- 90% of respondents found the device to be effective in use and 25% deemed the device to be very effective
- The primary reasons for discontinuing use of the device were that the original symptoms had resolved or the respondents found the device to be ineffective. However, in light of the 90% respondent efficacy rating, the overall respondents who found the device ineffective is comparatively low.
- The most common side effects associated with the device were found to be: Bruising or red marks on the skin; Pain/discomfort from the electrical pulse during application and Pain increased (statistically negligible number of respondents). These side effects have already been recognized and adequately covered in the Paingone device 'product information leaflet'.

In conclusion, the Paingone device has demonstrated very high usability, durability and ease of use characteristics. There are areas of feedback which has led to new product development e.g. Paingone Plus device. This is in response to the respondents who stated they would benefit from an easier 'clicking' process. Additionally, future surveys, which will now be conducted on an annual basis, will focus in more detail on requirements such as: Multi-lingual user information including Braille, closer analysis of respondent rationale who used the device more than twice daily; improved marketing materials to allow future customers to select the most appropriate device for their needs and investigate specific reasons why respondents were unable to use the device post purchase.

METHODOLOGY

As part of Medi-Direct International's ongoing post-marketing surveillance activities for its medical device Paingone Pen, an end-user survey was conducted during March and April 2017. The survey sample size (360 respondents) was determined using a statistics package for a population of 3021 (number of customers purchasing a Paingone Pen over a calendar year up to March 2017), with a confidence level of 95%, margin of error set as 5% and response distribution at 50%.

OBJECTIVE

The broad objective of this survey was to obtain data concerning usability of the device.

This data is to be reviewed and, where applicable, will inform ongoing quality management procedures and activities.

METHOD

The study was conducted by phone. To be eligible to participate in the survey, respondents had to have owned and used the device for at least one month.

RESTULTS & ANALYSIS

NATIVE LANGUAGE

The entirety of respondents spoke English as their native language. This indicates that almost all users are adequately served by the English language instructions provided with the device.

GENDER

FIG. 1 - DISTRIBUTION OF GENDERS ACROSS SURVEY RESPONDENTS

There was close to a 50/50 split between genders among the survey respondents.

From this, it can be inferred that the data gathered from this survey and the conclusions drawn from its analysis are applicable to both male and female users of the Paingone device.

AGE

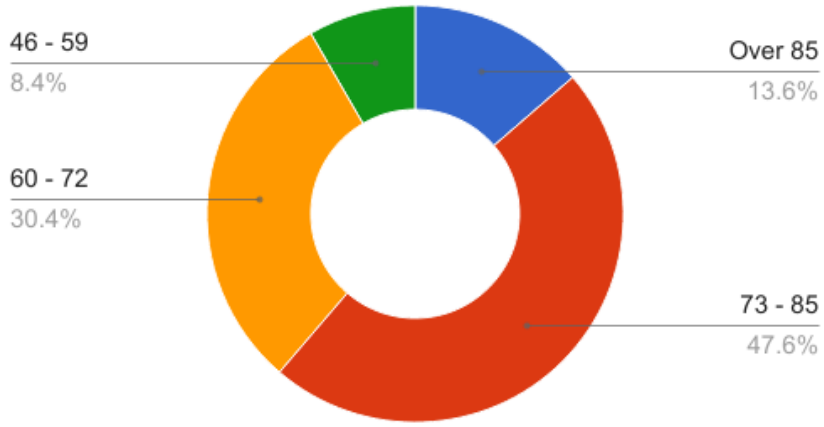

FIG. 2 - DISTRIBUTION OF AGE ACROSS SURVEY RESPONDENTS

More than 90% of respondents were over 60 years of age.

Given the large number of older users, the specific requirements of these users could be given even greater consideration when developing products or supporting materials. For example, larger font sizes and braille could be considered for the device labelling.

Some respondents were younger, indicating that the device is also of interest and of use to a range of ages.

