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The Electrosurgical Authority®

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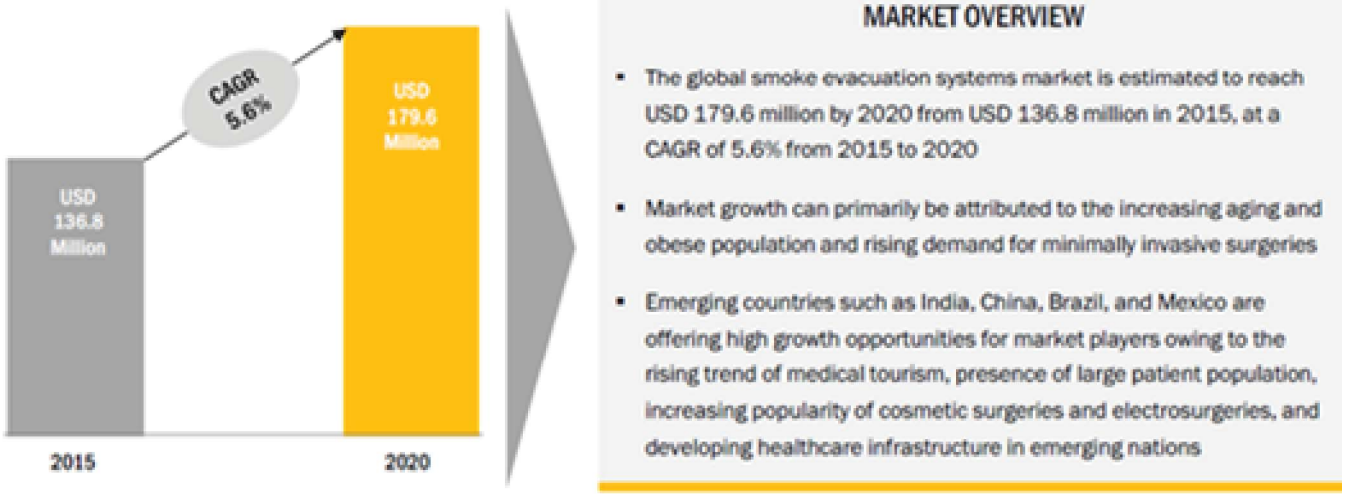
1. EXECUTIVE SUMMARY

The overall smoke evacuation systems market was valued at an estimated USD $136.8 million (in 2015) and is expected to grow at a CAGR of 5.6% in the next five years.[i] International growth is anticipated to be even greater due to the large geographical magnitude. While the worldwide potential is impressive, there are many obstacles to overcome including price erosion and long, competitive sales cycles. Tenders are the norm internationally which drives pricing down. The challenges clearly do not exceed the overall opportunity.

MEGADYNE's 2015 smoke evacuation product revenue was $4.5M. 2016 trending indicates this product line is **on** track to be over $5M in 2016, 11% growth and a fraction of the overall market potential.

The Market Overview below illustrates the market potential for surgical smoke.



Smoke Evacuation System Market Overview

Product innovation and effective and efficient distribution will position MEGADYNE to capture a significant share of this market potential. Vital to the smoke product line's success will be a smoke evacuator box with features, capabilities and pricing/placement programs that will allow the company to creatively and strategically position/place smoke evacuators in high volume accounts with minimal or no capital investment at clinical facilities. The revenue driver for this category is the disposable products that facilitate the capture and filtering of surgical smoke. The margin flexibility of MEGADYNE manufactured smoke pencil(s), equipment and related accessories will help cushion the cost and placement of capital for greater reach and penetration of MEGAYDNE smoke products.

TABLE 1 SMOKE EVACUATION SYSTEM MARKET SIZE, BY PRODUCT, 2013–2020 (USD MILLION)

Product	2013	2014	2015-e	2020-p	CAGR (2015–2020)
Smoke Evacuation Pencils & Wands	37.0	39.5	42.2	57.8	6.5%
Smoke Evacuators	30.6	32.4	34.3	45.4	5.7%
Smoke Evacuation Filters	23.7	24.9	26.1	33.1	4.9%
Smoke-Evac Fusion System	12.2	13.0	13.8	18.5	6.0%
Accessories	9.5	9.9	10.4	12.9	4.5%
Smoke Evacuation Tubings	9.2	9.5	9.9	11.9	3.6%
Total	122.2	129.3	136.8	179.6	5.6%

Currently, MEGADYNE partners with I.C. Medical to market and private label a line of high-end smoke evacuation products. Initially, this partnership was formed to help MEGADYNE round out the company's product line within the electrosurgery segment. Unfortunately, the partnership with IC Medical has not been without its challenges. Innovation has been slow, cost concessions virtually nonexistent, and cooperation for CE and strategic initiatives limited.

Even with these obstacles, the smoke disposable accessory category has grown 72% in the last 5 years (2010-2015). A key driver for this revenue (67% in 2015) is the UltraVac disposable smoke evacuation pencil. The graph below details the Ultra Vac telescopic smoke evacuation pencil unit sales since 2010. Due to CE issues (IC Medical related) and delays in product releases (new UltraVac with cord inside of the tubing), international sales declined heavily in 2015 (41%). During the same period, US sales of the UltraVac increased 47% and this growth trend is expected to continue.

To continue to be successful in this category, MEGADYNE needs to control product design and distribution for maximum product acceptance and profitability. This will require the introduction of a MEGADYNE manufactured line of smoke evacuation products including both disposables and hardware.

2. DEFINITIONS AND ACRONYMS

ESU: Electrosurgical Generator
AORN: Association of peri Operative Registered Nurses
ULPA: Ultra Low Penetration Air (filter)
RoHS: Reduction of Hazardous substances
REACH: Registration, Evaluation, Authorization and restriction of Chemicals

3. CLINICAL BACKGROUND

By nature, monopolar electrosurgery creates electrosurgical smoke. During electrosurgery electrical current flows from the generator through the handheld electrosurgical pencil and active electrode, through the patient's body and is returned back to the generator via a return electrode to complete an electrosurgical circuit. In this process human tissue is heated, cells are vaporized and steam and smoke plume are generated. The byproducts of electrosurgical smoke have more than an unpleasant smell. They also include toxins with mutagenic and carcinogenic potential and according to AORN should be removed by use of a smoke evacuation system.

The US Department of Labor estimates that 500,000 workers, including surgeons, nurses, anesthesiologists and surgical technologists are exposed to laser or electrosurgical smoke. The Center for Disease Control (CDC) sites research studies confirming that this smoke plume can contain toxic gases and vapors such as benzene, hydrogen cyanide, and formaldehyde, bio aerosols, dead and live cellular material (including blood fragments) and viruses. Furthermore, studies indicate that surgical smoke not only has unpleasant odors but has been shown to have mutagenic potential. At high concentrations, the smoke causes ocular and upper respiratory tract irritation in health care personnel, and creates visual problems for the surgeon.

Although surgical smoke evacuation devices have been available for decades, hospitals and clinicians have been slow to adopt this technology. Many do not believe that the smoke plume is hazardous (education) and smoke evacuation devices have been cumbersome, limiting surgeon acceptance. Avocation for the removal of surgical smoke has increased over recent years. In December of 2015 NIOSH (the National Institute for Occupational Safety and Health) released the results of a 4,500 healthcare worker survey. Their findings included this observation. *"Healthcare workers continue to be exposed to hazardous surgical smoke despite the existence of evidence-based practices and recommend controls available to protect them."* In addition, AORN has drafted new Guidelines for surgical smoke evacuation that includes much stronger language recommendations for the removal of surgical smoke. These guidelines should be published in 2017.

Increased emphasis by these two highly reputable organizations is breathing new life into the surgical smoke evacuation cause. Historically, utilization of surgical smoke evacuation hand pieces has been a huge hurdle. Even when hospital administration is supportive of smoke evacuation initiatives, convincing surgeons to consistently use the equipment has been challenging and often stalls usage and adoption. Smoke evacuation hand pieces are perceived as

cumbersome, awkward, and obtrusive to surgical technique. Until recently, manufacturers have done little to overcome the ergonomic objections by surgeons. The new guidelines by AORN, statements by OSHA and legislation pending in CA are good indicators that surgical smoke evacuation is here to stay and on its way to becoming a standard practice in the OR.

Smoke evacuation pencils are fairly simple medical devices equipped with only two switches ("CUT" and "COAG"). Industry standards dictate that the "CUT" button is always yellow and the "COAG" button is always blue. The primary difference between traditional electrosurgical pencils and smoke evacuation pencils is the need for tubing which tends to add bulk to the pencil size and decreases the ergonomics due to the drag of the tubing attached to the pencil. Tubing lengths range from 10 – 15 ft. Smoke pencils with ergonomic features, telescopic capabilities and competitive pricing are the preferred devices. Smoke evacuation pencils will continue to lead this category as they allow capturing surgical smoke at the source for the most effective smoke removal.

