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PRELIMINARY EVALUATION OF A COMMERCIALLY AVAILABLE ELECTRIC AEROSOL INHALER FROM CHINA

OBJECTIVE: Provide a preliminary understanding of the design and features of a recently introduced electronic cigar (E-Cigar) that yields nicotine containing aerosol when puffed. Determine aerosol and nicotine yields for the E-Cigar under a set of machine smoking conditions that would help define puffing parameters that could be used for future studies.

SUMMARY: The commercially available electronic cigar from Beijing SBT RUYAN Technology & Development Co., Ltd, produces a heated aerosol containing tobacco extract and nicotine. The rechargeable battery is easily replaced, as is the cartridge containing the aerosol generating material (propylene glycol) and tobacco extract. The electronics contained within the cigar are such that heat is applied only during a puff, generating substantial amounts of aerosol. When compared to Eclipse cigarettes on a laboratory smoking machine using a modified Eclipse "intense" puffing regimen (22 puffs, 60ml, 3s duration, one puff every 30s), wet total particulate matter and nicotine yields were comparable. For the electronic cigar, one battery charge produced aerosol for almost 400 puffs, while the extract cartridge produced aerosol for over 600 puffs, the equivalent to more than 25 Eclipse cigarettes.

STATUS: This preliminary study is complete.

KEYWORDS: Electric cigar, pipe, aerosol, nicotine, propylene glycol, yield, PREP

Introduction: Beijing SBT RUYAN Technology & Development Co., Ltd (Abbr. RUYAN Tech.) is a subsidiary company, owned by the Hong Kong based SBT Corporation. Further information about the company and their products can be viewed at their website:
<http://www.sbtry.cn/rykj-cn/jt-cn.htm>.

In 2004, Ruyan Tech, introduced for commercial sale in the Chinese market a battery-operated electronic cigar capable of generating significant amounts of nicotine containing aerosol when puffed in the manner of a traditional tobacco burning cigar (see World Patent WO 2004/095955 (11.11.2004 Gazette 2004/46)). Two commercial versions of the device exist at this time, the Ruyan Atomizing Electronic Cigar and the Ruyan Atomizing Electronic Pipe. This report provides information on the electronic cigar.

A brief except from their website describing the electric cigar follows (grammatical errors have not been corrected):

RUYAN 牌 ANI is a none-igniting substitute of the cigarette, it has some characteristics with the traditional cigarettes, such as making you refresh, fulfilling the smokers' needs; But it has much more different with the traditional cigarettes substantially, such as no tar, no ignition, no 460 kinds of chemical substances that can lead to respiratory and cardiac system diseases, no the carcinogenic in the traditional cigarettes...

So the smokers who use RUYAN@ANI will avoid tar and many dangerous substances to get into their lungs and bodies.

In addition, the instruction manual for the devices includes the following (taken from the manual for the electronic pipe):

The Ruyan atomizing electronic pipe is a nonflammable atomizing electronic pipe, which performs and carries the similar functions and features as the ordinary pipe. It produces a refreshing feeling and fulfills the smokers' addiction through the delivery of the senses of satisfaction and relaxation. Besides, the product also carries the functions as a smoke-quitting substitute. The major differences between the Ruyan atomizing electronic pipe and ordinary pipe are:

- 1. No tar or the harmful constituents to the human body, hence contains no carcinogenic compounds;**
- 2. No ignition required, hence will not lead to the production of more than 4,000 constituents from chemical reaction during ignition;**
- 3. No "second hand smoke" or environmental pollution;**
- 4. No possibility to cause fire. It can be used safely at fire prevention area;**
- 5. According to the smoke-quitting proposal, the target of quitting smoke can be reached non-painfully in a short period of time.**

The Reduced Risk and Applied Product Development group at RJRT purchased three electronic pipes and three electronic cigars through colleagues visiting China. The cigars and pipes were purchased for study in the laboratory in an effort to better understand the design of the products and how they function. The bulk of our work to date has been directed at understanding the electronic cigar.

Methods: One of the purchased cigars was carefully dissected in the QA Instrumentation Laboratory. Digital photos were taken throughout the process to document the construction of the cigar and to allow inferences to be made concerning the functions of the various components.

Another electronic cigar was studied in the smoke lab to determine aerosol yields when “smoked” on a modified Borgwaldt 20 port linear smoking machine. Since no defined smoking regimen exists for testing a device of this nature, we decided to test the aerosol yields from the electronic cigar using puffing parameters that have been used in the past to study Eclipse cigarettes. It was theorized that since the aerosol yield from the electronic cigar was in all likelihood closer in composition to the smoke yielded from Eclipse cigarettes than the smoke yielded from tobacco burning cigarettes, using puffing parameters that have been associated with Eclipse cigarettes could provide a foundation for making future comparisons.

To maximize the potential aerosol yield from the electronic cigar, we decided that using the puffing parameters associated with the Eclipse “intense” puffing regimen would be used. The Eclipse “intense” puffing regimen consists of 22 puffs, 60ml volume, with each puff lasting 2 seconds. One puff is taken every 30 seconds until the final puff is taken. This puffing regimen is typically referred to via the shorthand descriptor “60/30/2”.

After some initial attempts to measure aerosol yield from the electric cigar, it was determined that under the 60/30/2 puffing regimen, yields were relatively low. In some informal tests, we determined that by increasing the puff duration by 1 second, (i.e. 60/30/3), aerosol yields from the electronic cigar increased dramatically. Data from both 60/30/2 and 60/30/3 regimens are presented in the Results section (below).

Results:

Anatomy of the Electronic Cigar - One of the electronic cigars was carefully dissected in the QA laboratory in an effort to 1) identify as many of the individual components as possible; 2) document the design of the cigar; and 3) infer as much as possible concerning how the cigar functions. A collection of digital photographs were taken and are available for viewing at: (<file:///wpbasisp1/rdlibrary/report/R015/R015631A.PDF>). A small subset of the photos will be included in this report to facilitate understanding of the design of the electronic cigar.

Figure 1 depicts the electronic cigar and accessories in the original retail box. Included along with the electronic cigar (A) are: a battery charger (B); two lithium rechargeable batteries (4.2V) that seem identical in physical size to standard AAA batteries (C); and two plastic covers that fit tightly over the mouthpiece of the electronic cigar when the cigar is not in use to keep the mouth end of the cigar from getting soiled (D).