PURCHASE DATE

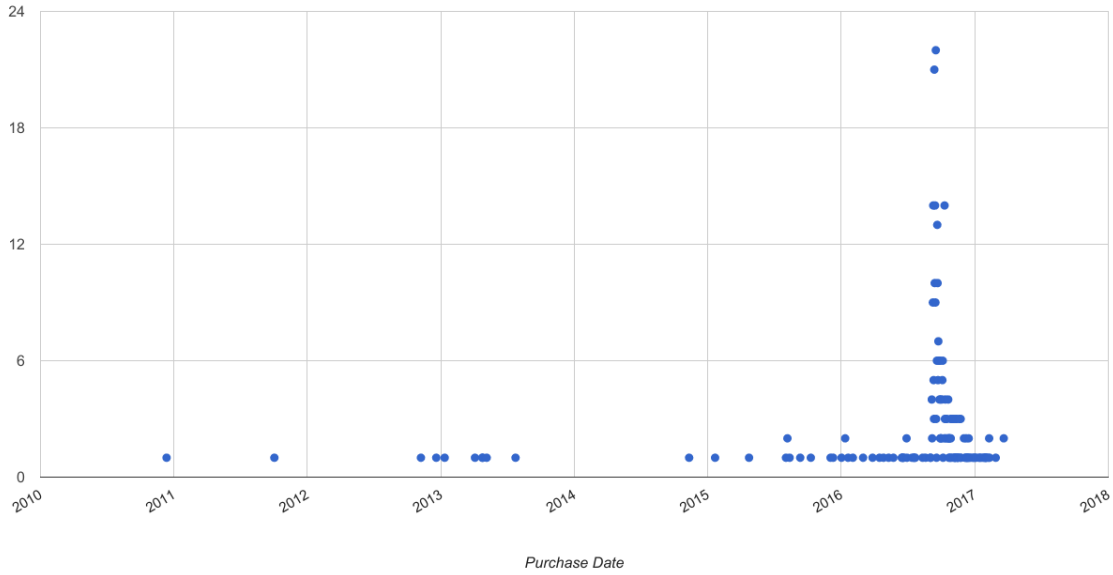

FIG. 3 – CORRELATION OF RESPONDENT PURCHASE DATES

The majority of Paingone devices were purchased within the last 6 months.

However, several respondents had purchased Paingone much longer ago, as far back as December 2010. This suggests that some Paingone devices are still being used and are effective as much as 7 years after the date of purchase.