4. PRODUCT CONCEPTS AND REQUIREMENTS

This project represents development of a full scale smoke evacuation product line broken up into three distinct phases (as detailed in the pages to follow) including both hardware and related disposable components. Ideally, the company would launch the entire smoke product offering at one time for maximum profitability and minimum risk. However, to best maximize resources and opportunities, MEGADYNE will launch a smoke program in staged releases.

To compensate for the lack of a full market line offering, MEGADYNE will increase inventories of disposable and capital equipment from our current supplier to ensure customer product availability until the line can be fully developed and launched. MEGADYNE is committed to ensuring smoke evacuation customers continue to have access to smoke evacuation products that meet their needs and expectations.

The first Megadyne manufactured smoke evacuation pencil (the ZIP Pen™) was released to market in July, 2015. This device was designed to overcome a key obstacle for surgeon dissatisfaction in regards to smoke evacuation hand pieces, ergonomics. In addition to filling a market need, this device was also designed to meet MEGADYNE's gross margin and revenue targets based on the following customer inputs and requirements.

Phase 1 – Completed July, 2015

A complete list of the Phase 1 smoke team deliverables is shown below for historical reference. All Phase 1 items have been completed:

- Non-telescopic, ergonomic smoke evacuation pencil (ZIP Pen p/n 252510, 252510EC). A 15 ft. length of the ZIP Pen (p/n 2521515 and 252515EC) were not able to be released

during Phase I due to needing additional packaging development and therefore will be released separately.

- Extension Nozzles 2.7" and 5.2" (p/n 2540J, p/n 2560J). Part code additions after phase 1 include: 251010J, 251010EC, 251015J, 251015EC, 251010BN, 251010ECBN, 251015BN, and 251015ECBN.
- ULPA filter with fluid trap compatible with IC Medical Smoke Evacuator (p/n 2211J)
- Charcoal filter, compatible with IC Medical charcoal filter. Megadyne p/n 2220J

Phase 1 Clinical Requirements and Design Inputs:

PHASE 1	
PRODUCT DESCRIPTION	**COMMENTS/DESIGN INPUTS**
The MEGADYNE Smoke Evacuation Pencil (non-telescopic) with holster with both 10 feet and 15 feet of sterile tubing, including BN options as needed. *Part Numbers* *252510* *252510EC* *252515* *252515EC* *252510BN* *252510ECBN* *ME7251C* *ME7251E* *ME725M1C* *ME725M1E*	• Unique smoke evacuation pencil design that allows the smoke tubing to be separated (zipped) from the pencil structure in such a way that the tubing can be used as a handle (trigger method) for surgeon ergonomics. This smoke evacuation pencil will be designed for durability so clinicians are not able to pull apart the tubing from the mid tube connector of the pencil housing. Tubing size to be large enough to provide sufficient flow rates for smoke evacuation comparable or better than the "cord in the tube" version UltraVac (2110-10). • A non-telescopic, ergonomic smoke evacuation pencil in 10 and 15 ft. lengths with 22 mm connector. ACE 700 to be initially launched in 10 ft. lengths only (ME7251C ME7251E ME725M1C, ME725M1E) • Must evacuate smoke away from the surgical site in an efficient and effective manner. • Must be ergonomic and minimally obtrusive to the surgical process/procedure. • Blade must be coated with MEGADYNE's proprietary E-Z Clean® coating. • Must have a cut and a coag button. Initial release will feature a button style rather than a rocker switch. • Electrode Tip exposure should be comparable to current UltraVac (2110-10) nozzle to tip exposure. • Must be able to add extension blades (0014A, 0014). • BN sterile options for 10ft codes as needed (2525-10BN, 2525-10ECBN). • Must be able to visualize the electrode tip during the procedure. • Button configuration to be large (same as current

	MEGADYNE ES Pencil (0039) or larger), require minimal force (250 to 700 g) to push/activate and have a tactile feel with button push.
Holster	• Large enough to hold pencil. Same color as standard ES pencil holsters (Pantone 427) with a slot for the tubing to extend out of the holster. Packaged with the Megadyne smoke pencil.
Pencil Material/ Branding	• The body, cord and plug of the pencil should be gray (Pantone 427) with green (Pantone 356) TPR accented design/grip. • Pencil and plug should have space for the MEGADYNE logo molded into the housing or in a green coloring.
Active Electrode/	• Eelctrode to nozzle clearance to remain consistent with that of the "cord in the tube" version UltraVac (2110-10). • Electrode should fit securely into the pencil collet with wobble comparable to Megadyne disposable pencil (e.g. 0035H) and remain secure during cleaning of the tip without being removed from the pencil unless so desired by the surgical team. Electrode must also be able to be removed in instances where clinicians desire to insert a different tip or tip configuration during a surgical procedure.
Nozzles *These also apply to Extension Nozzle Part numbers:* *2540J* *2560J*	• Nozzle for smoke suction to be made of a clear material. • Nozzle to be designed so that the active electrode tip is easily insert able into the collet and fully seated without coming loose and while minimizing wobbling. Comparable to existing disposable pencil (0035H). • The electrode should also not be able to be inserted incorrectly and should be guided into the collet position. • Adequate spacing should be allowed for suction capabilities between the Nozzle and the electrode. Comparable to the Ultravac "cord in the tube" version (2110-10). • Design of nozzle and device shall allow adequate visibility of surgical area. • The Nozzle will be of an angled design with the top portion cut back to expose the blade.
Collet	• Collet should be strong enough to accommodate a 6.5" electrode (0014). The electrode should be firmly placed into the collet without risk of accidental removal when cleaning eschar off the electrode. Removal force should be snug, but capable of being removed during a surgical procedure.
Pencil Plug/ Connectors	• Pencils must have standard three-prong plug and be compatible with most standard ESUs in the market.
Cord	• Pencil cord must be placed inside of the tubing, (exiting a

	minimum of 4 feet from the distal end of the pencil) and should not restrict flow of the suction in manner that would impede smoke evacuation any greater than "cord in tube" predicate devices (2110-10).
Cord/ Packaging	• Pencil cord to be wrapped in a material that will keep the cord contained during shipping and in packaging.
Tubing	• Tubing should be strong enough to prevent shredding when pulled, but also minimize drag on the surgeon's hand. Convoluted tubing should be used as available.
Tubing/Pencil Body Connection	• The manufacturing of this connection must be robust to withstand forceful pull on the tubing without damage or destruction/separation from the pencil.
Tubing Swivel Connection	• Tubing will swivel near the pencil connection as to minimize drag and maximize surgeon ergonomics.
Pencil to filter connectors fits to include:	• The MEGADYNE Smoke Evacuation Pencil must be adaptable to the current IC Medical ULPA filter (2210) as well as 22 mm systems such as ERBE via the C connector (2150), EC connector (2155), or other adapter options. Adaptation to other sizes (i.e. ConMed AerDefense, Covidien RapidVac and Buffalo ViroVac) may need to be accommodated via other adapter options, such as the C connector (2150).
Sterilization	• Methods of sterilization can be either gamma or EO.
COGS	• COGS target for the non-telescopic pencil is desired to be $7.00 or less (packaged, sterile FOB Taiwan with a holster). Recent estimates indicated a cost of $7.66 FOB Taiwan and a burdened cost of $8.52 which will impact forecast numbers. (This is a marketing and not a customer requirement)
Packaging	• Packaged sterile 20 per box. • BN (if applicable by catalog number) for kit packer purchase option will follow in phase 2 to meet project resource requirements. • Package estimates for BN @ 30 per box, gaylords packaged at around 480 per gaylord. • 6-pack configuration for ME7251C, ME7251E, ME725M1C, ME725M1E
Packaging	• Shelf life for initial release will be a minimum of 3 years and expanded to 5 years after launch as confirmed by testing.
Packaging	• Sterile pencils will be packaged robustly to meet international shipping demands and in a manner that prevents damage during normal shipping and handling.

Universal ULPA Filter p*art number 2211J*	• Non-sterile ULPA replacement to the IC Medical 2210 filter. The ULPA Filter offering will be designed to function (filter) as efficiently and effectively as the current device and competitive devices at a minimum of 99.999 (ULPA) filtration (when tested with 0.1 to 0.2 micron particles) without causing occlusion alarms. • Must be compatible with IC Medical smoke evacuator (2100, 2200). • Filter life should match that of the IC Medical ULPA Filter. • Must accommodate the MEGADYNE versions of the IC Medical pencil, (MEGAYDNE p/n 2110-10 and 2120-09) smoke pencils. • Filter packaging should match current IC Medical standards (bagged with labeling inside of the pouch). • Target COGS $10. (This is a marketing target rather than a customer requirement) • Packaged 10 per box.
Charcoal Filter p*art number 2220J*	• Non-sterile charcoal filter for the current Mega Vac Smoke evacuation system, comparable to the IC Medical 2220 filter with Megadyne labeling • Charcoal filter packaging should match current IC Medical (bagged with labeling on the filter). • Packaged 1 per box. • COGS targeted at $40 (This is a marketing target rather than a customer requirement)
Extension Nozzles 2.7” Sterile Extension Nozzle p*art number 2540J* 5.2” Sterile Extension Nozzle *part number 2560J*	• Sterile, plastic extension nozzles to fit onto the MEGADYNE, ergonomic smoke pencil Nozzle with the purpose of allowing smoke capture with longer electrode configurations. • 2.7” nozzle extension • 5.2” nozzle extension • Nozzles should allow a clear view of the surgical site. • Snap on easily and securely as not to fall off during use. • Should be made of a material that will not shatter or easily break if used for “prying.” • Packaging will be in a Multi-Vac and or Tyvek pouch, Sterile. Packaged 10 per box. • COGS targeted at under $2. (This is a marketing target rather than a customer requirement)
Adapter(s)	• Adapters will be developed/provided as necessary to ensure the connection of the MEGADYNE smoke evacuation pencil with a variety of manufacturer’s smoke boxes either via a universal connector size, by adapters or by removing

	the connector as necessary. • Consideration should be made for IC Medical's current ULPA filters and customers (aka Canada) who may continue to purchase that filter and need that size connector. • Connection should accommodate the ConMed Aer Defense, Rapid Vac, MiniVac, ERBE and be as universal in fit as possible.