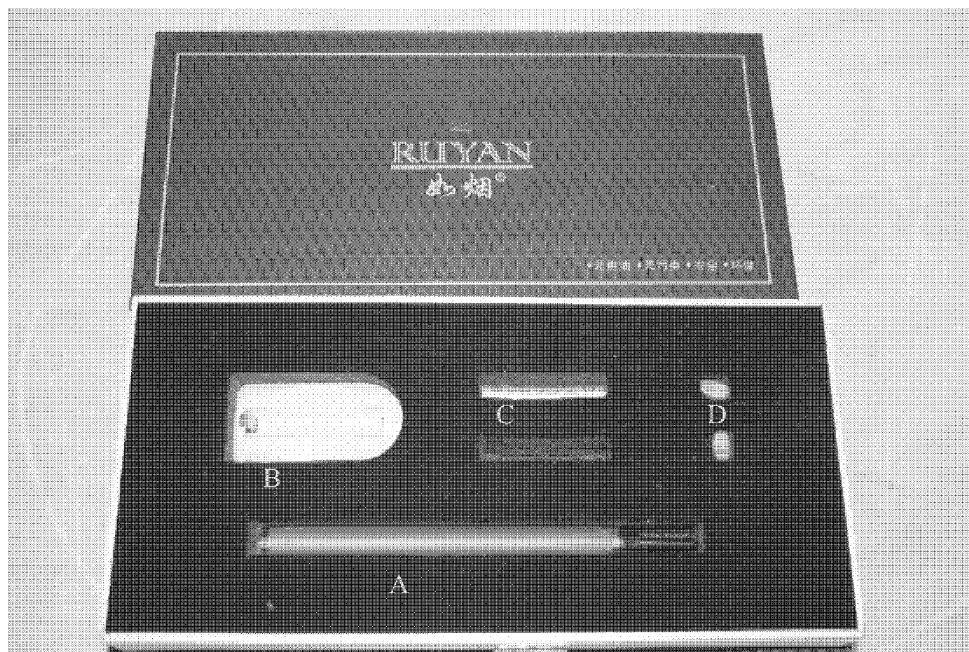


Figure 1

Figure 2 shows the fully assembled cigar as it would be used by the smoker. The cigar body is round, except for the flattened mouthpiece. Approximate size of the assembled cigar is 146mm long with a diameter of 13mm.

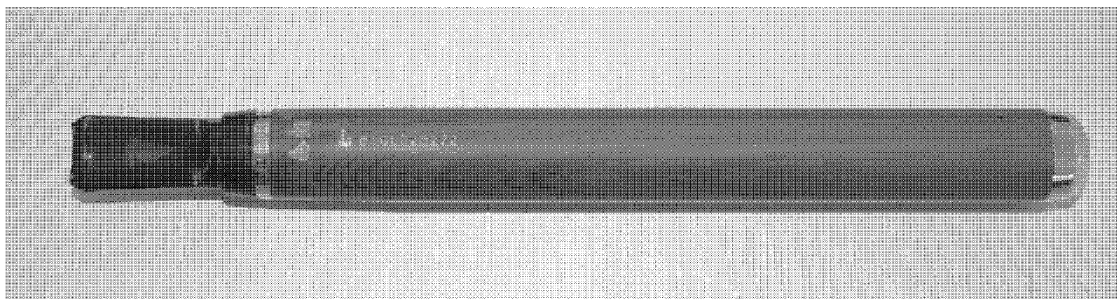


Figure 2

In Figure 3, the mouthpiece/extract cartridge unit (B) and the front-end plastic “widow” (C) have been separated from the cigar body (A). Parts B & C, are designed to be easily removed from the body of the electronic cigar by un-screwing from the threaded gold rings (D). For a detailed description of the mouthpiece/extract cartridge see Moore, 2006 (ACD-M DSM 2006, 142A).

The mouthpiece/extract cartridge unit is designed to be periodically replaced with a new unit when aerosol levels from the cigar diminish. The plastic window is easily removed to allow a discharged battery to be replaced with a freshly charged battery (E). The gold colored rings (D) are normally permanently glued to the inside of the cigar body and can also serve as contact points for the electrical circuitry (note solder drop on forward ring [arrow]). Finally, a small whole in the cigar body provides access to a reset contact for the electronic circuit (F).

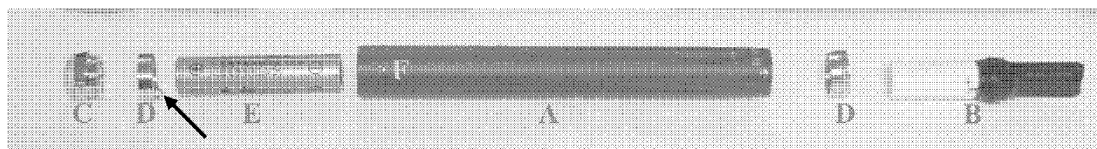


Figure 3

The stainless steel sleeve or main body of the electronic cigar (component A in picture above) was cut longitudinally to expose the interior and allow access to the internal components (Figure 4).

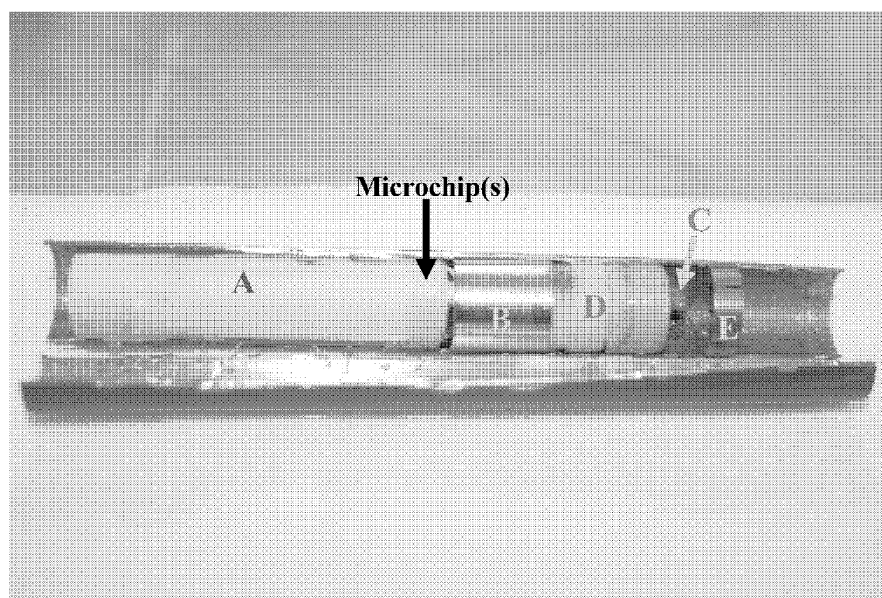


Figure 4

The interior of the electronic cigar body (Figure 4) houses the battery holder (A) and the micro chip(s) controlling the electronic circuitry (black arrow), a stainless steel ring (B), the two heater elements (one contained within the steel ring, the other nearest the mouth end of the cigar (C) and the air-flow sensor switch (internal to D). Metal ring E appears to be inserted for structural support to maintain the shape of the electronic cigar where the extract cartridge is inserted to

make contact with heater element C. All internal components of the electronic cigar are held rigidly in place with epoxy that coats the internal surface of the stainless steel tube. The precise positioning of the components and their relationship to one another strongly suggests to us that the electronic cigar is assembled by hand.