CONDITIONS

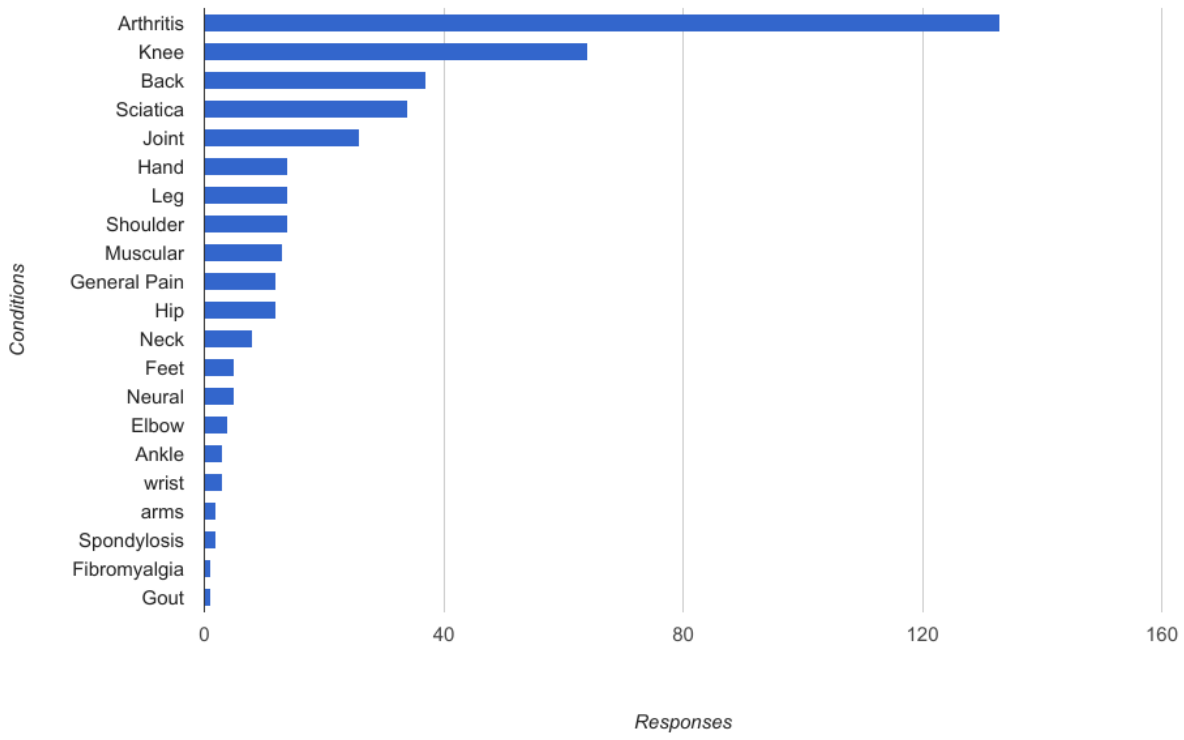

FIG. 4 – CONDITIONS FOR WHICH PAINGONE PEN WAS USED FOR

This data demonstrates that Paingone is used by customers for a variety of conditions and its use is not limited to any one particular area of the body.

The most common conditions are: arthritis, joint pain, and associated back pain

This multiplicity of possible applications is addressed by the user manual, which indicates that Paingone can be placed directly on the pain, wherever this may be (with just a few exceptions) or following the acupoint guide which lists acupressure points for a variety of conditions.

INSTRUCTIONS

Labelling on the outer packaging of the device includes advice to read instructions before use.

This labelling appears to be effective and results in the absolute majority of customers (93.1%) reading the user manual.

WAS ANYTHING CONFUSING ABOUT THE INSTRUCTIONS?

Almost all respondents found the instructions to be clear. Based on this data, no amendment to the user manual for purposes of clarity is currently required.

ANY QUESTIONS THE MANUAL DID NOT ANSWER?

As above, almost all respondents were satisfied by the information provided in the user manual. There is no indication that additional information is currently required.

WHAT MIGHT MAKE THE PRODUCT OR INSTRUCTIONS BETTER?

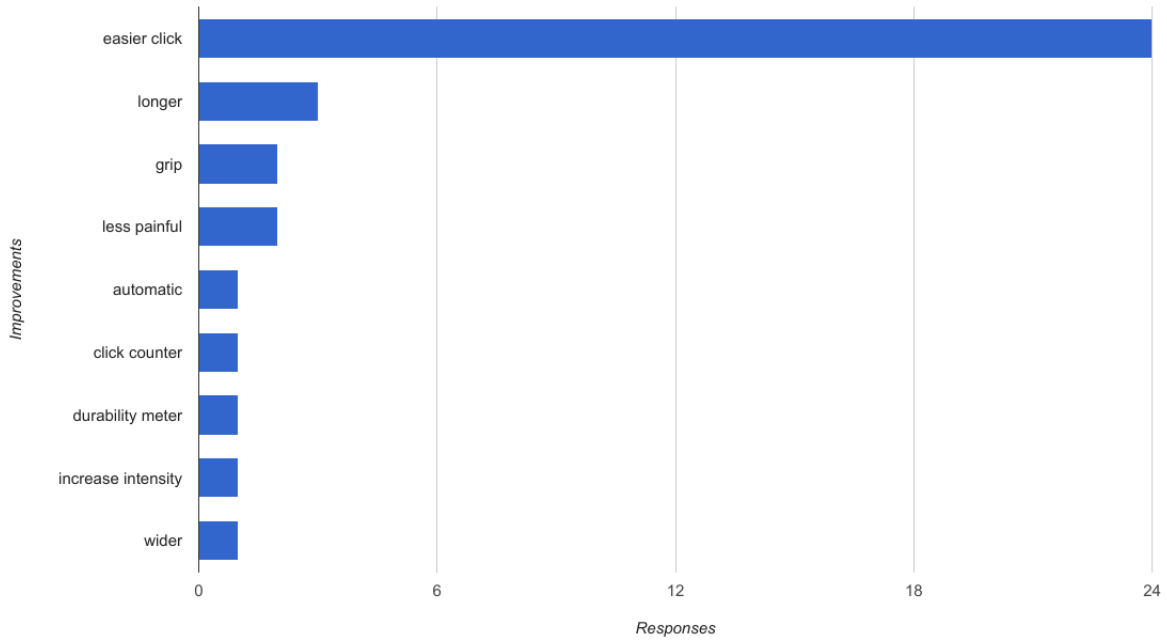

FIG. 5 – IMPROVEMENTS SUGGESTED BY SURVEY RESPONDENTS

The most common suggestion is to improve the button on the device and to make this easier to operate. This has already been considered and addressed through the introduction of the automated Paingone Plus.