Phase 1 – COMPLETED
Information below is for historical reference. All Phase 1 items have been completed.

Non-telescopic, ergonomic smoke pencil
Phase 1 of this project will feature the introduction of an innovative, ergonomic and effective smoke evacuation pencil with 0012 PTFE electrode in 10 ft. and 15 ft. configurations. This non-telescopic smoke evacuation pencil will provide for greater pricing flexibility and will provide MEGADYNE with greater profitability potential by enabling the company the opportunity to increase market penetration (via capital placement and marketing programs) and increased opportunities to secure tenders in international markets.

The non-telescopic, ergonomic smoke pencil will include a standard MEGADYNE E-Z Clean® 0012, ACE12, or ACE12M blade for production efficiencies, while providing the same electrode tip exposure as with the current Ultra Vac smoke evacuation pencil. Electrode removal force will allow for secure electrode placement, (remaining secure when the electrode is cleaned by pulling on the electrode). The electrode should also be able to be removed from the pencil by surgeons or clinical staff desiring to change the electrode during cases.

Attachable, extension nozzles
To meet customer needs for smoke evacuation capabilities when using longer electrodes MEGADYNE will offer customers an attachable extension nozzle for when longer electrodes are used in the MEGAYNE Smoke evacuation pencil. These will be available in lengths to accommodate 6.5" and 4" blades to meet CDC recommendations that the nozzle inlet should be kept within two inches of the surgical site to effectively capture airborne contaminants. These extension nozzles will be packaged sterile in separate pouches for customer convenience. Availability of stable (minimum wobble) extension nozzles will provide customers with a viable extension option to higher priced telescopic versions and will help MEGADYNE overcome customer objections until a telescopic or other option can be developed and released to market. Recent market competitive offerings have created a need for extension nozzles with a radiopaque material for visualization under x-ray/fluoroscopy and this will be addressed in future releases.

COGS for the extension nozzles should be as minimal as possible to keep the product competitive in the marketplace. Ideally, as a Marketing target, the extension nozzle(s) would be priced at

under $3 packaged. Initial cost estimates range from @ $1.58 for the 2.7" size (for 4" electrodes) and $1.86 for the 5.7" size (for 6.5" blades). The nozzles are a strategic product intended to overcome a competitive advantage by those companies offering electrode/ Nozzle extendibility within their smoke pencil offerings. While it is estimated that only a relatively small percentage of surgeons actually use the extension option, it is necessary to have a competitive response to the electrode extension feature. To be competitive in the market, the Nozzle extensions pricing should be reduced to @ $2.00 or less if at all possible.

Filters
In addition to the non-telescopic smoke evacuation pencil and extension nozzles, replacement filters for the current Mega Vac smoke evacuation systems will need to be developed to ensure existing customers (Mega Vac) have access to supplies and compatibility with the new non-telescopic smoke pencil as well as UltraVacs. These filters include the following:

ULPA Filter (IC Medical replacement)
To successfully service existing MEGADYNE smoke customers and transition them to MEGADYNE's new line of smoke evacuation accessories, it is necessary to produce an alternative to the existing ULPA filter (via IC Medical). It is important to note that this universal ULPA Filter will allow MEGADYNE to more effectively manage current IC Medical inventory and use this new filter for both the new MEGADYNE product and both the domestic and international versions (EC) of the 2110-09s. Ideally, the ULPA filter media will provide the same filtration capabilities as the current (IC Medical and other competitive systems.) A minimum of 99.999% and 0.1 to 0.2 micron capture should be achieved. Ultimately, the ULPA Filter offering will be designed to function (filter) as efficiently and effectively as the current device and competitive devices.

Charcoal Filter to match current IC Medical version
For the reasons mentioned above regarding the company's commitment to current users of the Mega Vac smoke line, MEGAYNDE will also develop a MEGADYNE version of the current Charcoal filter (p/n 2220J). This filter will be designed to fit into the existing back panel charcoal filter port and filter as per the current product design, at a reduced cost for improved profitability and customer satisfaction.

Adapters/Connectors
Connection to "other" competitive smoke evacuation "boxes" is necessary for MEGADYNE's new ergonomic smoke evacuation pencil to capture significant market share. The connection for this pencil will be designed to be utilized with a variety of manufacturer's smoke boxes either via a universal connector size, by adapters or by removing the connector as necessary.

Competitive Models for Compatibility:

- Stryker Neptune
- ConMed Aer Defense

- Buffalo Filter Viro Vac, Visiclear
- Covidien Rapid Vac
- ERBE
- LINA
- Others as necessary

PHASE 2 OVERVIEW

Phase 2

An overview list of Phase 2 smoke team deliverables is listed below. A detailed list of clinical and customer inputs can be found on page18.

- MEGADYNE branded Smoke Evacuation Box (p/n 2400)
- Primary (ULPA/charcoal) Filter for MEGADYNE Smoke Box (p/n 2550)
- Fluid trap for MEGADYNE Smoke Box (p/n 2555)
- Nozzles for extension blades with 4" and 6.5" electrodes (p/n 2540 & 2560)
- Telescopic, ergonomic smoke pencil to include the "electrode in the tube" concept, p/n 2510-10, 2510-10EC.
- Attachable shroud to convert a standard pencil to smoke compatible. p/n 2520-10, 2520-10EC – Pending evaluation of market need, forecast and associated development costs
- Speculum tubing, p/n 2395
- Laparoscopic tubing, p/n 2390
- 22 mm laser tubing, p/n 2335
- RF Sensor, p/n 2255
- 1m Jumper Cable, p/n 2406
- 2.1m Jumper Cable, p/n 2403

These products may be released independently or in one phase to accommodate development schedules. Product and customer inputs for Phase 2 are detailed on the following pages.

Phase 2

The portable surgical smoke evacuator segment is expected to grow at a CAGR of 6.9%, to reach USD 45.4 million by 2020. Technological developments and new product launches for minimally invasive surgical procedures are the key factors propelling the growth of the smoke evacuators market.

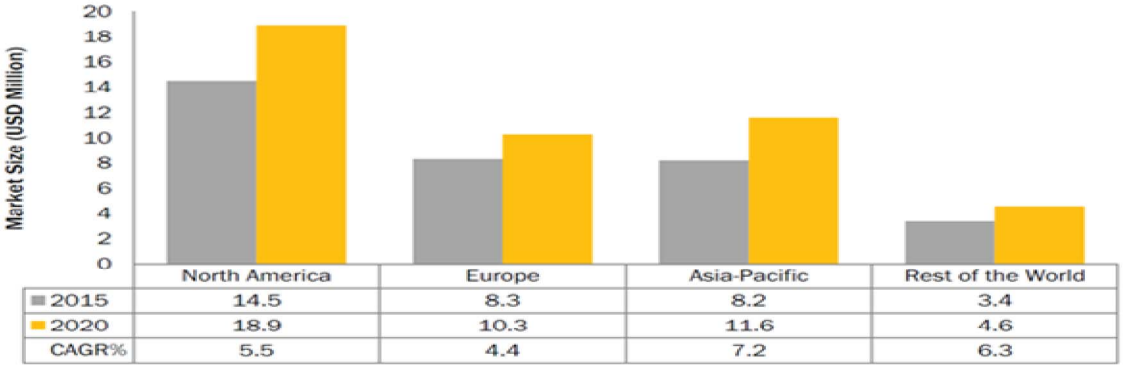
TABLE 2 SMOKE EVACUATORS MARKET SIZE, BY TYPE, 2013–2020 (USD MILLION)

Product	2013	2014	2015-e	2020-p	CAGR (2015–2020)
Stationary Systems (Centralized Smoke Evacuators)	22.7	24.0	25.3	32.7	5.3%
Portable Systems (Individual Smoke Evacuators)	7.9	8.5	9.1	12.7	6.9%
Total	30.6	32.4	34.3	45.4	5.7%

MEGADYNE smoke evacuation "box"

A MEGADYNE smoke evacuation "box" is vital to the success of MEGADYNE's smoke evacuation product offering as it liberates the company from other manufacturers' cost and distribution limitations, allowing MEGADYNE to offer value added capital placement programs and/or increased capital margins at the company's discretion. While MEGADYNE's Smoke Evacuator Sales have declined in recent years, growth domestically is anticipated as illustrated below.