One aspect that cannot be shown in the photos is that the battery holder contains several channels that are recessed from the inside of the cigar. These channels are formed along the outside of the battery holder between the holder and the inside of the cigar tube. We believe these are air channels. When the cigar is puffed, air enters the cigar through 4 very small holes contained in the plastic "window" (in the front of the cigar) and then flows along the outside of the battery holder in the channels. At the interface of components A & B, the air is directed through the metal ring (B), where the air-flow closes a switch which activates the heaters which in turn generate the aerosol that exits the mouth-end of the cigar. More operational details are provided below.

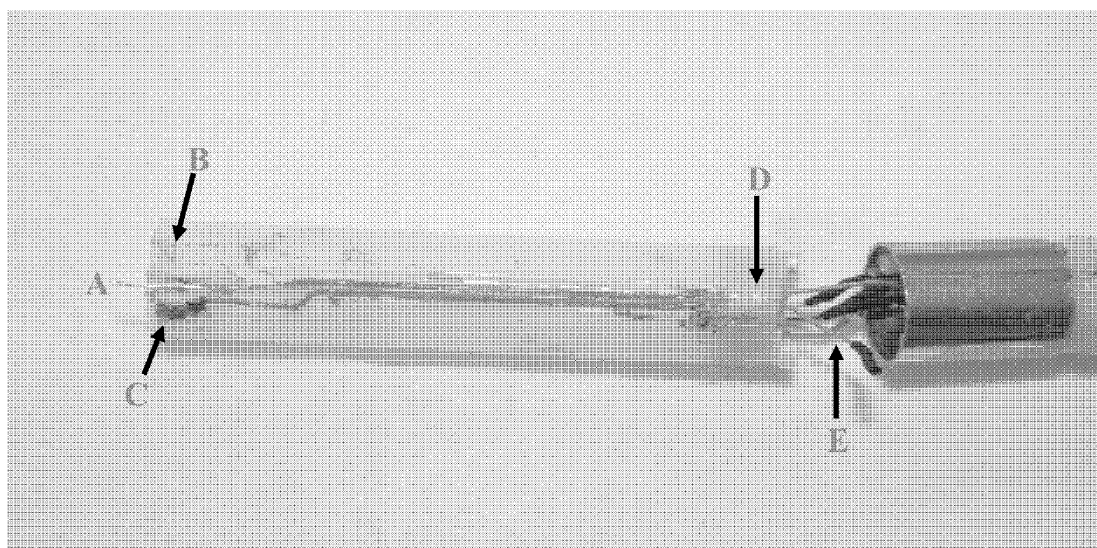
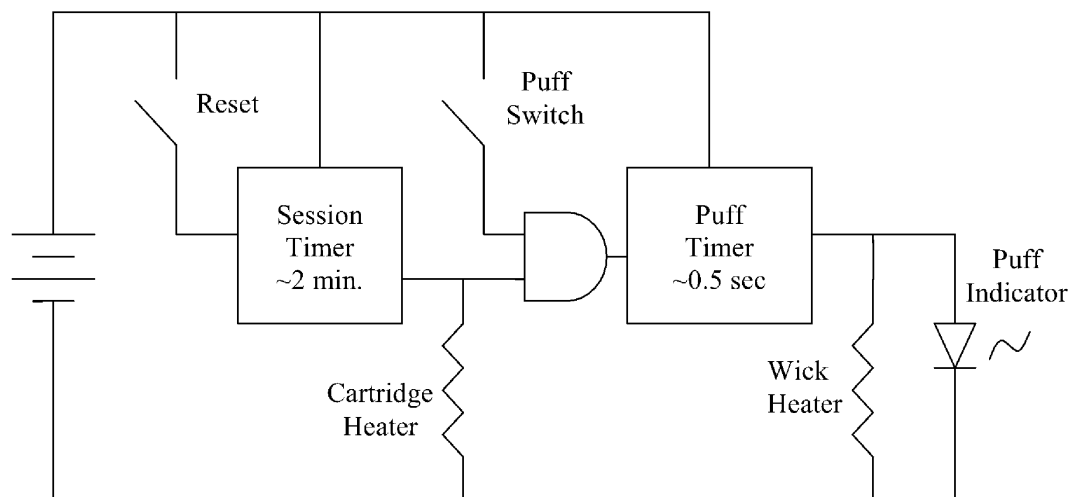


Figure 5

A close-up of the battery holder and internal metal ring is provided in Figure 5. In the front of the battery holder are a ground wire (A) which is normally soldered to the forward threaded ring, a light emitting diode (LED) (B) that provides the visual "glow" when the cigar is puffed, and a metal pad (C) that allows the electronic circuitry to be reset through a small hole in the cigar body (see Figure 3). Wires from the ground, LED and reset pad (A, B, C) travel back and into the electronic chip(s) that control the electronic circuitry (D). The chip(s) is contained in a section of the battery holder that is filled with opaque epoxy resin, which prevents identification of the number and type of electronic chip(s) used. We are currently attempting to remove the electronics in a manner that will allow us to identify the number and type of chip(s) used. A group of wires then exits the section containing the electronic chip(s) (E) and travels to the air-flow switch and heaters (Figs 6 & 7).



The schematic diagram (above) represents our current “best guess” of the electronic circuitry contained within the electronic cigar. To date, we have not been able to extract the actual microchip(s) used in the cigar from the opaque epoxy resin and consequently, cannot determine the exact electronic circuit that is being used.