Marketing materials could assist customers in their purchase decision by guiding them toward the Paingone Plus if they suffer from arthritis/hand/joint pain. This would help to deliver greater customer satisfaction.

This question could also be improved in future surveys by focusing only on the product or only on the user manual.

DIFFICULTIES USING THE DEVICE

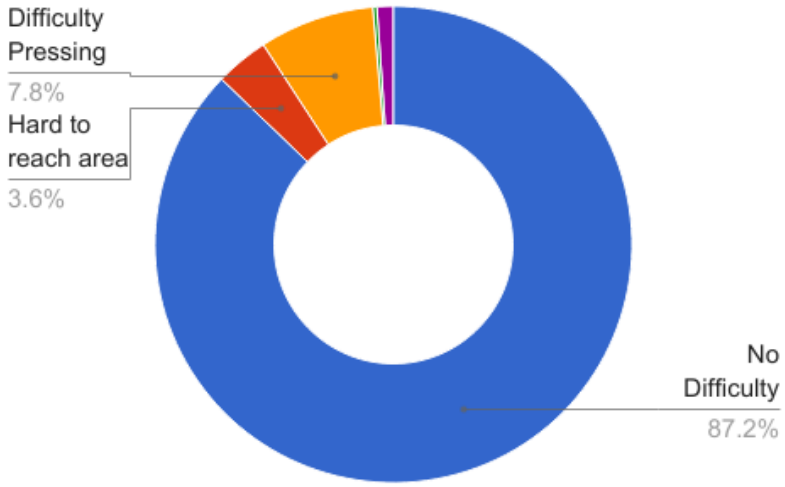

FIG. 6 – DISTRIBUTION OF DIFFICULTIES FOUND WHEN USING PAINGONE PEN

The majority of customers (87.2%) had no difficulty using the device. This could indicate that the device is simple and intuitive or that it rarely malfunctions or that customers are able to follow the instructions easily.