FIGURE 19 NORTH AMERICA IS EXPECTED TO HOLD THE MAJOR SHARE OF THE SMOKE EVACUATORS MARKET IN 2015



	North America	Europe	Asia-Pacific	Rest of the World
2015	14.5	8.3	8.2	3.4
2020	18.9	10.3	11.6	4.6
CAGR%	5.5	4.4	7.2	6.3

To address all markets in intended use, the MEGADYNE smoke evacuation "box" is intended to remove and filter smoke and aerosols from a surgical site.

The smoke box will accommodate smoke evacuation in both open and laparoscopic procedures and satisfy the following customer inputs:

- Quiet (low noise) during operation for minimal disruption in the OR.
  - Quiet during use (comparable to or better than current MegaVac standards)
- Evacuate smoke effectively in open and laparoscopic procedures.
- Provide smoke evacuation capabilities for electrosurgery, laser, advanced energy and harmonic applications,
- Be easy to operate (push button, intuitive interface).
- Have a footprint for boom and/or cart placement is possible while maintaining the low noise requirement.
- A low COGS, targeted around $2,000 while meeting the minimum noise requirements.
- And others as identified in the customer input table starting on page 17.

Custom Filters for the MEGADYNE smoke evacuation "box"

Filters are integral components for the evacuation of surgical smoke and provide the filtration necessary to protect both patient and surgical staff from the hazards of surgical smoke. Filter disposables will also provide recurring revenue for the company. A custom filter and a fluid trap will be available for the MEGADYNE smoke evacuation "box" as listed on the following page:

Primary Filter (ULPA/Charcoal)

- This is the primary filter for the MEGADYNE smoke evacuation smoke box and will provide both ULPA level filtration as well as charcoal filtering for smell and particulates. ULPA filtration capabilities should at a minimum match the current IC Medical Ulpa Filter and charcoal filter specifications while providing sufficient flow and particulate capture. Life expectancy of the primary filter should be a minimum of 18 hours in high flow and 24 or more hours in low flow. COGS at or below $65 is desired to provide pricing flexibility and maximum profit opportunities. Cost above $65 is acceptable realizing margins will be impacted.

Fluid Trap

- The fluid trap is an optional component designed to prolong the use of the primary filter (ULPA) by trapping fluids. The Fluid Trap will be limited multi use (up to a maximum capacity indicator) and will fit securely onto the primary filter.
    - COGS should not exceed $2.80.
    - Red cap to be included with each fluid trap to address biohazard concerns.

An adaptable shroud – Pending evaluation of market need, forecast and associated development costs

An adaptable shroud (Attacha Vac) will be provided to allow standard electrosurgical pencils to have smoke evacuation capabilities. This product will be designed to replace the current Attacha Vac (212009J and 212009ECJ) offering and can either be an OEM option or as resources allow, a MEGADYNE designed product.

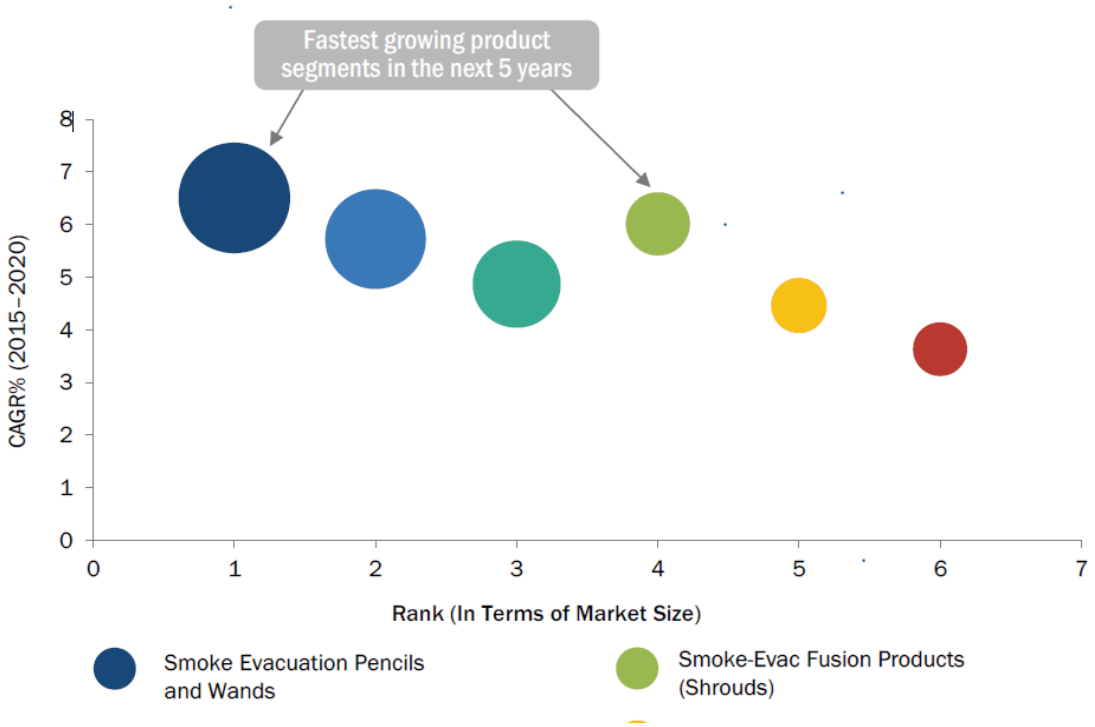
Attachable shrouds provide a customer option to higher priced integrated smoke pencils. While the pricing is low, adaptable shrouds are historically not preferred by surgeons due to poor ergonomics, larger size, and lack of integrated cord. However, this option is desired for competitive bids and to provide accounts with the pricing and use options they desire.

COGs should be under $5.50. Unfortunately, Megadyne's volumes will not meet those necessary to meet this target cost. Regardless, it will be sourced and provided as a customer option to allow the company to maintain and grow its attachable shroud business. Ultimately, the goal is to convert these customers to higher value/price smoke evacuation products.

While Attacha Vac sales are relatively flat, this product is strategically and competitively necessary to provide customer choice in features and pricing. It is estimated that the attachable

shroud market potential is estimated to reach USD 18.5 million by 2020, at a CAGR of 6.0% from 2015 to 2020 as shown below.

FIGURE 6 GLOBAL SMOKE EVACUATION SYSTEM MARKET, BY PRODUCT, 2015 (USD MILLION)



Other disposables included in phase 2 include:

- 22mm tubing (with sponge guard) that includes a universal connector (p/n 2150) and 10' tubing length. COGS original target was at $10 sterile. Volume predictions will not allow us to meet this target and will impact margins accordingly. (Predicate Buffalo VTWT524/VTWT624)
- Speculum Tubing, 10 Ft of tubing with universal connector.
    - Designed to be similar to the short silicone tube attached to the 10' tube via a barb similar to the current IC Medical Speculum Tubing offering.
- Lap Tubing/Sterile, 10 Ft of tubing with universal connector.
    - Designed to be similar to the length of tubing and use of a luer loc connector as the current IC Medical Speculum Tubing offering.

A detailed listing of Phase 2 products and customer inputs is listed below:

PHASE 2	COMMENTS/DESIGN INPUTS
Smoke Evacuator (box) *Part number 2400*	A quiet (meets or exceeds current Mega Vac dBA) smoke evacuator designed for use in open and laparoscopic procedures. The MEGADYNE Smoke Evacuator will be designed with the following inputs: • Footprint to be placed on an OR Boom system or cart. • An "interlink" cable system that provides connection to electrosurgical generators (also vessel sealing systems if achievable) for activation of the smoke evacuator when the energy device is "on" via a preset time or as desired by the clinician. • Manual operation via an on/off switch/button on the front panel. • A manual mode will operate flow continuously in the open mode. • A manual lap mode to intentionally deflate the pneumoperitoneum in the lap mode after case completion. • Also, optional manual footswitch operation. Footswitch cable will connect on the back of the system. • Modes and corresponding front panel display button selection options for open and laparoscopic procedures. • Open mode flow rate to be equilvent to or better IC Medical high flow rate @ 0-85 LPM). • Low flow (lap mode) to be developed to support smoke removal while maintaining cavity inflation. • Ease of Use operation including a push button design interface for mode selection and time and flow settings. • Time and flow setting will provide 5 push button options for individual time and flow selections. • Filter life indicator showing (Green) when the filter life is between 100-25%, Yellow when the filter 25% or below. Red when the filter life has reached capacity, allowing for a 4 hour "grace period" additional use before the system will require a filter change. Minimum filter life should be 18 hours of use in high flow mode and 24 hours or more in low flow mode. • A method to attach an external exhaust connection should be accounted for on the back of the smoke evacuator for connection to a house vacuum while in open mode. • Must accommodate 110V and 220-240V power inputs and cable to meet international requirements by country + 50- 60 Hz. • COGS should be under $2,000 while meeting the noise requirements.