Figure 6

In Figure 6, metal ring A is the same metal ring that appears on the extreme right of Figure 5. Contained within and exiting from the mouth end of ring A are B, the magnetic reed air-flow switch, a second stainless steel ring that contains a circular ceramic heater (C), and a second heater/wick (D) that sits on top of the ceramic heater and protrudes into the spongy extract cartridge in the assembled cigar. The second heater/wick is made of what appears to be a metallic cloth material that is somewhat bendable but will hold its shape.

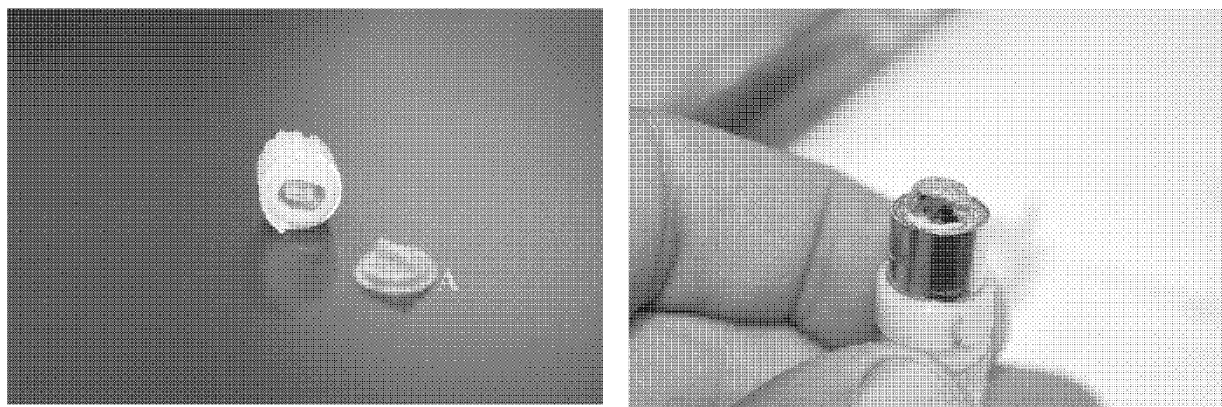


Figure 7

Figure 7 offers close-up views of the mouth end of the air-flow switch and plastic “cover” (A) which we feel prevents liquid extract from dripping down into the electronic components (left panel). The right panel of Figure 7 provides a close-up of the heater/wick assembly which sits “on top of” (i.e., closer to the mouth end) of the ceramic heater. The heater/wick assembly helps draw liquid extract from the cartridge down to the heaters.

When air is drawn through the cigar during a puff, a magnetic reed switch contained in the apparatus in the left-hand panel of Figure 7 vibrates closed and energizes the cigar. At the same time, a signal is sent to the LED that causes the LED to glow, indicating the cigar is active. A signal is also sent to the ceramic ring heater which we believe provides a low level of background heat and acts to “pre-heat” the air entering the heater/wick assembly. Finally, a 66 ohm heater coil contained in the heater/wick assembly provides a higher temperature heat which creates aerosol from the liquid contained in and around the metallic wick. Puffing on the electronic cigar quickly produces an aerosol that is composed principally of propylene glycol and nicotine.

The electronic cigar is currently available for sale in China, and a similar (in appearance) item is offered for sale in the over the internet at www.e-cig.com. Also available for sale in China is an electronic pipe (Figure 7) which appears to operate in a similar manner as the cigar, although we have not dissected the pipe to determine its internal structure.

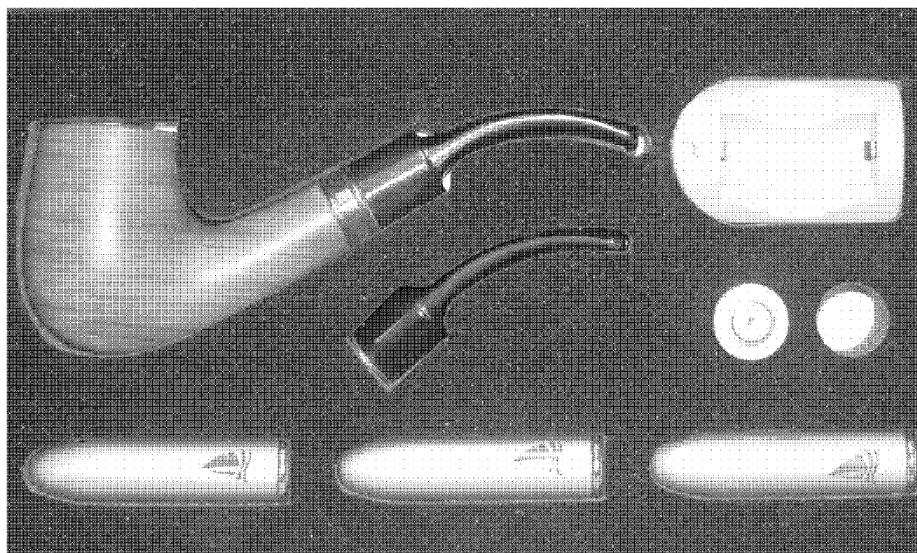


Figure 7

Though not currently available commercially, the manufacturer of the electronic cigar has stated that a smaller version, closer in size to a cigarette, will be commercially available in late 2006 or early 2007 (Figure 8). A working prototype of the cigarette model (pictured) was found to generate significant aerosol when puffed, though the aerosol was judged to be somewhat “lighter” in taste than the aerosol from the electronic cigar and pipe configurations.