EFECTIVENESS

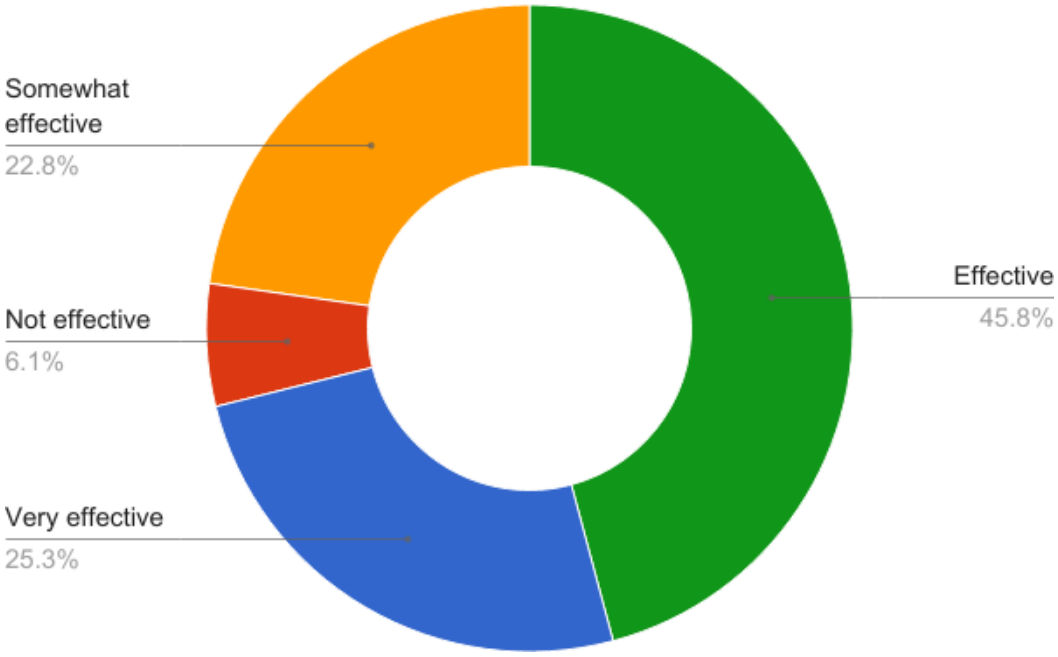

FIG. 7 – DISTRIBUTION OF PERCEIVED EFFECTIVENESS OF USING PAINGONE PEN

More than 9 in 10 respondents find Paingone to be effective to some degree for their condition.

1 in 4 finds Paingone to be "very effective".

SIDE EFFECTS

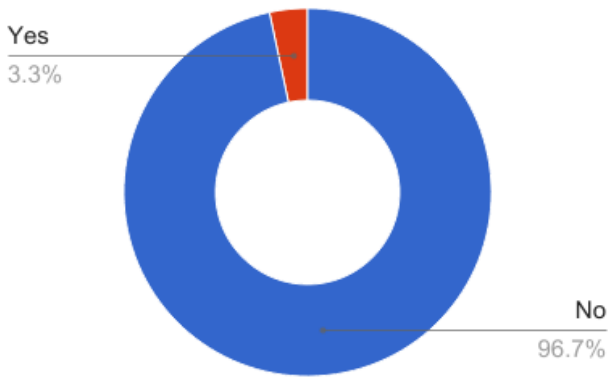

FIG. 8 – RESPONDENTS ANSWERS TO THE POLAR QUESTIONS "HAVE YOU ENCOUNTERED ANY SIDE EFFECTS?"

Almost the entirety of respondents (96.7%) found Paingone Pen to be free from any side effects. Therefore the safety of the device is corroborated by this data.

This data set also indicates that 'pre-screening' of customers by marketing materials and device labelling is effective. That is, customers who should not use the device are effectively advised against using it by the product literature.

For those respondents who answered 'yes' to encountering side effects, they were asked what these side effects were. These responses can be summarized into the following effects:

- **Bruising or red marks on the skin** – This is a known issue that can affect some sensitive skins. It is addressed in the warnings section of user manual.
- **Pain/discomfort from the electrical pulse during application** – A known issue and addressed in the user manual
- **Pain increased** – A statistically negligible number of users reported an increase in pain.

