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International filing date: 06 March 2017 (06.03.2017)
Document type: Certified copy of priority document
Document details: Country/Office: US
Number: 62/303,770
Filing date: 04 March 2016 (04.03.2016)
Date of receipt at the International Bureau: 18 July 2018 (18.07.2018)

Remark: Priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a),(b) or (b-bis)
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Document details:  Country/Office: US
                   Filing date:  04 Mar 2016 (04.03.2016)
                   Application number: 62303770

Date of availability of document:  18 Mar 2016 (18.03.2016)

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THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

July 18, 2018

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 62/303,770
FILING DATE: March 04, 2016

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US62/303,770

Certified by

[Signature]

Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office
**Application Data Sheet 37 CFR 1.76**

<table>
<thead>
<tr>
<th>Title of Invention</th>
<th>Detection of Tetrahydrocannabinol and Related Compounds in Human Breath Using High-field Asymmetric Waveform Ion Mobility Spectrometry (FAIMS)</th>
</tr>
</thead>
</table>

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

**Secrecy Order 37 CFR 5.2:**

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

**Inventor Information:**

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<tr>
<th>Inventor 1</th>
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<tbody>
<tr>
<td><strong>Legal Name</strong></td>
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<tr>
<td><strong>Prefix</strong></td>
</tr>
<tr>
<td>Richard</td>
</tr>
<tr>
<td><strong>Residence Information (Select One)</strong></td>
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<tr>
<td>US Residency</td>
</tr>
<tr>
<td>City</td>
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</table>

**Mailing Address of Inventor:**

| Address 1 | c/o Univ. of Florida Research Foundation, Inc. |
| Address 2 | P.O. Box 115500 |
| City | Gainesville | State/Province | FL | Country | US |
| Postal Code | 32611-5500 |

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| Postal Code | 32611-5500 |

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<tr>
<td><strong>Legal Name</strong></td>
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<tr>
<td><strong>Prefix</strong></td>
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<td>Michael</td>
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WEB ADS 1.0
**Application Data Sheet 37 CFR 1.76**

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**Residence Information (Select One)**

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**Mailing Address of Inventor:**

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</table>

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.

**Correspondence Information:**

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

- An Address is being provided for the correspondence information of this application.

<table>
<thead>
<tr>
<th>Customer Number</th>
<th>97592</th>
</tr>
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<tbody>
<tr>
<td>Email Address</td>
<td><a href="mailto:burri@islandip.com">burri@islandip.com</a></td>
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<td>2082.114</td>
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<th>Suggested Figure for Publication (if any)</th>
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</table>

**Filing By Reference:**

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

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<th>Application number of the previously filed application</th>
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WEB ADS 1.0
Application Data Sheet 37 CFR 1.76

| Title of Invention | Detection of Tetrahydrocannabinol and Related Compounds in Human Breath Using High-field Asymmetric Waveform Ion Mobility Spectrometry (FAIMS) |

**Publication Information:**

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

**Representative Information:**

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative information during processing.

Please Select One: ☐ Customer Number ☐ US Patent Practitioner ☐ Limited Recognition (37 CFR 11.9)

Customer Number 97592

Prefix | Given Name | Middle Name | Family Name | Suffix
--- | --- | --- | --- | ---
Registration Number

Prefix | Given Name | Middle Name | Family Name | Suffix
--- | --- | --- | --- | ---
Registration Number

Additional Representative Information blocks may be generated within this form by selecting the Add button.

**Domestic Benefit/National Stage Information:**

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the application number blank.

Prior Application Status

| Application Number | Continuity Type | Prior Application Number | Filing or 371(c) Date (YYYY-MM-DD) |
--- | --- | --- | ---
62301127 | | | 0001-01-01

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.

**Foreign Priority Information:**

WEB ADS 1.0
### Application Data Sheet 37 CFR 1.76

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This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX), the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(g)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

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Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

### Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.
Application Data Sheet 37 CFR 1.76  
Attorney Docket Number 2082.114
Application Number
Title of Invention Detection of Tetrahydrocannabinol and Related Compounds in Human Breath Using High-field Asymmetric Waveform Ion Mobility Spectrometry (FAIMS)

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant must opt-out of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is ONLY reviewed and processed with the INITIAL filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People’s Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby grants the USPTO authority to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO’s Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

A. Applicant DOES NOT authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

B. Applicant DOES NOT authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

WEB ADS 1.0
**Application Data Sheet 37 CFR 1.76**

| Title of Invention | Detection of Tetrahydrocannabinol and Related Compounds in Human Breath Using High-field Asymmetric Waveform Ion Mobility Spectrometry (FAIMS) |