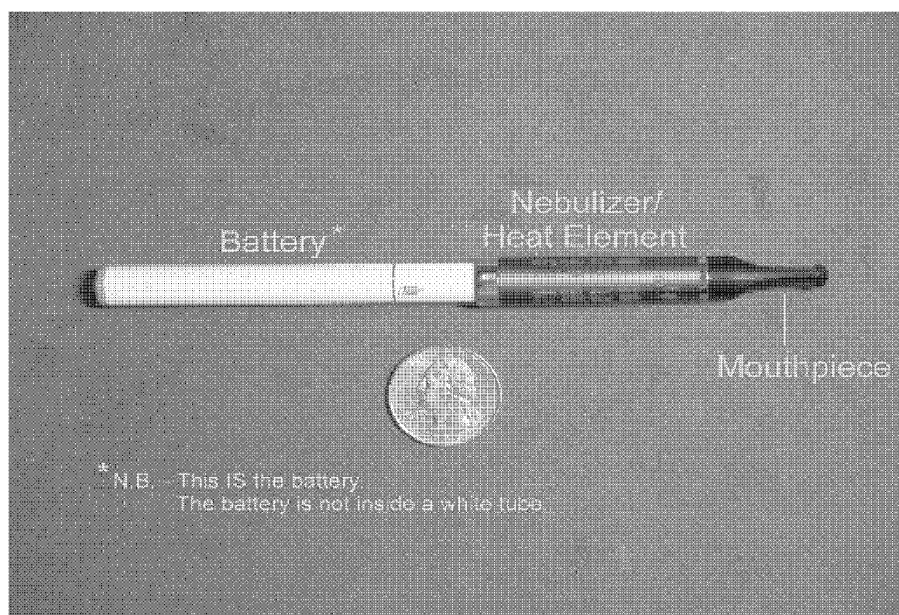


Figure 8

Aerosol Yields of the Electronic Cigar

Analyses of the extract cartridge and extract liquid were performed in the Analytical Chemistry division and the results reported in 2 R&D memos (Moore, ACD-M DSM 2006, 142A; Scott, ACD-M WAS 2006, 144). The reader is referred to these two memos for a detailed description of the cartridge and extract. For purposes of this report, we will only mention that the liquid extract contained in the cartridges was composed principally of propylene glycol, and also contained a natural tobacco extract. It appears the nicotine content of the extract had been enhanced in all three levels of nicotine-containing cartridges (Low, Mid, High). A "0" cartridge contained little, if any, nicotine.

Literature supplied with the electronic cigar stated that nicotine content of the cartridges is as follows: High = 18mg, Mid = 14mg, and Low = 11mg of nicotine. However, as detailed in ACD-M WAS 2006, 144, significant differences in these values were observed when a small number of cartridges were analyzed to determine nicotine content. Additional studies will be required to understand why these differences occurred.

Several small studies were conducted in the FTC smoke lab on aerosol yields from the electronic cigar. Since no standardized smoking regimen exists that can be applied to a study of aerosol yields from the electronic cigar, we decided to compare yields to adopt a puffing regimen that had been applied previously to the study of Eclipse cigarettes. Our rationale was that using Eclipse cigarettes and an Eclipse puffing regimen would provide the foundation for future comparisons of the electronic cigar to a well characterized, commercial cigarette. The first questions we wanted to answer were how much aerosol is generated by the electronic cigar, and how long does the cigar "last" under specified puffing conditions.

As a starting point, in an attempt to potentially maximize yields from the electronic cigar, we decided to use what has been termed Eclipse "intense" puffing parameters. Standard FTC puffing parameters are one 35ml puff, lasting 2 sec in duration, taken once every 60 sec (35/60/2). Puffing stops when the cigarette burns to a specified butt length (overwrap + 3mm). Since Eclipse does not burn down, our studies of aerosol yields from Eclipse have been conducted to a specified number of puffs, not a specific butt length. Over the years, the Eclipse "intense" puffing regimen was developed to help fully characterize and understand aerosol yields from Eclipse. The Eclipse "intense" puffing regimen consists of 60ml puffs, lasting 2 sec in duration, one puff taken every 30 sec (60/30/2). Since Eclipse does not burn down, puffing is stopped after 22 puffs, which ensures that the Eclipse fuel source has been consumed.

The aerosol yield studies used "Medium" ("Med" or "Mid") and "High" extract cartridges that came with the original electronic cigars (OEM cartridges) and cartridges that had been purchased from the previously mentioned website (Aftermarket cartridges). The initial attempts to study the electronic cigar using Eclipse "intense" conditions indicated that the cigars yielded less than 50% of the aerosol yielded by Eclipse under the same puffing conditions.