Primary Filter (MegaFilter) *Part number 2500*	▪ Combination ULPA and charcoal filter, non-sterile. ▪ ULPA level filtration minimum of 99.999%. ▪ Primary filter will have a useful time of not less than 18 hours. ▪ Charcoal filtering for smell and particulates ULPA filtration capabilities should match or exceed the current IC Medical ULPA Filter and charcoal filter specifications. Ideally, testing will be performed to confirm particulate capture/removal. • User experience must allow for easy insertion and removal of the filter into the smoke evacuator, including a mechanism (audible/visual or tactile) that confirms correct insertion. • Removal of the filter out of the smoke evacuator should have a smooth feel and be able to be accomplished one hand for the average operator. • The filter should have an area which can be gripped for ease of removal. • Pull force on the pencil/filter connection should be less than the force to remove the filter before the filter detaches from the smoke evacuator. ▪ Filter connector must accommodate the universal connector .COGS should not exceed $65 to provide pricing flexibility and maximum profit opportunities. ▪ Packaged 1 per box.
Optional RF Sensor *Part number 2255*	▪ A portable RF sensor that senses the activation of a monopolar device by the surgeon and simultaneously actives the smoke evacuator for the delay time set will be provided as an option to the smoke evacuator. This device will plug into a port on either the front or the back of the system and be connected via a lightweight but durable cable to the energy device cord. Connection should fit both an active and return electrode cable. Connection and disconnection of the chosen cable should be ergonomic and require a minimum amount of effort or pulling.
Fluid Trap *Part number2555*	• The fluid trap is an optional (non-sterile) device designed to prolong the use of the primary filter (ULPA) by trapping fluids. • The fluid trap will fit onto the primary filter opening and accommodate the universal connector. • The fluid trap may be a limited multi use as per hospital policy. • The fluid trap should be made of a durable plastic material with a maximum fill line indicator. • Fluid trap should be designed to minimize profile size while maximizing fluid capture and design aesthetics when attached to the primary filter. COGS should not exceed $2.80. Packaged 10 per box.
Attachable pencil Attachable shroud for smoke evacuation.	Hand piece to attach a standard electrosurgical pencil (and also sized to accommodate the Megadyne E-Z Pen®) tubing for an adaptable smoke evacuation pencil. In addition to the E-Z Pen, the attachment must be compatible with the following competitive pencils: • Covidien • ConMed

Sterile 10 ft. tubing - TBD *Part Numbers 252010, 252010EC*	• Megadyne (including E-Z Pen®) Must also be pliable enough to expand to meet E-Z Pen width requirements. Filter connection should fit the "new" MegaVac Max smoke evacuation filter. Must also be adaptable to ERBE and ConMed hardware. COGS not to exceed current Attacha Vac.
Speculum Tubing/Sterile *Part Number 2395*	The speculum tubing should be similar to the current MEGADYNE part number as much as possible in material and function. The 2195 is 10mm by 10ft. This accessory is used for LEEP procedures and features a connector at the proximal end. The distal end will be the Megadyne universal connector (p/n 2150). COGS not to exceed current. Cost increases will impact margins
Laparoscopic Tubing/Sterile *Part Number 2390*	Laparoscopic tubing should be similar to the current MEGADYNE part number 2190 as much as possible in material (straight tubing) and function. 2190 Size is 6mm by 10 ft. Includes a luer lock for connection to laparoscopic trocars and filter adapter at the distal end. The distal end will be the Megadyne universal connector (p/n 2150). COGS not to exceed current. Cost increases will impact margins
22mm tubing for laser *Part number 2335*	22mm tubing (with sponge guard) that includes a universal connector (p/n 2150) for connection to the filter. COGS @ $10 desired.
Direct Connect Cable *Part number 2403, 2406*	Create a direct connection between the new Megadyne smoke evacuator and a monopolar generator or other advanced energy device that will allow the smoke evacuator to activate when the energy device activates. This functionality is intended for energy devices beyond monopolar, since monopolar can be activated vis the 2255 RF sensor by design.

Phase 3

Telescopic Smoke Evacuation Pencil

A MEGADYNE designed/manufactured telescopic smoke pencil (or an alternative design with a smoke solution integrated with various blade length options) is highly desired based on current market demand and customer inputs. This telescopic smoke capturing smoke evacuation pencil would compete directly against the existing IC Medical Ultra Vac and other pencils with telescopic features such as the ConMed GoldVac™ and Buffalo PlumePen™.

Rocker switch versions of the smoke pencil may be included as part of later line extension project as market demand dictates.

PHASE 3	COMMENTS/DESIGN INPUTS
• Phase 3 Telescopic smoke evacuation pencil *Part Numbers* *251010J* *251010EC* *251015J* *251015EC* *251010BN* *251010ECBN* *251015BN* *251015ECBN*	• A telescopic, smoke evacuation pencil to include the "electrode in the extending tube/nozzle design" found in the current Ultra Vac product. • Universal and 22mm proximal tubing connector configurations. • Positive locking nut feature for the extending tube. • Tactile button switches.
Additional Smoke Pencil/Electrode Configurations	• Additional electrode configurations may be added for a later phase depending on the company's strategic objectives and customer inputs. These electrodes could include a 0012AM, ACE Blade, Mega Fine, and others as determined based on customer demand after launch
Holster	• Pocket is at least as deep as the current Ultra Vac holster. Same color as standard ES pencil holster. Included with every part number, even BN configurations.
Pencil Material/ Branding	• The cord, plug, and tubing materials should match that of the ZIP Pen, including colors. The gray body material should also match that of the ZIP Pen. • Pencil body and plug should have the MEGADYNE logo molded into each housing. • Pencil body gripping surfaces should be textured similar to standard Megadyne electrosurgical pencils. • Hand piece diameter and length dimensions, as well as button locations should be as close to the current Ultra Vac pencil as the design will allow. • Extension length of telescoping tube should be as close to the same length as the current Ultra Vac pencil as the design will allow. •
Active Electrode/TIP: 0012	• E-Z Clean® Tip 0012 ▪ (Additional tip configurations may be released in subsequent phases). ▪ Tip should be positioned in the center of the nozzle for maximum smoke capture. • Tip to nozzle distance to be as close to that of the "cord in the tube" UltraVac as the design will allow. • Activation force for buttons (Cut and Coag) must be reasonably equivalent to single use electrosurgical pencils such as those currently manufactured

	by Megadyne.
Nozzle	• Nozzle for smoke suction to be made of a clear material at the proximal end for tip visualization. • Nozzle/collet to be designed toeliminate incorrect seating of the electrode in the collet. • Suction airflow should be as good or better through the pencil than the current Ultra Vac "cord in the tube" pencil design. The nozzle should be dimensionally designed as close to the current Ultra Vac "cord in the tube" pencil as the design will allow. • Nozzle/collet should be designed as close to the current Ultra Vac "cord in the tube" pencil as the design will allow.
Collet	• Electrode should fit securely into the pencil collet and meet the Standard for retention. Removal force must be reasonably equivalent to the current Ultra Vac "cord in tube" pencil design.
Telescopic Feature	• Telescopic extension material should be comparable to the current UltraVac "cord in tube" pencil and maintain mechanical integrity when a minimum of 5 lbs of force is applied to the tip of a fully extended tube. (not activated). • Electrical continuity to the electrode must be maintained when the telescoping tube is fully extended both with and without a minimum of 5 lbs force applied in an upward direction from the bottom to the top side of the pencil • Telescopic feature must have a tactile, lockable mechanism to secure telescoping tube length at any position from fully extended to fully retracted. Locking feature should be low profile like the Ultra Vac locking nut mechanism and have a torque force low enough for reasonable lock adjustment.
Pencil Plug/Connectors	• Pencil must have standard three-prong plug design matching current Megadyne pencil products.
Buttons	• Tactile finger feel of the buttons should closely resemble that of Megadyne standard electrosurgical pencils.
Cord	• Pencil cord must be equivalent to ZIP Pen and likewise placed inside of the tubing with the same exit approx. 4 feet from the distal end of the pencil
Cord/Packaging	• Pencil cord to be wrapped (in a material that will keep the cord contained) in packaging and during shipping.
Smoke Tubing	• Convoluted smoke tubing equivalent to ZIP Pen should be used. • Tubing weight should not exceed that of the ZIP Pen. • Tubing "memory" should be equivalent or better than ZIP Pen.
Smoke Tubing/Pencil	• This connection must be robust enough to withstand a pull force on the tubing without disconnecting from the pencil before the tubing