**Applicant Information:**

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

- [ ] Assignee
- [ ] Legal Representative under 35 U.S.C. 117
- [ ] Joint Inventor
- [ ] Person to whom the inventor is obligated to assign
- [ ] Person who shows sufficient proprietary interest

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor: 

If the Applicant is an Organization check here: [ ]

**Organization Name** Cannabix Technologies Inc.

**Mailing Address Information For Applicant:**

| Address 1 | 7934 Government Road |
| Address 2 |
| **City** | **State/Province** | **Postal Code** |
| Burnaby, BC | OT | V5A 2E2 |

Country: CA  

Phone Number: 6045517831  

Fax Number: 6046762767  

**Email Address**

Additional Applicant Data may be generated within this form by selecting the Add button.
## Application Data Sheet 37 CFR 1.76

<table>
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<tr>
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## Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

### Assignee

1. Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Assignee Information" section will appear on the patent application publication as an assignee. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

If the Assignee or Non-Applicant Assignee is an Organization check here. [ ]

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## Mailing Address Information For Assignee including Non-Applicant Assignee:

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Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.
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</table>

**Signature:**

**NOTE:** This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the “Authorization or Opt-Out of Authorization to Permit Access” section, then this form must also be signed in accordance with 37 CFR 1.14(c).

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a [juristic entity](#) (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, all joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of all joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

<table>
<thead>
<tr>
<th><strong>Signature</strong></th>
<th>/Stephen R. BURRI #56087/</th>
<th><strong>Date (YYYY-MM-DD)</strong></th>
<th><strong>First Name</strong></th>
<th>Stephen</th>
<th><strong>Last Name</strong></th>
<th>BURRI</th>
<th><strong>Registration Number</strong></th>
<th>56087</th>
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Additional Signature may be generated within this form by selecting the Add button.
## Provisional Application for Patent Cover Sheet

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

### Inventor(s)

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<tr>
<th>Given Name</th>
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<td>YOST</td>
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**Inventor 2**

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**Inventor 3**

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<td>US</td>
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</table>

All Inventors Must Be Listed – Additional Inventor Information blocks may be generated within this form by selecting the **Add** button.

### Title of Invention

**Detection of Tetrahydrocannabinol and Related Compounds in Human Breath Using High-field Asymmetric Waveform Ion Mobility Spectrometry (FAIMS)**

### Attorney Docket Number (if applicable)

2082.114

### Correspondence Address

Direct all correspondence to (select one):

- [ ] The address corresponding to Customer Number
- [ ] Firm or Individual Name

**Customer Number**

97592

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

- [ ] No.

Yes, the invention was made by an agency of the United States Government. The U.S. Government agency name is:

Yes, the invention was under a contract with an agency of the United States Government. The name of the U.S. Government agency and Government contract number are:
Entity Status
Applicant asserts small entity status under 37 CFR 1.27 or applicant certifies micro entity status under 37 CFR 1.29

- Applicant asserts small entity status under 37 CFR 1.27
- Applicant certifies micro entity status under 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent.
- No

Warning
Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

Signature
Please see 37 CFR 1.4(d) for the form of the signature.

<table>
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<tr>
<th>Signature</th>
<th>Stephen R. BURRI #56087/</th>
<th>Date (YYYY-MM-DD)</th>
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<td></td>
</tr>
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</table>

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in handling the provisional application.
Privacy Act Statement

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Mobility Spectrometry (FAIMS)
High-Field Asymmetric Waveform Ion Related Compounds in Human Breath Using
Detection of Tetrahydrocannabinol and...
Overview

- Background
- High-field Asymmetric Waveform Ion Mobility Spectrometry (FAIMS)
- Experimental Setup
  - Standards (THC, Cocaine)
  - Breath Simulation
  - Actual Breath Sampling (Nicotine)
- Conclusions
Background

Solution: Portable, FAIMS-based instrument.

FAIMS offers a highly selective means of separating ions at atmospheric pressure for up to 2 hours after consumption. Studies show that THC can be detectable in breath to accurately determine levels of THC present. Law enforcement does not have a scientific approach to accurately detect THC.