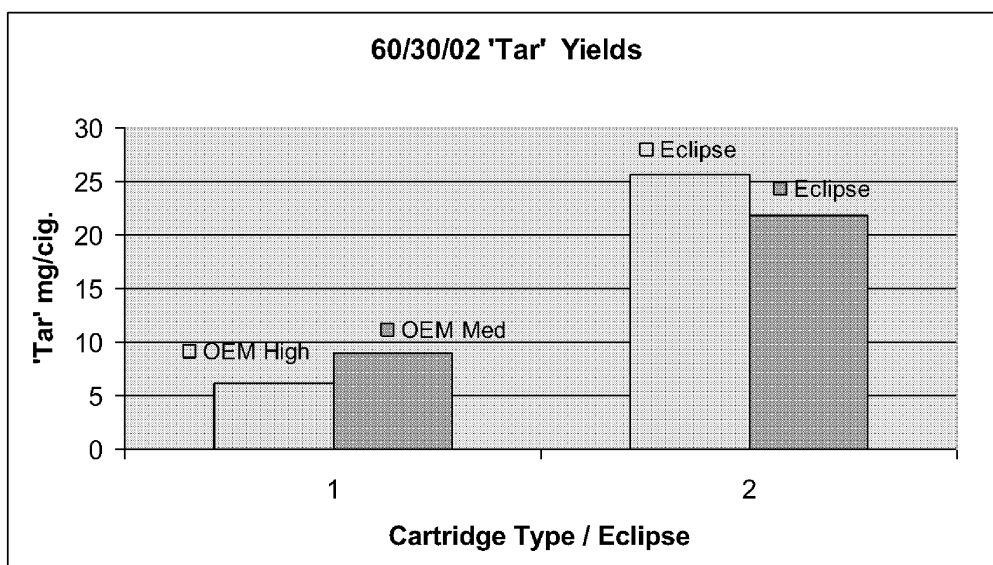


Figure 9

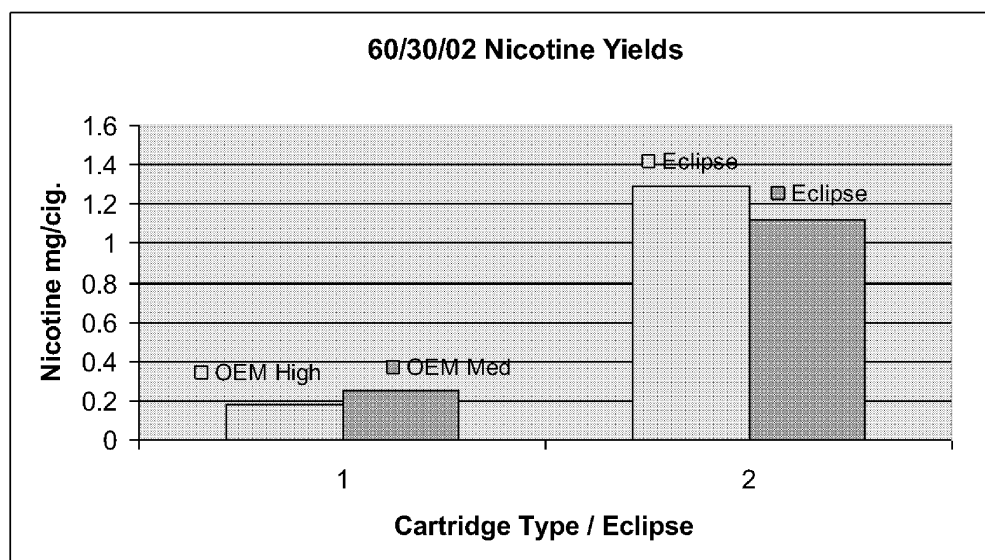


Figure 10

In an attempt to increase aerosol yields from the electronic cigar, we decided to lengthen the duration of the individual puffs from 2 sec to 3 sec duration. This was decided after casual observations that slightly longer puffs by smokers using the electronic cigar and pipe seemed to generate significantly more aerosol. The puffing regimen with 3 sec duration puffs is indicated via the shorthand notation "60/30/3" in subsequent charts. As can be seen in Figures 11 and 12, aerosol yields from the electronic cigar increased significantly and in some cases exceeded yields

from Eclipse. The increased yields were in all likelihood due to an increase in temperature of the heating elements, resulting in more efficient aerosol generation.

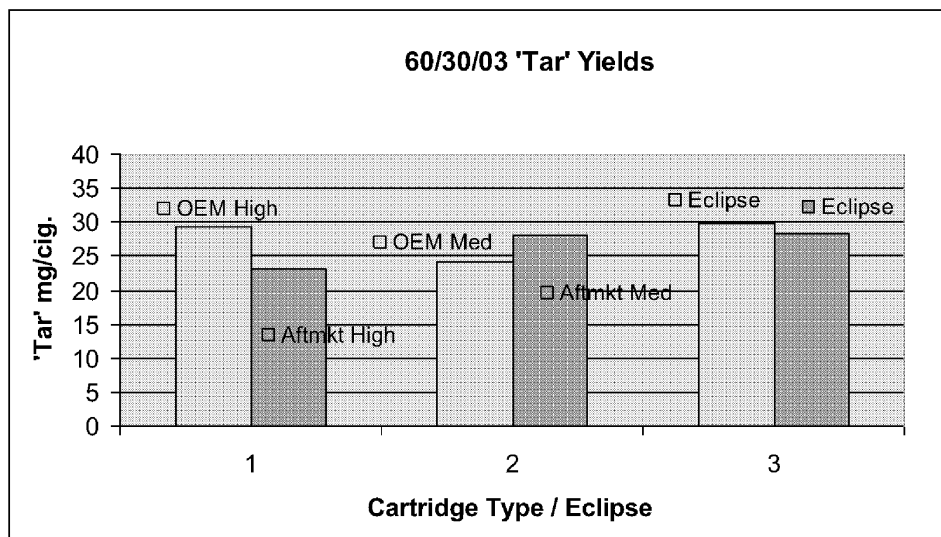


Figure 11

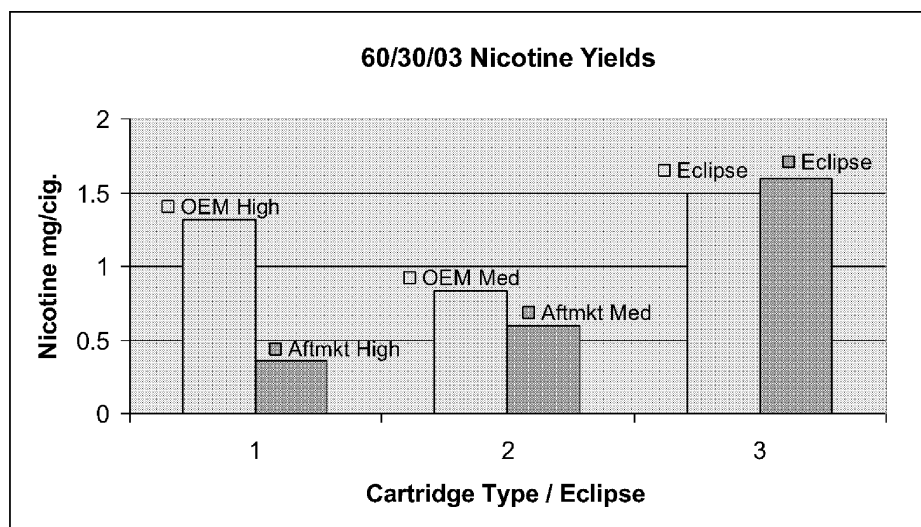


Figure 12

In an additional study, one OEM “Medium” cartridge was puffed continuously using 60/30/3 puffing parameters to determine how long it would yield aerosol. Again for this study, 22 puffs were used to define one “cigarette” smoking. After each 66 puffs (defined as 3 “cigarettes”), the Cambridge pad on the smoking machine was removed, weighed, saved for analysis of nicotine and water, and a new pad inserted for the next 66 puffs.

As can be seen in Figures 13 and 14, one "Medium" cartridge yielded significant amounts of aerosol for more than 600 puffs. With 22 puffs defining one "smoking" of an Eclipse cigarette, this cartridge in the electronic cigar yielded aerosol equivalent to 25 to 30 Eclipse cigarettes. The reader should note that the battery in the electronic cigar was recharged after 396 puffs, indicating that the extract cartridge "outlasts" the battery charge.