Body Connection	breaks. • Swivel connection between pencil body and tubing should rotate smoothly (not stick) and minimize torque on the handpiece.
Tubing Swivel Connectors	• Tubing should swivel at all tubing swivel connectors to minimize torque forces on the handpiece created by the tubing.
Pencil to filter connectors fits to include:	• Connector options on the proximal end of the tubing are to accommodate as many smoke evacuator filter inlet sizes as identified and provided by Marketing at the time of development. • The MEGADYNE Telescopic Smoke Evacuation pencil must have connection options for the current IC Medical Ulpa filter connector as well as 22 mm systems such as ERBE. Adaptation to other sizes (i.e. ConMed AerDefense, Stryker Neptune, Covidien RapidVac and Buffalo ViroVac) may need to be accommodated via other adapter options. • Adapter options should ensure the connection of the MEGADYNE smoke evacuation pencil with a variety of manufacturer's smoke boxes either via a universal connector design, by adapters, or by removing the connector from the tubing.
Sterilization	• Methods of sterilization can be either gamma or EO
COGS	• COGS target for the telescopic pencil is desired to be $12.00 or less (packaged, sterile FOB Taiwan with a holster) for the 10 ft. version and $14.00 or less for the 15 ft version.
Packaging	• Packaged sterile 20 units per box. • BN for kit packer purchase options. • (Package estimates for BN @ 20-30 units per box, gaylords packaged at around 320-480 units per gaylord).
Packaging	• Shelf life for initial release will be a minimum of 3 years and expanded to 5 years at the earliest possible date after launch as confirmed by testing.
Packaging	• Sterile pencils will be packaged to meet international shipping demands that prevent damage during normal shipping and handling. Multi-Vac packaging to match that of the ZIP Pen should be considered for line continuity.

5. USABILITY

Intended Use

The MEGADYNE ergonomic smoke pencil and telescoping smoke pencil are accessories to a general purpose electrosurgical generator and are designed to remove surgical smoke during both

open and laparoscopic procedures while also conducting radio frequency (RF) current for the cutting and coagulation of targeted tissue during general surgical procedure.

Intended Patient Population

MEGADYNE Smoke Evacuation Pencils, Smoke Evacuators and related accessories are for use on general population surgical patients. There is no age limit for the usage of MEGADYNE Smoke Evacuation Pencils and accessories. MEGADYNE Smoke Evacuation Pencils and accessories are used wherever general electrosurgery is used. MEGADYNE Smoke Evacuation Pencils can be used on any part of the body or tissue where it is necessary to perform surgery as deemed applicable by the surgeon. This includes tissues of all impedance levels (low, medium or high).

Condition of Use

Electrosurgery is a specialized process and is performed only by trained surgical professionals and is restricted to use by or on the order of a physician. Smoke evacuation disposable devices are powered by electrosurgical generators. Setup of the equipment is conducted by trained medical personnel working in a surgical environment. No special skills are required for set-up of the equipment other than the ability to use hands to plug items into the appropriate receptacles of the smoke evacuator and electrosurgical generator with force of less than 10 lbs. The smoke evacuator will feature both open and laparoscopic modes with adjustable time and flow setting options which will be clearly marked on the front faceplate by graphical indicators. The bio hazard of blood into the filter will be mitigated by an optional fluid trap and cap to be applied prior to disposable into a red bag container. Variable lap mode flow and time settings will be available to accommodate adjustments for a variety of insulator calibration and flow variations and will be tested to confirm the system in the lap mode does not inadvertently deflate the pneumoperitoneum. The range of lap modes will provide sufficient adjustments to avoid deflation.

The MEGADYNE Smoke Evacuation Pencils, pencil attachment, laparoscopic tubing, and speculum tubing are sterile devices intended to be single use and are marked accordingly. Filters and connectors are non-sterile and are also marked accordingly. All MEGADYNE smoke evacuation devices and hand pieces are intended for use exclusively in an operating suite (which may include hospital ORs, surgical center ORs, physician office based operating suites or other dedicated OR environments. By definition of Operating Room, this excludes use in ambulances, hospital transport or other non-surgical environment). Use is restricted to by or on the order of a physician.

MEGADYNE smoke evacuation devices are not implanted devices and are used exclusively to remove surgical smoke caused by electrosurgical or laser devices. Time of use for these devices is procedural dependent. Activation occurs when surgical smoke is being created and needs to be removed via smoke evacuation.

Usability will be confirmed via a Usability Design Validation Plan.

Other personnel
In addition to use by trained medical personnel, the hardware components of the smoke evacuator will also be handled by biomedical and cleaning personnel. Biomedical personnel will test, install and preform calibration checks on the smoke evacuator as per hospital protocol as documented in the user/service manual. Disposal of the smoke evacuator unit will be performed as indicated in the User's/Service Manual and per applicable RoHS and REACH standards. Cleaning personnel will clean the faceplate of the smoke evacuator also as documented in the user manual and/or per hospital protocol.

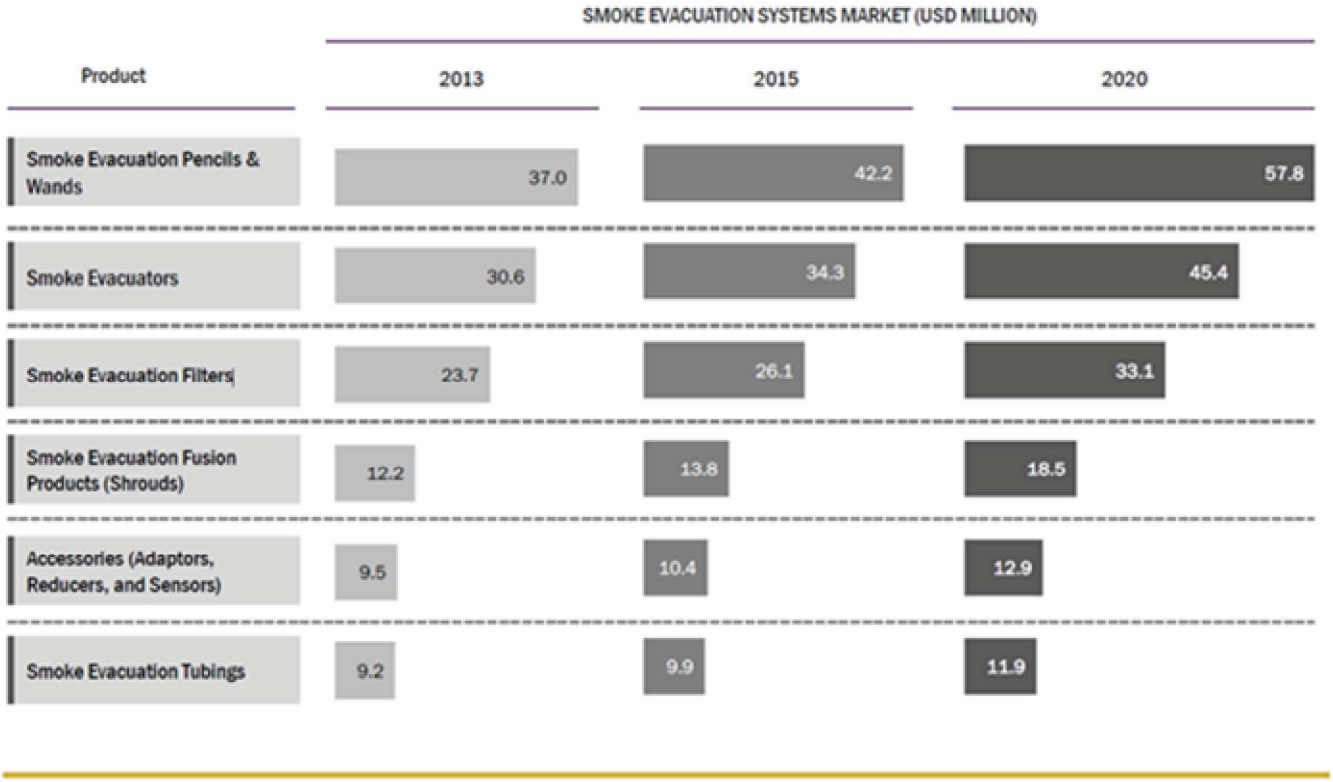
Transportation and Storage
MEGADYNE Smoke Evacuation hardware and disposables will be shipped via standard transportation methods including air, OTR, and Sea. Packaging methods will withstand stacking on pallets and exposure to temperature and humidity as per relevant standards and historical expertise to maintain package sterility.

Storage of the MEGADYNE Smoke evacuator and related accessories will meet or exceed requirements set forth in applicable standards and will take into effect historical data related to current comparable devices as presented in complaint data to identify previous product storage related issues.

6. MARKET OPPORTUNITY & CHALLENGES

The smoke evacuation market is not new to MEGADYNE. MEGADYNE introduced the IC Medical line of smoke evacuation equipment and accessories to its customers in 2003. Revenues for the disposable portion of this line have grown from $1.8M in 2008 to $3.9M in 2016 YTD. Key drivers published on the surgical smoke evacuation market are listed below. Not mentioned is the potential for local and/or federal legislation requiring the use of smoke evacuators in operating rooms. This factor would greatly impact the surgical smoke evacuation opportunity for growth. Being positioned for such opportunities at the time of implementation is vital.