USAGE

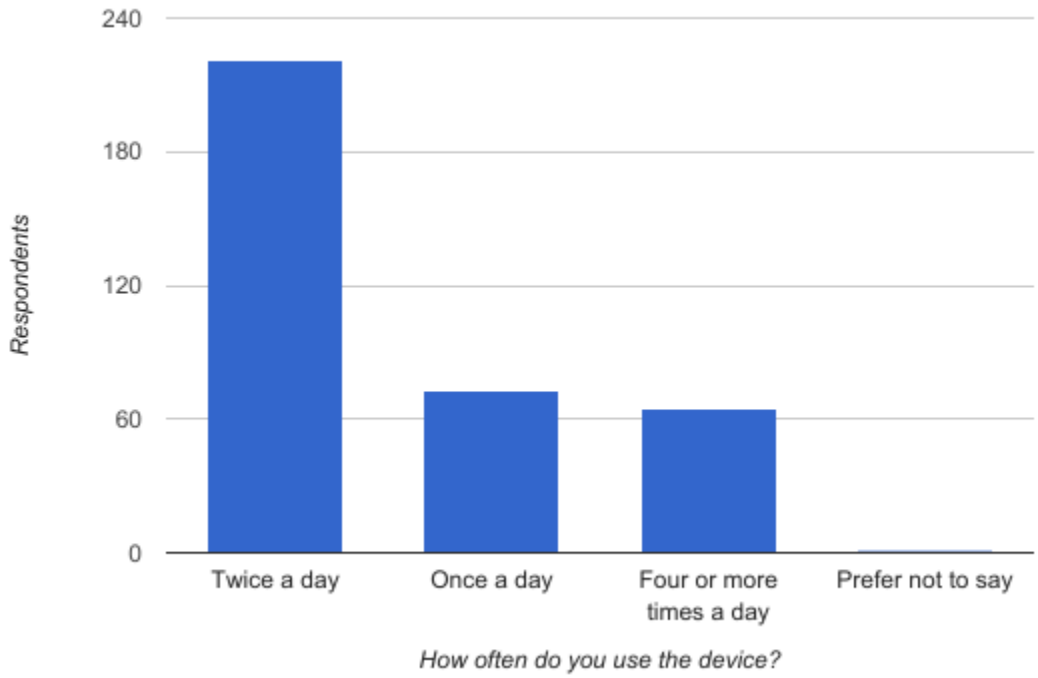

FIG. 9 – APPLICATION FREQUENCY PER DAY

4 in 5 users find that one or two applications per day are sufficient.

The current user manual advises "Re-apply when necessary, up to 4-5 times a day on each desired area". This could be clarified further and made to better reflect the data from this survey. It could indicate that most users find 1-2 daily applications sufficient, but that some users may need further applications to help manage their pain.

This data set could also be investigated more closely in future surveys to give more precise information, specifically about people who use the device more than twice a day.

DURATION OF USE

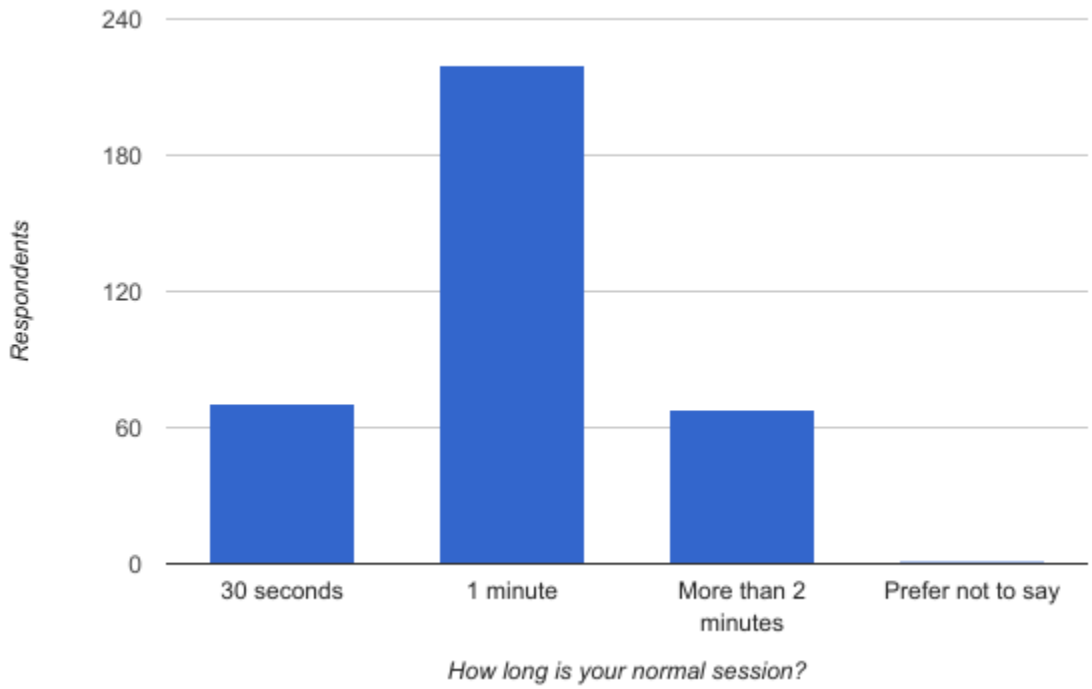

FIG. 10 – APPLICATION DURATION

A majority of users (4 in 5) find it takes between 30 seconds and 1 minute to apply Paingone. This reflects information in the user manual which indicates that application typically takes 1 minute.

Almost 1/5 of users take more than 2 minutes to apply Paingone. This could include users who find it more difficult to press the activating button. These users might benefit from the automatic Paingone Plus device.

DURABILITY

Almost all users (98.3%) agreed that Paingone is not easily damaged, indicating that current manufacturing methods and choice of materials are helping achieve device safety and durability.