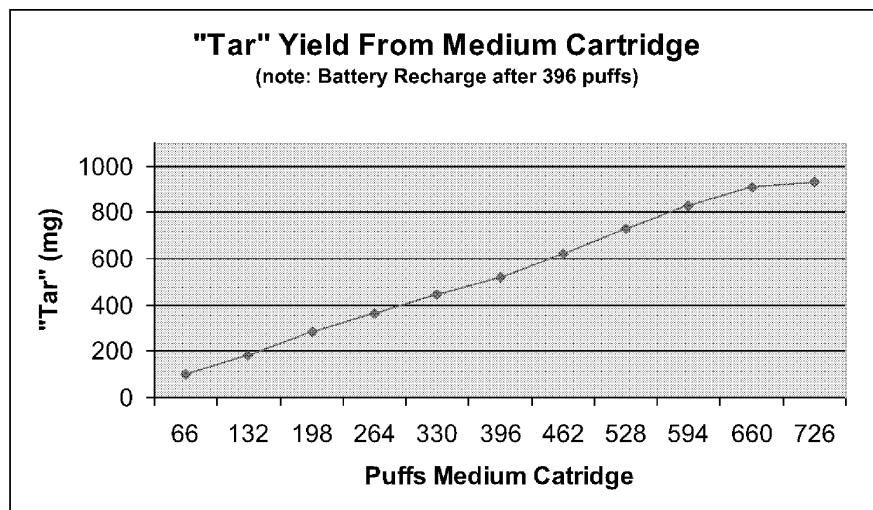


Figure 13

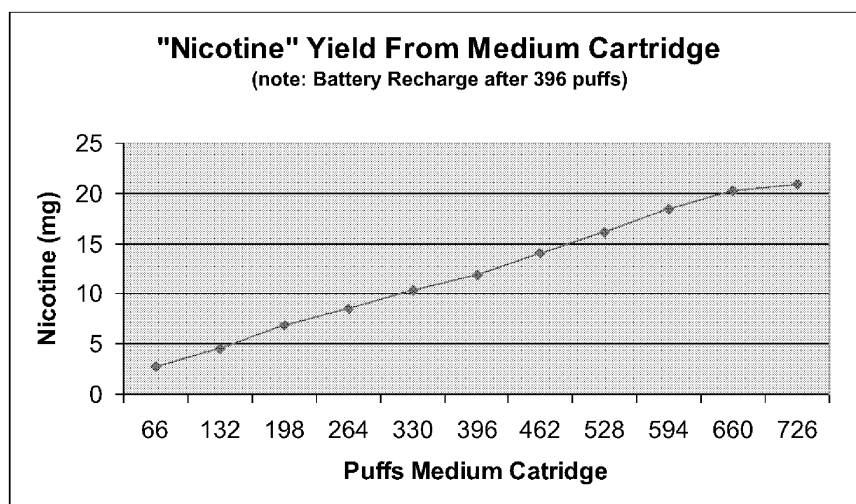


Figure 14

As a visual illustration that the particulate yield from the electronic cigar contains few, if any, combustion products, the photograph in Figure 15 was taken. The aerosol particulate trapped on the filter pad from two Eclipse cigarettes (22 puffs each, 60/30/3) was light-brown in color indicating some combustion products are present in the particulates generated from Eclipse. The

filter pad containing the trapped particulate aerosol from 44 puffs on the "Medium" cartridge in the electronic cigar did not indicate any change in color.

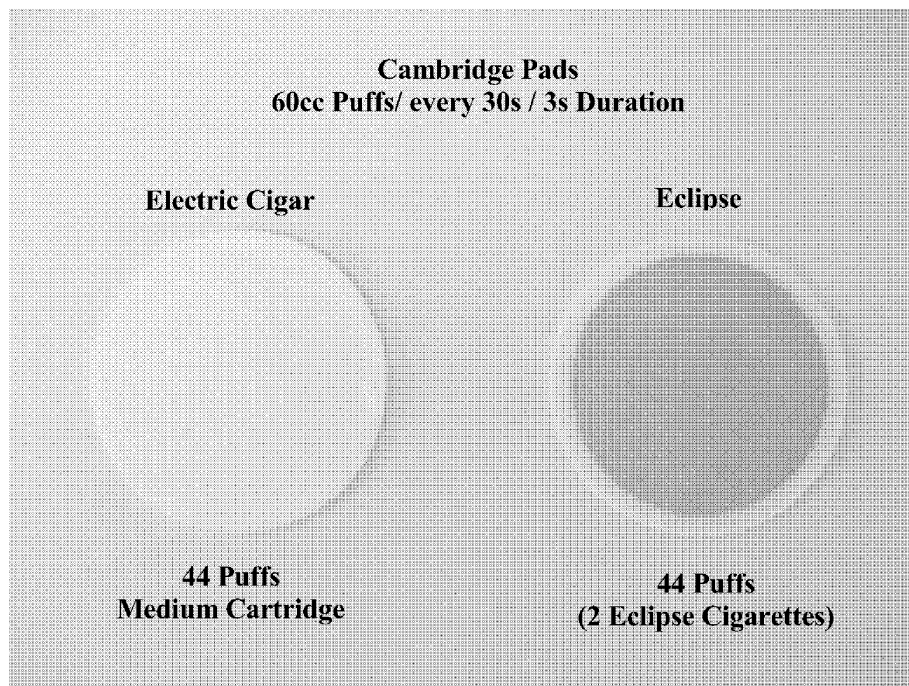


Figure 15

Discussion

Construction/Design

The Ruyan electronic cigar is commercially available in China. It contains no tobacco, but does contain a replaceable cartridge that is soaked in a solution of propylene glycol and tobacco extract, containing nicotine. It is sold in China with the principal claim that it is a smoking cessation aid since (according to the manufacturer) the various nicotine levels of the extract cartridges (High, Medium, Low, Zero) allow the smoker to gradually reduce their nicotine intake and eventually stop smoking. The literature, however, also contains statements to the effect that the cigar will "fulfill the smokers' addiction through the delivery of the senses of satisfaction and relaxation", with "no tar or the harmful constituents to the human body, hence no carcinogenic compounds", "no second hand smoke", and "no possibility to cause fire."

While the idea of generating a cigarette-like aerosol without burning tobacco is not new (see: Whittenmore, Jr. US 2,057,353; McCormick, US 2,104,266; Brooks, et al., US 4,947,874; Counts, et al., US 5,060,671; Counts, et al., US 5,144,962)) the Ruyan electronic cigar seems to have addressed several shortcomings of some of the earlier attempts at producing a cigarette-like

aerosol without combustion. While based principally on anecdotal comments of both smokers and non-smokers, we thought it valuable to include these observations (below) to provide the reader with a feel for some of the challenges the electronic cigar seems to have met.

The electronic cigar is of a comfortable size and shape. It is easy to hold, and while heavier than a tobacco cigar of the same size, is not excessively or uncomfortably heavy. The battery is easily changed, charges fairly rapidly (~2 hours after the initial 8 hour charge) and provides sufficient energy for approximately 400 (3sec) puffs. Shipping the electronic cigar with two batteries ensures that the smoker does not have to experience any "down time". The extract cartridges are also easily changed, and in our "longevity test" of one cartridge, provided significant aerosol for more than 600, 3sec puffs. The cigar can sit idle for days, even weeks, and instantly provides aerosol when puffed again. The draw characteristics are similar to a tobacco cigar of the same size.