FIGURE 12 PENCILS AND WANDS PRODUCT SEGMENT WILL CONTINUE TO DOMINATE THE GLOBAL SMOKE EVACUATION SYSTEM MARKET IN 2020



"The smoke evacuation pencil and wand segments are estimated to command the largest share of 30.9% of the global smoke evacuation systems market." Clearly, disposables are the driver for this category and capital is just one vehicle that provides the means (suction).

Capital

As mentioned previously, MEGADYNE currently OEMs the Mega Vac line of smoke evacuation products from its vendor partner, IC Medical. This relationship restricts the company's margin potential and account acquisition potential. The opportunity to dramatically increase margins while gaining control of product innovation and distribution is an attractive option for MEGADYNE. Until recently, IC Medical had not introduced a new product in over 10 years. They have also proven unwilling to provide distribution exclusivity putting MEGADYNE sales personnel in the uncomfortable position of competing against the same products by other distributors in the market. This creates customer confusion and sales frustration.

Lack of product exclusivity has greatly limited MEGADYNE's ability to achieve full sales emphasis due to competitive overlap. Customer confusion is yet another byproduct of our non-exclusive product relationship. MEGADYNE continues to compete against IC Medical for GPO

and IDN contracts which greatly limit our ability to obtain contracts and major account opportunities.

IC Medical's inability to respond to market and partnership demands further reinforces the need for Megadyne produced and managed products. Sales of the MegaVac smoke evacuators (hardware) p/n 2100 and 2200) have slowed in recent years due to cost, lack of a CE (now resolved) and increased competition.

Integrated, Telescopic Surgical Smoke Evacuation Pencil
To date, IC Medical is the only integrated smoke hand piece that allows the electrode to extend with the telescopic smoke nozzle for smoke capture at the source. Great care must be taken to avoid patent infringement issues with IC Medical and other smoke device manufacturers. FDA and approvals from other regulatory bodies including CE approvals will be necessary for this project.

The ConMed GoldVac™ offers a telescopic nozzle, but requires replacing the electrode to meet the extended nozzle length. Buffalo Filter's PlumePen™ also offers an extendable nozzle, but also requires adding a new electrode to achieve the desired length. Both these options add cost and inconvenience to the surgical team. With the IC Medical patent expirations in 2016 and late 2017, new product releases that overcome these obstacles is highly anticipated.

Smoke evacuation pencils are available in both rocker and button configurations depending on the manufacturer. Button configuration is seen as a surgeon preference. MEGADYNE currently offers a button configuration in its Ultra Vac smoke evacuation pencil offering with proven customer acceptance. The scope of this project currently includes only a button pencil offering, which may create a barrier for customers with a rocker preference. This is noted and may be offered in subsequent phases as market inputs dictate. In the meantime these customers will be presented with the button configuration or an adaptable shroud as noted below. MEGADYNE's own history with a button only smoke pencil configuration supports this decision. It is also important to note that many competitive pencils offer a 15' cord to accommodate alternatives for positioning such as boom placement or procedures requiring greater distance from the surgical site. Options will be considered to meet this market need.

A less desired, but viable option for smoke evacuation hand pieces is an adaptable smoke shroud. This option is not preferred by surgeons from an ergonomic standpoint, but does allow an affordable option to achieve the removal of harmful smoke toxins for smaller cases. While the Attacha Vac accounts for a significantly smaller portion of sales (less than 10%) compared to the integrated smoke hand piece, it provides a strategic positioning vehicle for smoke conversions by overcoming initial price obstacles and enabling customers to use pencils currently available in their existing kits.

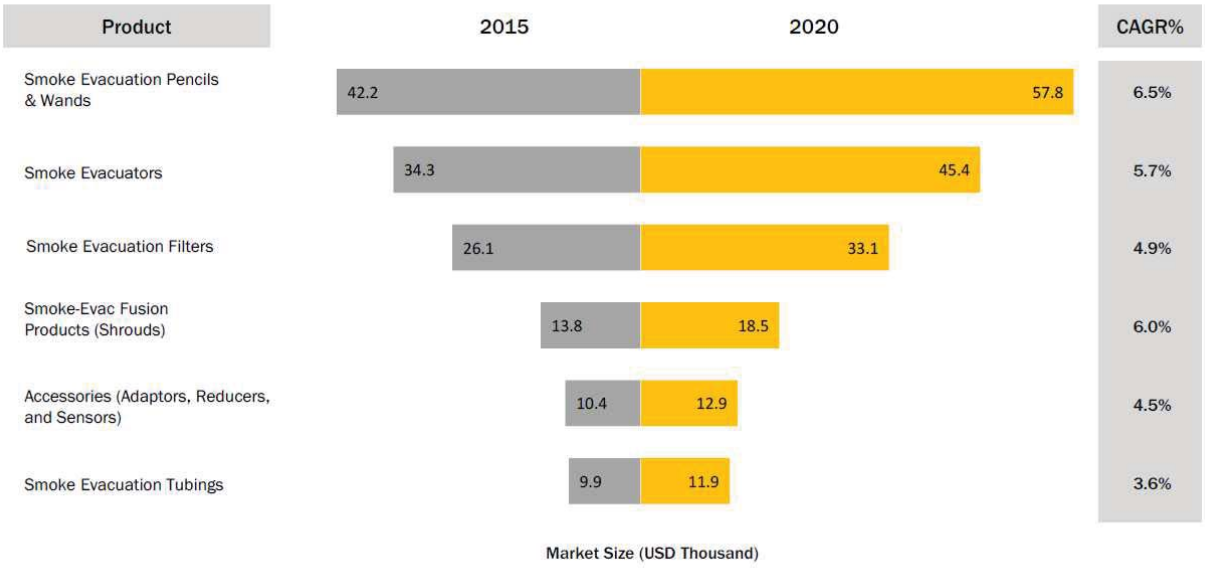
While the integrated (UltraVac type) is typically the surgeon's preference, an attachable shroud is necessary for bids and to overcome initial barriers to conversion. MEGADYNE's UltraVac outsells the Attacha Vac unit sales numbers by more than 10 to 1. However, without the

AttachaVac option, many of these sales may not have been achieved. Customers want options and sales needs the ability to offer a variety of products at varying price points, especially for tenders. This philosophy has served MEGADYNE well as the UltraVac sales results reflect.

To compete on GPO contracts and tenders our COGS must be improved. MEGADYNE tier 1 pricing Broadlane GPO for the 2120-09 (Attacha Vac) is currently just under $17 each. Comparatively, shroud pricing for the Valleylab version of the AttachaVac is listed at @$9 on published GPO pricing (2008 Amerinet) and has been reported as low as $6. Interestingly, Valleylab also configures a smoke shroud preconfigured with a rocker switch pencil and edge tip. GPO (Amerinet 2008) pricing of $17.20 is reported for this configuration which further validates the proposed pricing of both MEGADYNE's shroud and the MEGADYNE Smoke Evacuation Pencil. To be competitive a COGS should not exceed current cost for the MEGADYNE shroud alternative.

Smoke evacuation pencils represent both the largest segment of the smoke evacuation category (58%) and the fastest growing (6.5%) as the chart on the next page illustrates.

FIGURE 7 GLOBAL SMOKE EVACUATION SYSTEM MARKET, BY PRODUCT, 2015 VS. 2020



This growth potential is recognized by virtually all electrosurgical manufactures as well as others (Stryker) who see this as revenue opportunity. As might be expected, pricing has already becoming competitive and this trend is expected to continue as others enter this market.

Competition/Pricing

As previously noted, the current key competitors in the smoke evacuation market include:

Manufacturer/Device	*Pricing ASP (varies by*

	contract/country)
• Buffalo Filter's PlumePen™	• $22 (Denmark)
• ConMed GoldVac™	• $26 ($19 Europe)
• IC Medical/ERBE/DeRoyal (Denmark)/DeRoyal (Denmark and US Broadlane)	• $25
• Lina Grey/white shark – non telescopic	• $14-$16
• Lina SawShark – Telescopic	• $20
• Cimpax – non-telescopic	• $18
• Valleylab Shroud	• $9
• Stryker ESP via Lina	• $20- 21
• MEGADYNE Smoke Evacuation Pencil non-telescopic	• $20-22/$14-16 Int'l • List = $30

Pricing

Phase 1 of the MEGADYNE Smoke Evacuation Pencil (ZIP Pen) project delivered a low COGS (non-telescopic) sterile smoke evacuation pencil with tubing and holster at a cost slightly under $9. The introduction of this product (the ZIP Pen) provided customers with a choice of smoke evacuation devices and a variety of price points for choice in device and price. This product also provided MEGADYNE with enhanced pricing flexibility and improved gross margin potential.