SERVICE LIFE

Of the respondents, who purchased the Paingone device in 2016 or earlier, 83% are still using the device.

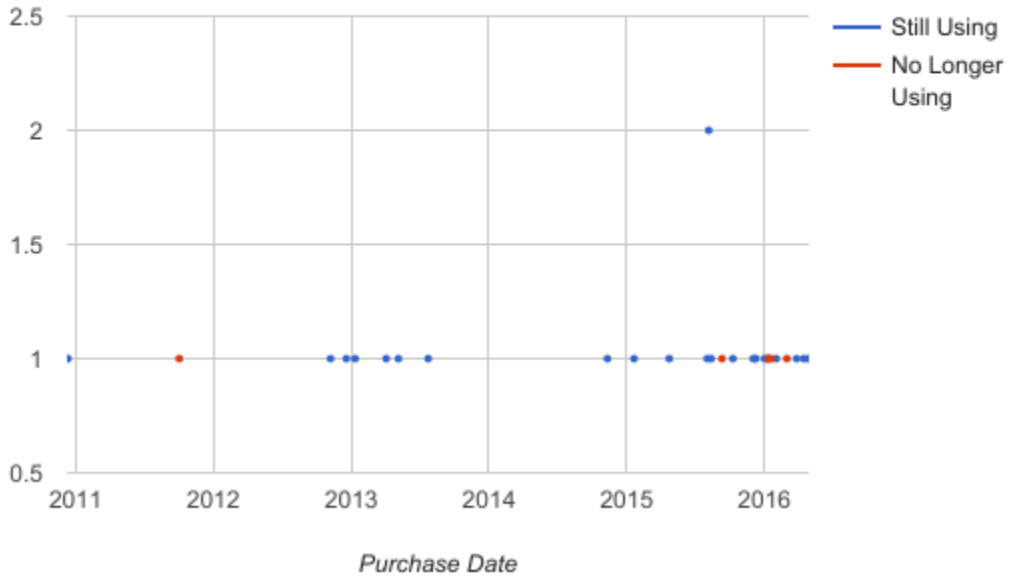

FIG. 11 – PURCHASE DATES OVER A YEAR OLD COMPARED WITH SERVICE LIFE

REASONS FOR NO LONGER USING PAINGONE PEN

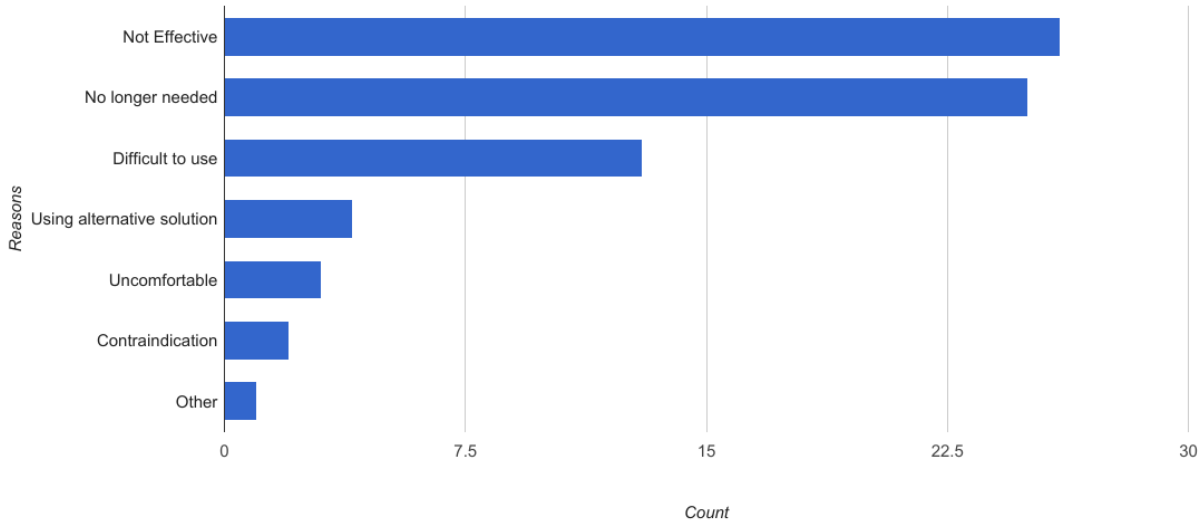

FIG. 12 – TOP REASONS FOR NO LONGER USING PAINGONE PEN

The biggest reason for no longer using Paingone was where customers found that Paingone had little beneficial effect for them.