Legal in more states. Medical and recreational marijuana use is becoming

Background
Mass spectrometry provides characteristicization, allows for calibration, validation

This change is unique for every molecule

Separation in FAIMS is based on change in mobility under high electric field

Allows isolation of THC from other components in breath

Already used successfully for alcohol

Real-time

Non-intrusive

Why breath?
asymmetric waveform

Low and high E components to have a ΔK

Ions can be separated based on ΔK

becomes a function of electric field (E)

As E field increases (~5000 V/cm) ion mobility (k)

Specrometry (FAIMS)

High-field asymmetric waveform Ion Mobility
Components

Improvements/Integration of field instrumentation

Live breath testing

Simultaneous breath using headspace sampling

Determine limits of detection

Optimize instrumental parameters

Characterization using THC standards

Experimental phases
spectrometry (DMS)

Planar FAIMS is also known as differential mobility

Two modes of injection: orthogonal and parallel

Homemade-built at UF

FAIMS Cell Geometries - Planar
Current design - orthogonal injection
around curve
(resolving power (focusing effect
curved cells ideally offer greater
Home-built at UF
FAIMS Cell Geometries - Hemispherical)
Ionization source amount of THC actually present at
Not perfect \( \not\in \) Need to quantify

- LC bubbler
- 80% N\(^2\)/20% CO\(^2\) to simulate breath
- Flow controllers
- Generator
- Used gas introduction from FAIMS
- Headspace sampling
- No additional curtain or sheath gases
- Transmission in indirectly-injected cell
- Ion guide focuses ions and improves planar FAIMS cell with ion guide analysis
- Used for Headspace and Direct Breath

Interface

Extracitive Electrospray Ionization (EESI) Breath
Headspace EESI FAIMS/MS Experiment
- Effects
- Geometry to maximize field
- Ion focusing
- Direct injection
- curved FAIMS cell
- Further improvements to
  Ion Guide
  Parallel injection
  moment
- Hemispherical cell at the
  Planar cell outperforms
- Same trends
- CV/DV behavior shows the
  Hemispherical vs. Planar FAIMS Cells
Full Width at Half Max

I

1/2 * f_{max}

x

CV

CV^2

CV^3

Resolving Power (R_p)

CV / ACV

FWHM

Fixing CV for known analyte (e.g., THC)

CV scanning (characterization)

FAIMS has two modes

Interpreting FAIMS Data
CV = 2.75V

Signal intensity = 2.78 x 10^8 counts

R^d \sim 2.75V/0.6V = 4.58

CV scan -5 to 5V in 2 min

DV = 5000V

1 ppm cocaine

Planar EAMS Cell with Ion Guide
CV = 2.52V

Signal intensity = 1.67 x 10^7 counts

$R_p \sim 2.52/0.8V = 3.15$

CV scan - 5 to 5V in 2 min

DV = 5000V

100 ppb cocaine

Hemispherical FAIMS Cell

RT: 0.00 - 1.99 SM: 7B
Ion Mobility Behavior of THC

THC: K increases as E increases → A-Type

- Electric Field Strength (E)
- Dispersion Voltage (V)

CV/DV Plot for THC

Ion Mobility (k)
Typical human breath averages 12 seconds in duration.

Transmission at Fixed CV

CV Fixed at 1.9 V for 20 sec
DV 5000V
Detection Limit is 10X Lower and Improving

Level present in breath after 2 hours (Beck et al.)

AFIMS/MS of THC

Calibration Curve

Detection of THC by Hemispherical AFIMS
- Increased resolving power
- Separations at lower voltages
- FAIMS cells
- Facilitates longer residence times, leads to smaller
- Facilitates the number of oscillations in FAIMS cell
- More time spent at peak voltages
- Less time spent in electrical transitions
- Square wave generator replaces sum-of-sines
- Novel high-voltage square wave generator
Progress

Front-end interface to quantity breath is in

about 5 doses of THC

Small cigar contains ~50 mg nicotine, which is

Can't directly measure THC in FL...

Difficult to find a direct comparison

Nicotine
FAIMS/MS of Nicotine

Calibration Curve

Detection of Nicotine with Planar FAIMS
30 min after smoking cigar

3 breaths in 1 min

CV set to 2.1V
DV 4000V
Planar FAIMS with ion guide

Live Breath after Smoking Tobacco
Live Breath after Smoking Tobacco
Detection of Cocaine with Planar FAIMS
- Smaller "footprint" in field instrument
- Voltages will scale down with smaller FAIMS cells
- Interface designed specifically for breath
- ESI not practical (6kV)
Components have been built and are being integrated.

Validated by mass spectrometry.

A portable FAIMS-based instrument is underway.

Other analytes such as cocaine have been evaluated.

A sample can be taken in less than 20 sec.

Of nicotine in human breath.

Concept proven with successful detection of low-ppb levels

Simultated human breath can detect levels of THC said to be present after 2 hours.

Interest and their metabolites in human breath.

FAIMS is a suitable method for detection of analytes of

Conclusions
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<td>Detection of Tetrahydrocannabinol and Related Compounds in Human Breath Using High-field Asymmetric Waveform Ion Mobility Spectrometry (FAIMS)</td>
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<td><strong>First Named Inventor/Applicant Name:</strong></td>
<td>Richard A. YOST</td>
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<td><strong>Customer Number:</strong></td>
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