Continuing with comments on the electronic cigar, the first reaction (again anecdotal responses) of those who have tried it is that they are surprised at how much aerosol is generated during a puff. For those who have smoked an Eclipse cigarette or the Accord cigarette, the increased aerosol yield from the electronic cigar is instantly noticeable. If the "smoke" from the electronic cigar is inhaled, there is essentially no visible aerosol when the smoker exhales. When the smoker puffs on the electronic cigar and does not inhale, the smoker's exhaled breath does contain visible aerosol, however, the exhaled aerosol dissipates quickly (perhaps even faster than exhaled Eclipse smoke dissipates). There is essentially no odor when "smoking" the electronic cigar and both smokers and nonsmokers (who have puffed the e-cigar) have commented that the "taste" of the aerosol is reasonably acceptable. Some have even commented that they prefer the "taste" of the aerosol generated by the electronic cigar to that of Accord or Eclipse smoke. The aerosol from the e-cigar is judged to be at a similar temperature (slightly above ambient) as cigarette smoke, though no experimental temperature measurements have been made.

Our dissection of the e-cigar revealed an intricate and well-engineered design. The complexity of the design and the small margin for error in assembling the cigar suggest to us that it is hand-assembled. Hand assembly probably accounts for the relatively high cost of the e-cigar, approximately \$230.00 - \$260.00 US, although the exact electronic components of the cigar are not known and could also contribute significantly to manufacturing costs. (The website mentioned in the introduction offers a similar product at ~\$130.00). The pictures contained in the body of this report will provide the reader with a better understanding of the design of the electronic cigar than any verbal description we can provide here. We will simply note that when the cigar is puffed, air travels through 4 small holes equally spaced around the perimeter of the plastic window in the front of the cigar, travels through channels between the battery holder and cigar body, through the "on-off reed switch" which activates the heaters and light, through and around the heater/wick assembly, around the extract cartridge and out through the mouthpiece. Slower, longer puffs seem to generate more aerosol than shorter puffs, perhaps allowing more time for the heaters to reach a higher temperature.

Laboratory Testing

Aerosol yields from the electronic cigar were studied in the FTC smoking laboratory but were done on a very preliminary basis due to a limited supply of extract cartridges and having only one cigar available for testing. Since no accepted machine smoking regimen exists for the e-cigar, we began our testing using machine parameters associated with Eclipse "intense" smoking tests, i.e., one two second, 60mL puff taken every 30 seconds (60/30/2), for a total of 22 puffs. These parameters were chosen thinking they would provide a suitable baseline for comparing the yields from the electronic cigar with yields from Eclipse cigarettes. Our initial tests indicated that compared to Eclipse, the e-cigar yielded noticeably less aerosol under these puffing conditions (see Figs 9 & 10).

We then decided to lengthen the duration of the puff by one second (from 2 seconds to 3 seconds) based in part on comments from smokers who puffed on the cigar and indicated that a longer, slower puff seem to yield more aerosol. These observations were confirmed in the laboratory when the e-cigar yielded significantly more aerosol when the longer puffs were used. In fact, aerosol yields approached the Eclipse cigarette yields under the same 60/30/3 smoking regimen (see Figs 11 & 12). And, as discussed previously, the e-cigar yielded essentially the same amount of aerosol (measured in 66-puff "blocks") for more than 600 puffs from one "Medium" cartridge (Figs 13 & 14).

Finally, Fig 15 illustrates differences in the particulate matter collected from the e-cigar and Eclipse aerosols by showing a side-by-side comparison of two Cambridge filter pads following 44 puffs (60/30/3) on either the e-cigar or two Eclipse cigarettes. While the light brown color of the Eclipse pad would appear very pale in color compared to a pad exposed to 44 puffs on tobacco burning cigarettes, the e-cigar pad did not show any discoloration at all. And while gas-phase components were not collected from these brief studies, it would be expected that the e-cigar would not generate significant amounts (if any) of combustion related gas phase compounds (e.g. carbon monoxide).

To date, this report¹, coupled with the previous analytical chemistry reports cited above, represents our working knowledge and laboratory data collected on the Ruyan electronic cigar. Any future testing of the electronic cigar will be determined based on the level of interest in gathering additional data.

¹ The reader should note the information contained in this report was accurate at the time the final draft was prepared for review and signatures. The e-cigar and e-cigarette aerosol generators appear to be evolving rapidly. For example, while this report principally focuses on the Ruyan e-cigar, the website offering a similar looking (aftermarket) device (see introduction) was updated to offer an electronic cigar, electronic cigarette and electronic pipe. However, replacement cartridges were no longer offered for sale at this website. Instead, the vendor now offers "E-Cig Liquid" that the smoker uses to replenish the aerosol generating material. The following is a quote copied from the current website that describes the "E-Cig Liquid":

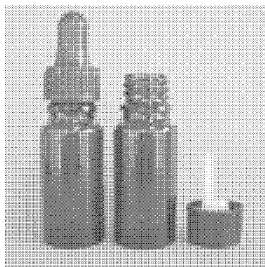
Our E-Cig smoking liquid has been purified from tobacco, according to the standard FDA GRAS, by biological technology, removing the harmful substances in the tobacco and keeping the harmless or useful substances,

as well as adding different essence. It not only keeps the cigarette's or cigar's basic smoking function, but also removes the harmful substances for your health.

You can just put few drops on the smoking liquid container of E-CIG whenever you want, and then you will enjoy the same feeling as a tobacco cigar or cigarette without suffering any tar and carbon monoxide smoking damages.

1ml E-CIG Smoking Liquid equivalents about half carton of cigarettes, that is, a smoker will consume 1ml E-CIG Smoking Liquid in 3-4 days if they consume 1-2 packs of cigarettes in one day. 1ml E-CIG Smoking Liquid costs only less than one pack of cigarette. Smoking E-CIG is not only the healthiest, but also is much less expensive than smoking cigar, cigarette or pipe.

E-CIG Smoking Liquid can be formulated to taste like different brands of tobacco cigar or cigarettes with OEM ordering.



(See <http://www.e-cig.com/liquid.htm>)

References:

Moore, D.S. FT-IR Analysis of aerosol cartridge. ACD-M DSM 2006, 142A

Scott, W.A. Chinese pipe insert evaluation. ACD-M WAS 2006, 144

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