After this, the second biggest reason was where customers found that painful symptoms had subsided.

Most significantly, some users found Paingone difficult to use. In response to feedback like this the Paingone Plus has been developed which offers greater ease of use, via automated application.

A very small number of users found the therapy painful. This issue is addressed in the user manual and current marketing.

PRE-EXISTING CONDITION OR TREATMENT

Only a small minority of respondents (4.2%) found that they could not use Paingone after purchasing the device.

This indicates that pre-screening achieved by marketing materials and device labelling is adequate.

Subsequent QMS surveys could investigate the specific reasons why people were unable to use the device.

COMPREHENDING THE INSTRUCTIONS

Almost all respondents (98.2%) found the instructions to be clear. Based on this data, no amendment to the user manual for purposes of clarity is currently required.

In addition, almost all respondents (98.8%) were satisfied by the information provided in the user manual. There is no indication that additional information is currently required.

WHAT MIGHT MAKE THE PRODUCT OR INSTRUCTIONS BETTER?

The most common suggestion is to improve the button on the device and to make this easier to operate. This has already been considered and addressed through the introduction of the automated Paingone Plus.

Marketing materials could assist customers in their purchase decision by guiding them toward the Paingone Plus if they suffer from arthritis/hand/joint pain. This would help to deliver greater customer satisfaction.

This question could also be improved in future surveys by focusing only on the product or only on the user manual.

CONCLUSIONS

Gender and Age

There is an approximate 50:50 split between the genders of respondents. Primarily, the Paingone device is used by the over 60's (90%); however there is also strong evidence of use in the under 60's (8.4%).

Purchase Date

Whilst the majority of the Paingone devices were purchased within the last 6 months, several respondents purchased the device around seven years ago and still use it with beneficial effect. This attests to both the products efficacy and durability.

Conditions

The Paingone device has been purchased for a wide range of Musculoskeletal disorders and its application is not limited to 'one site' application. The most common conditions treated are: arthritis, joint pain and associated back pain.

Instructions for Use

All respondents in this survey spoke English and the 'user manual' was read by 93.1% of these respondents.

The instructions were found to be clear and almost all respondents stated they were satisfied with the provided information.

Effectiveness

90% of respondents found the Paingone device to be effective to some degree in treating their condition; 25% found it to be very effective.

Usage and Side Effects

80% of respondents found that one or two applications per day were sufficient. The majority of respondents (80%) stated it took between 30 seconds and one minute to apply the recommended treatment. Alost 20% of respondents stated that it took more than two minutes to apply the Paingone device.

The most common side effects were:

- Bruising or red marks on the skin
- Pain/discomfort from the electrical pulse during application
- Pain Increased (statistically negligible number of respondents)

Durability and Service Life

Almost all the respondents (98.3%) stated that the device is not easily damaged.

Of the respondents, who purchased the Paingone device in 2016 or earlier, 83% are still using the device.

Reasons for Discontinuing Use

The two primary reasons for discontinuing use were cited as:

- Paingone device had little beneficial effect
- The original painful symptoms had subsided

A few of the respondents also found the device difficult to use, or found the therapy to be painful.

Recommendations and Future Development

In the majority of cases, the clarity of instructions detailing the Paingone device's usage was found to be more than adequate, especially in relation to side effects.

The primary complaint regarding the device was one of ease of application, as discussed, and this has been addressed with the development of the Paingone Plus device. The focused use of marketing materials will be used to ensure that any future user will be directed to the device most appropriate for their individual needs.

Other future developments could include 'broadening the device market' by developing multi-lingual instructions or Braille. The market will need to be tested prior to adoption to ascertain genuine need.

Future surveys could address the frequency of application, which at the moment indicates that the majority of respondents found 1-2 applications per day sufficient. This could then lead to a change in the guidance for use.

In conclusion, the Paingone device has demonstrated very high usability, durability and ease of use characteristics for the overwhelming majority of respondents. This is indicative of the device's success since launch.