Pricing flexibility and control of the manufacturing process are also key incentives for the telescopic smoke evacuation pencil project. Initial pricing of the telescopic MEGADYNE Smoke Evacuation Pencil (sterile w/holster) will list at $28 and provide an ASP of approximately $22 in the US and $16 internationally. The improved margins (over current product) will enable us to reduce this pricing as necessary due to contracting and competitive landscapes. The ability to sell smoke evacuation pencils at competitive price points (while maintaining acceptable margins) enables MEGADYNE to compete for international tenders as well as GPO, IDN, Distributor and Kit Packer contracts in the US.

Low cost to manufacture (of a MEGADYNE manufacturer and branded smoke evacuator) will give MEGADYNE the flexibility and margins to fund capital placement programs necessary for market adoption due to capital budget restraints under current market condition. Increasing MEGADYNE's penetration into the smoke market will also help increase E-Z Clean tip utilization as each smoke pencil will include an E-Z Clean tip.

Sales

The smoke evacuation market is a mature market historically lacking in adoption (domestically) due to limited education regarding the hazards of electrosurgical smoke and poor surgeon acceptance of existing devices. The market is shifting and the introduction of cost competitive products will keep Megadyne competitive in the marketplace. Introduction of a Megadyne telescopic smoke evacuation pencil will help the company control pricing and distribution without the uncertainty presented by its partner relationship. Converting existing customer to a newer,

Megadyne version of the UltraVac will not be without incident. However, with proper planning and the right product, many customers will automatically convert to this new "version" of the UltraVac. It will come at a cost to sales representatives and customer service time and resources however, the payout to the company could be substantial. The sales team will need to be properly motivated and trained to maximize the potential of this new product.

The release of a new MEGADYNE smoke evacuator at the time of the telescopic pencil (UltraVac) launch will be instrumental to its success. Control of the manufacturing process will enable the company to better control the production cost of the smoke evacuator. Reducing the box cost will help overcome customer objections due to capital budget restraints through for box placement programs.

Product Launch

The timing of the smoke box FDA/CE clearance, as compared to the telescopic pencil release, will allow field testing of the device prior to a full market launch. This opportunity will allow the company to gain valuable insights as to the pricing, positioning and sales techniques prior to launch. These insights will help build product confidence prior to release.

Providing cost effective capital options for high use smoke disposable accounts will be key to adoption. This strategy is dependent on meeting COGS targets on the capital (Smoke Evacuator) component. Initially, targets of $1,000 were anticipated, however design inputs for quiet motors and an overall quiet system have made this initial COGS unobtainable. Current COGS estimates range up to $2,000, making a capital placement program challenging. Usage targets will be put into place to ensure the profitability of a capital placement program and tested through select accounts. Overcoming the capital hurdle will be paramount to obtaining new and converting competitive accounts.

Customer Education

Education and creating the need for smoke evacuation has been the biggest challenge in the US. Internationally, the scenario is completely different. Socialistic approaches to healthcare have proven more advantageous to the adoption of smoke evacuation. Countries such as Denmark have mandated smoke evacuation. Sales to such government mandated countries are a large portion of MEGADYNE's existing UltraVac sales. Due to this disparity in adoption (US. vs. International) it is important to balance the need for innovative devices at higher margins with the very price competitive markets outside of the US.

Gathering smoke evacuation advocates and champions will be essential for success. MEGADYNE will need strong educational campaign support of this product line as well as comprehensive training for sales representatives. MEGADYNE's Smoke Evacuation CE Program will continue to open doors with hospital educators and nurses. Additional programs including regional educational events will need to be developed and promoted to increase education, awareness and sales support. MEGADYNE will groom smoke "experts" to speak on our behalf regarding the hazards of electrosurgical smoke. Sales must be armed with effective tools and published articles to assist in educating customers on the hazards of electrosurgical smoke upon release of this product.

Marketing alone will not be enough to secure the success of this product line. An elevated sales emphasis and compensation plan will also be required. To succeed, reps must be motivated and compensated to get these products into the OR and past VAC and other committees. This will take time away from other sales activities and it must not be optional for sales representatives to opt out of selling this line.

Each sales representative must receive a minimum of one demo unit per territory, with an additional pool available for large evaluations (up to 5 per territory) and another pool for service and repair loaners as necessary to maintain the line. The Service Department will be responsible for the management and allocation of the loaner pool and will need resources allocated for this purpose.

Service and Repair
A key component of the Megadyne Smoke evacuation (hardware) release will include a service plan for all hardware related components. This plan will include any recommended or required maintenance at a facility level as well training and parts availability at Megadyne's authorized service centers prior to launch. Distributors outside of the US should agree to be trained in smoke evacuation equipment repair prior to initiating sales in their region or arrange for such service through an approved service facility.

Preventative maintenance of the smoke evacuators will be managed proactively by the Service team to keep the demo unit documentation current to meet all current standards and policies.

7. COMPATIBILITY REQUIREMENTS

The MEGADYNE Smoke Evacuator and related smoke product accessories should be compatible with standard electrosurgical generators. These may include: The Valleylab FX, FT-10, Valleylab Force 2, Triad, ConMed, 5000, 2450, Excalibur, Aaron Bovie 3250, Bowa ARC 303, Olympus, Martin Maximum and ME MB 3 and others as indicated by the international team.

The MEGADYNE Smoke Evacuator should activate automatically via direct connection to an energy source. While the smoke evacuator will most often be used with electrosurgical generators, it should also be compatible for use with other energy devices such as vessel sealing and ultrasonic devices such as the harmonic scalpel via manual/footswitch or other integrated cable connection. Accessory devices should be designed for compatibility with the new MEGADYNE smoke evacuator, the current MegaVac Smoke Evacuators and adaptable to a wide variety of competitive smoke evacuation products via adapters or other methods.

8. MARKET REGIONS & REGULATORY SUBMISSIONS

MEGAYNE will market the smoke evacuation line worldwide. FDA and CE registrations will be necessary and the product(s) will be released to market as determined appropriate by the company.

Some products will launch immediately, others may be held back to coincide with the telescopic pencil release.

Regulatory will submit a registration plan prior to product release.

9. RECOMMENDATION

MEGADYNE has established itself as a leader in electrosurgery. With products like E-Z CLEAN electrodes, the MEGA Soft reusable return electrodes, and the MEGA Power electrosurgical generator MEGADYNE is looked to for high quality and innovative products.

The MEGADYNE line of smoke evacuation products offers the technological advancement and ergonomics to potentially revolutionize the smoke evacuation market and increase the visibility of MEGADYNE in the marketplace.

Full implementation of the plan includes having adequate inventory on hand at launch as well as a strong strategy for managing the transition from our existing supplier to a complete offering of MEGADYNE smoke evacuation accessories and equipment. Managing inventory will be to retain current customers and *transition* them to the new product(s). MEGADYNE must balance the need to establish launch qualities with the realization that waste may occur if adoption is slower than anticipated. 3 year sterilization at launch of sterile product will be adopted; however, 5 year sterilization must be pursued as closely after launch as possible to accommodate the needs of international suppliers.

The MEGADYNE smoke evacuation line offers the potential for long term financial growth and increased brand recognition for MEGADYNE. The Smoke market is quickly evolving and existing innovation has been lackluster. The introduction of an innovative, ergonomic smoke evacuation pencil with wide-spread adoption could shift the market and position MEGADYNE as the market leader in smoke evacuation. The opportunity and timing is prime. We have the product, the timing is right and we are able to execute the release of an innovative product the markets needs at pricing that will allow us the margin and pricing flexibility to succeed domestically and internationally.

FORECAST

MEGADYNE Smoke Evacuation Pencil forecast estimates for the Smoke Evacuation Line

Catalog#	Description	Samples	Year 1	Year 2	Year 3	Year 4	Year 5
2400	Megadyne 500	570	530	990	1391	1710	TBD
2550	Mega Filter		3000	3000	4000	5000	TBD
2555	Fluid Trap		20,000	67,500	81,900	81,900	TBD
2335	22mm tubing with Sponge Guard (Sterile)	150	500	600	605	605	TBD
2390	Lap Tubing (Sterile)	150	8,022	13,200	14,520	14,520	TBD
2395	Speculum Tubing (Sterile)	150	1,294	1,553	3,267	3,267	TBD
252010	New Attacha Vac w/ Universal Connector	750	10000	12000	13000	13000	TBD
252010EC	AttachaVac w/ EC Connector	750	10000	12000	13000	13000	TBD
2255	RF Sensor 10 ft	50	100	150	225	225	TBD
2406	6 ft Interlink cable		15	19	22	25	TBD
2403	3 ft Interlink cable		15	19	22	25	TBD
251010J	UltraVac 10 ft.	4000	59000	176200	202600	233000	TBD
251010EC	UltraVac 10 ft. EC version	4000	14600	43900	50500	58100	TBD

11. REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	10-272-01	Initial Release	2011-01-26
B	14-022-01	Update to current products and product inputs for development of new product line.	2014-03-21

[i] Smoke Evacuation System Market: Global Forecast to 2020: Markets and Markets. 2015
Market Dynamics: Smoke Evacuation System Market: Drivers, Restraints, Opportunities and Challenges